

MEDICAL POLICY



SUBJECT: SURGICAL MANAGEMENT OF OBESITY	EFFECTIVE DATE: 05/18/00
POLICY NUMBER: 7.01.29	REVISED 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
CATEGORY: Technology Assessment	PAGE: 1 OF: 23
<i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i> <i>Medical policies apply to commercial and Safety Net products only when a contract benefit for the specific service exists.</i> <i>Medical policies only apply to Medicare products when a contract benefit exists and where there is no National or Local Medicare coverage decisions for the specific service.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, the surgical treatment of morbid obesity by *open or laparoscopic Roux-en-Y gastric bypass, duodenal switch procedure (biliopancreatic diversion), and stand-alone sleeve gastrectomy (see Policy statement X for sleeve gastrectomy as a staged procedure)* have been medically proven to improve health outcomes and are therefore **medically appropriate** for selected patients. Patients must meet all of the criteria:
- A. Patients must be morbidly obese, which is defined as either having a BMI greater than or equal to 40 kg/m² or having a BMI greater than or equal to 35 kg/m² and existing comorbid condition(s) (e.g., hypertensive cardiovascular disease, coronary heart disease, pulmonary hypoventilation, hypertension, hypercholesterolemia, dyslipidemias, diabetes, sleep apnea, degenerative arthritis of weight-bearing joints, or other weight related arthropathies, and metabolic syndrome). Documentation of the comorbid existing medical condition(s) must be submitted by the primary care physician.
 - B. The condition of morbid obesity must be of at least 5 years duration.
 - C. A letter of support from the physician currently providing primary care to the member and who is familiar with his/her attempts at weight reduction, medical history and current health status (including obesity issues) is also necessary for the review process.
 - D. History of rigorous attempts at weight reduction.
 - 1. There must be written evidence of a weight loss history, either by the bariatric surgeon, primary care physician or nutritionist. This documentation should include the name of the weight loss program, length of participation in the program and any weight loss achieved. At least one program must have been a supervised weight loss program;
 - 2. Weight loss attempts need not be continuous, but a minimum total of six months is required.
 - a. If the patient has had no previous attempts at medical weight loss, participation for a minimum of six months in a preoperative bariatric surgery weight loss program is required.
 - b. If past prior attempts of weight loss are remote (greater than 5 years), then the patient is required to participate, for a minimum of six months in a preoperative bariatric surgery weight loss program.
 - E. There must be no significant liver, kidney, or gastrointestinal disease present. The presence of non-alcoholic steatohepatitis or “fatty liver”, which is associated with morbidly obese patients, would not be considered significant liver disease in this instance.
 - F. Treatable metabolic causes for obesity (e.g., adrenal or thyroid disorders) have been addressed.
 - G. Patients with a history of alcohol or substance abuse will not be considered unless there is a record of at least six months of abstinence. If there has been six months of abstinence, this condition must be addressed in a psychiatric consultation.
 - H. Patients must be screened by their physician for major psychopathology. All patients who have current symptoms which concern the physician, or who have had a psychiatric hospitalization must have a psychiatric *evaluation*. The psychiatric evaluation *should* be performed by a psychiatrist familiar with the implications of

Proprietary Information of Excellus Health Plan, Inc.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 2 OF: 23
---	---

weight reduction surgery. If psychiatrists with this expertise are not available, an evaluation by a clinical psychologist familiar with the implications of weight reduction surgery is also acceptable. A psychiatrist or clinical psychologist who is providing ongoing care for the patient may also provide this evaluation. If the patient already has an established psychiatric provider, that provider (e.g., psychiatrist or clinical psychologist) must provide a second letter of support for the proposed surgery. Psychological *testing* as screening tool or as part of the psychological evaluation prior to bariatric surgery is considered not medically necessary.

- II. Based upon our criteria and assessment of peer-reviewed literature, the surgical management of morbid obesity by *laparoscopic adjustable gastric banding* (e.g., LAP BAND, Realize™) is considered **medically appropriate** in the following circumstances:
 - A. The patient must meet all the requirements listed above in Policy Statement I, A-H; and
 - B. The dietary history does not include a large consumption of high caloric liquids (e.g., milk shakes) or sweets; and
 - C. The patient has no significant history of esophageal or gastric disease (*please note contraindications to adjustable gastric banding listed in the rationale section*); and
 - D. The patient must participate in a pre-operative bariatric program that requires a 5% weight loss to demonstrate commitment to behavioral and dietary changes. The 5% weight loss will be measured from the date of the patient's initial visit to the bariatric surgeon to the date of the request for pre-authorization of the adjustable gastric banding procedure.
- III. Based upon our criteria and assessment of peer reviewed literature, there is insufficient information to support use of surgical procedures for the management of obesity for *patients under age 18*. Therefore, surgery for obesity is considered **investigational** for this age group.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, the *mini-gastric bypass* (also called *loop gastric by-pass*), laparoscopic gastric plication, Endobarrier, and transoral gastroplasty/endoluminal procedures (e.g., Restorative Obesity Surgery, Endoluminal or ROSE, TOGA System, StomaphyX, EndoCinch, Overstitch device) for surgical treatment of morbid obesity have not been medically proven to improve health outcomes and therefore are considered **investigational**.
- V. *Surgical revisions* are considered **medically appropriate** for complications, such as malabsorption/malnutrition, obstruction, staple disruption, or stricture following the primary procedure. (*Please see Guidelines section, #IV*).
- VI. A *revision or removal of a laparoscopic adjustable gastric band* is considered **medically necessary** for complications or for a technical failure. Examples of laparoscopic adjustable gastric banding complications reported in the literature 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, vomiting), and port and/or catheter leakage.
- VII. A *revision or conversion* to another medically appropriate procedure because of unsatisfactory weight loss due to technical failure of the primary bariatric procedure such as pouch dilation or an initial pouch size that is too large (an ideal initial pouch size is approximately 20 cc) is considered **medically appropriate** if there is documentation regarding all of the following submitted with the request:
 - A. Primary procedure was initially successful in inducing weight loss; and
 - B. Patient has remained compliant to the prescribed nutrition and exercise program. (*See Guidelines section #IV*).
- VIII. Placement of a *second* adjustable gastric band is considered **investigational** as there is no published literature to support the efficacy of a second adjustable gastric band after failure to produce weight loss of the first procedure.
- IX. Based upon our criteria and assessment of peer-reviewed literature, use of an endoscopic/endoluminal procedure for *revisional* surgery (e.g., transoral outlet reduction) has not been medically proven effective and is considered **investigational**.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 3 OF: 23
---	---

- X. Repeat surgery for morbid obesity is considered **not medically necessary** for those patients who have either failed to lose weight or who have regained weight due to non-adherence with the prescribed nutrition and exercise program following their surgery.
- XI. Based upon our criteria and assessment of peer-reviewed literature, *sleeve gastrectomy* as the initial procedure of a staged bariatric surgery is considered **medically appropriate** in the high-risk, super-obese patient (BMI greater than or equal to 50). The patient must also meet all the requirements listed above in Policy statement I, A-H.
- XII. Based upon our criteria and assessment of peer-reviewed literature, *intra gastric balloon placement* has not been medically proven to be effective and is considered **investigational** as either the sole treatment for morbid obesity or as the initial treatment for weight loss in the super obese patient prior to a more invasive surgery such as gastric bypass.
- XIII. Based upon our criteria and assessment of peer-reviewed literature, use of bariatric surgery as a treatment for *non-obese patients with Type 2 diabetes mellitus* has not been medically proven to be effective and is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy # 11.01.11 regarding Cosmetic and Reconstructive procedures.

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.
- II. Gastric bypass surgery affects the absorption of medication and may lead to irregular blood levels of medication. Where drug level maintenance is critical, bypass surgery may be contraindicated. Examples include patients with seizure disorders requiring anti-seizure medications and patients with mental illness who require maintenance medication.
- III. Prophylactic cholecystectomy may be performed concurrent with bariatric surgery at the discretion of the surgeon, if cholelithiasis is present.
- IV. Some post bariatric surgery patients regain lost weight or never lose sufficient weight. Other patients may develop unacceptable postoperative symptoms. These failures may warrant reversal surgery or revision surgery (e.g., conversion to Roux-en-Y). 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.
- V. 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.
- VI. An expected outcome of successful bariatric surgery is redundant/excessive skin. Surgery to remove this skin is generally not considered medically necessary and therefore not covered.
- VII. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Obesity is a complex multifactorial, chronic condition that substantially raises an individual's risk of morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary artery disease, stroke, gall bladder disease, osteoarthritis, sleep apnea, respiratory problems and a variety of cancers.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 4 OF: 23
---	---

The 1998 National Heart Lung Blood Institute (NHLBI) expert panel defined Class I obesity as a body mass index (BMI) of 30-34.9 kg/m²; Class II obesity as a BMI of 35-39.9 kg/m²; and extreme obesity or Class III as a BMI greater than or equal to 40 kg/m².

Bariatric surgery can be divided into 2 categories: gastric restrictive procedures and malabsorptive procedures. Gastric restrictive procedures mechanically prevent the patient from overeating and the latter procedures interfere with the absorption of ingested nutrients. Examples of gastric restrictive procedures include vertical and horizontal banded gastroplasty and adjustable gastric banding. Malabsorptive procedures include biliopancreatic bypass, long limb gastric bypass and biliopancreatic bypass with duodenal switch. The Roux-en-Y gastric bypass is actually a combination of a gastric restrictive and malabsorptive procedure. A bariatric procedure is usually considered a success when at least 50% of excess body weight is lost or when the patient returns to within 30% of his/her ideal body weight.

A two-staged bariatric procedure has been proposed for those patients considered super obese (BMI greater than 50kg/m²) who are considered at the highest risk for surgery due to either their co-morbidities or their weight. The first stage involves performing a sleeve gastrectomy, which removes 60% of the stomach and restricts the amount of food consumed thus allowing for a significant amount of weight loss. The sleeve gastrectomy is considered a lower risk surgical alternative and serves as a bridge to other bariatric surgeries. The weight loss obtained from the sleeve gastrectomy is thought to decrease the patient's surgical risk dramatically, allowing for the second stage, such as a duodenal switch procedure, to be performed much more safely. Sleeve gastrectomy has also been proposed as a standalone bariatric procedure.

The intragastric balloon has 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 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.

The TOGA and StomaphyX Systems consist of a set of transoral endoscopically guided staples that are used to create a stapled restrictive pouch along the lesser curvature of the stomach. The EndoCinch was initially devised for the endoscopic treatment of gastroesophageal reflux disease (GERD). With EndoCinch, sutures are deployed in 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 OverstitchTM device allows for a full thickness endoscopic suturing compared to superficial thickness suturing provided by other devices. These endoscopic procedures may offer lower morbidity than other current bariatric procedures and are adjustable and reversible. They are being investigated as the primary bariatric surgery and as a revisional procedure to treat weight gain (e.g., large gastric pouch, large gastric stoma/dilated gastrojejunal anastomosis).

Laparoscopic gastric plication is a relatively new restrictive technique that involves sewing one or more folds in the stomach. Gastric plication reduces stomach volume by approximately 70%, and is potentially reversible.

Post bariatric surgery patients who regain lost weight, do not lose sufficient weight or develop unacceptable postoperative symptoms due to structural complications may warrant reversal or revision surgery. Reversal or revision of bariatric procedures is usually not warranted in patient failure due to noncompliance (e.g. gastric pouch dilation from 20cc to greater than 100cc in a patient not adhering to the recommended eating protocols). Conversely, revisional surgery for complications related to malabsorption resulting in hypoglycemia, malnutrition or weight loss of 20% below ideal body weight have been noted, particularly after malabsorptive procedures. Examples of laparoscopic adjustable gastric banding complications reported in the literature 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, vomiting), and port and/or catheter leakage.

RATIONALE:

The hallmark piece of literature published supporting the safety and effectiveness of bariatric surgery is the National Institutes of Health (NIH) Consensus Statement. Among their findings, the panel recommended (1) gastric restrictive or

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 5 OF: 23
---	---

bypass procedures could be considered for well informed and motivated individuals with acceptable operative risks (2) patients who are candidates for surgical procedures should be selected carefully after evaluation by a multidisciplinary team with medical, surgical, psychiatric and nutritional expertise, (3) the operation be performed by a surgeon substantially experienced with appropriate procedures and working in a clinical setting with adequate support for all aspects of management and assessment and (4) lifelong medical surveillance after surgical therapy is necessary.

The NIH Conference on the Surgical Management of Morbid Obesity (1998) states that obesity surgery should be reserved only for patients who have first attempted medical therapy. The NIH Consensus Conference states that the initial goal of medical therapy is a 10% weight reduction with a reasonable duration of 6 months. "The rationale for this initial goal is that even moderate weight loss can significantly decrease the severity of obesity-associated risk factors." The patient's ability to lose weight prior to bariatric surgery is an indication of the likelihood of compliance with the severe dietary restriction and behavioral changes required for the patient following surgery. Weight loss prior to surgery can also make surgical intervention easier to perform.

The Swedish Obese Subjects (SOS) intervention trial has reported on several hundred patients with up to 8 years of follow up. This trial demonstrated that surgery results in large amounts of weight loss compared to usual care (16% decrease in total body weight at 6 years versus an increase of 0.8% for usual care). Results of the SOS trial show substantial weight loss in the surgery group of a peak of 44 kg at 1 year and a gradual weight increase thereafter (mean loss of 30 kg at 2 years and 20 kg at 8 years). The SOS trial also shows that co-morbid conditions and quality of life are improved after surgery, with the most compelling evidence in the co-morbid conditions that exist for diabetics (a 18.5% decrease in diabetes vs. 3.6%). A decrease in the number of patients presenting with hypertension decreased in the short-term, but was not sustained 2 years following surgery.

In regards to specific bariatric procedures, there is sufficient data published in the medical literature to conclude that surgical management of obesity using open or laparoscopic Roux-en-Y gastric bypass procedures, sleeve gastrectomy or the duodenal switch procedure improves health outcomes for patients with morbid obesity. Improved health outcomes have been achieved outside the investigational setting.

The FDA has given premarket approval for the LAP-BAND® and Realize™ adjustable gastric banding devices. Adjustable gastric banding has been an evolving procedure with issues of migration and erosion being addressed by varying techniques and surgical modifications. Adjustable gastric banding is associated with fewer early complications, but more late complications and re-operations when compared to RGBP. Studies report reoperation rates due to adverse events at 5.6%-24%. Weight loss is also significantly less than Roux-en-Y gastric bypass in most reported studies of AGB. Evidence for 3-year outcomes related to weight loss after AGB was consistent with a 25% or greater excess weight loss reported. The reduction in BMI ranged from 7.9-15, but the typical patient in the studies remained obese (BMI greater than 30) in the majority of the studies. As studies demonstrate the % EWL is significantly less with adjustable gastric banding, the procedure works best for appropriately selected patients. Contraindications to adjustable gastric banding per the product insert of the LAP-BAND® are as follows:

1. Patients with inflammatory diseases of the gastrointestinal tract, including severe intractable esophagitis, gastric ulceration, duodenal ulceration, or specific inflammation such as Crohn's disease.
2. Patients with severe cardiopulmonary diseases or other serious organic disease which may make them poor surgical candidates.
3. Patients with potential upper gastro-intestinal bleeding such as esophageal or gastric varices or congenital acquired intestinal telangiectases.
4. Patients with portal hypertension.
5. Patients with congenital or acquired anomalies of the GI tract such as atresias or stenoses.
6. Patients who have/experience an intra-operative gastric injury during the implantation procedure, such as a gastric perforation at or near the location of the intended band placement.
7. Patients with cirrhosis.
8. Patients with chronic pancreatitis.
9. Patients who are addicted to alcohol and/or drugs.
10. Non-adult patients (patients under 18 years of age).

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 6 OF: 23
---	---

11. Patients who have an infection anywhere in their body or where the possibility of contamination prior to or during the surgery exists.
12. Patients on chronic, long-term steroid treatment.
13. Patients who are unable or unwilling to comply with dietary restrictions, which are required by this procedure.
14. Patients who are known to have, or suspected to have, an allergic reaction to materials contained in the system or who have exhibited pain intolerance to implanted devices.
15. Patients or family members with a known diagnosis or pre-existing symptoms of autoimmune connective tissue disease such as systemic lupus erythematosus or scleroderma.
16. Pregnancy: Placement of the LAP-BAND System is contraindicated for patients who currently are or may be pregnant. Patients who become pregnant after band placement may require deflation of their bands.”

In February 2011, the FDA granted approval for LAGB in patients with a BMI of 30-35 kg/m² in the presence of at least one weight-related comorbidity. The FDA labeling indicates that this procedure should be reserved for patients who are at the highest risk for weight-related complications and who have been unsuccessful in achieving medical weight loss. The evidence is insufficient to determine if LAGB improves the overall health outcomes for patients with BMIs that are lower than the current thresholds for bariatric surgery. The patients in these studies consist of a heterogenous patient population and the number and severity of comorbidities vary considerably. While the short-term evidence in current studies demonstrate weight loss in this patient population, and favorable changes in measures of diabetes, the impact of LAGB on other weight-related comorbidities is less certain.

JB Dixon, et al. (2008) performed a randomized controlled trial designed to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medication than conventional approaches to weight loss and diabetes control in patients with BMI of greater than 30 and less than 40. (Results were not reported separately for patients with BMI less than or greater than 35.) Sixty patients were enrolled and 30 were randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the 2-year follow-up. Remission of diabetes was achieved by 22 (73%) in the LAGB group and 4 (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 as ideal weight) versus a loss of 4.3% of excess weight in the conventional group. Mean hemoglobin A1c was less than 6.2% at baseline in 2 surgically and 4 conventionally treated patients versus 24 and 6 patients, respectively, at 2 years. At baseline, 2 surgically treated and 4 conventionally treated patients were using no pharmacotherapy versus 26 and 8, respectively, at 2 years. One surgical patient developed a wound infection, 2 developed gastric pouch enlargement and had laparoscopic revision to remove and replace the band. The remaining evidence at the present time consists of small case series and case reports with short follow-up from non-U.S. centers employing procedures considered investigational in this policy (e.g., stand-alone sleeve gastrectomy, mini gastric bypass). Overall, the data are insufficient to allow conclusions regarding the efficacy of bariatric surgical procedures in the treatment or cure of type 2 diabetes.

A September 2004 report addressing bariatric surgery in morbidly obese adolescents found, of all the patients who receive bariatric surgery, about 1% are adolescents. None of the studies investigating bariatric surgery in this age group reported long-term outcomes. Evidence is insufficient to determine if bariatric surgery allows for a clinically significant weight loss amount nor does the evidence allow any conclusions regarding improvements in co-morbidities, or the rates of harm in performing this type of procedure in this patient population. As yet, we do not know how bariatric surgery affects the growth and sexual development of adolescents with morbid obesity.

The short- and mid-term outcomes and complication rates of sleeve gastrectomy appear to be similar to those of other restrictive and malabsorptive procedures (Leyba, et al. 2011; Himens, et al 2010; D’Hondt, et al 2011; Chouillard, et al 2011). The procedure was proposed initially as the first step in a staged procedure for high-risk (super obese) patients, and longest follow-up data is available for these patients.

The ORBERA[™] IntraGastric Balloon (Apollo Endosurgery, Inc.) received FDA approval in August 2015. The FDA approval is for patients with a BMI of 30-40 to assist in losing and maintaining weight. The ReShape Integrated Dual Balloon System (REShape medical, Inc.) also received FDA approval in July 2015. The device is also intended to facilitate weight loss in obese adult patients with a BMI of 30-40 who have been unsuccessful in losing weight through diet and exercise. Patients must also have one or more obesity related conditions such as diabetes, high blood pressure or high cholesterol. Both approved devices are considered temporary and should be removed after 6 months. Peer-reviewed

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 7 OF: 23
---	---

literature is currently insufficient to determine the efficacy and safety of an intragastric balloon as a weight loss technique. A systematic review (M Fernandes, et al. 2007) to assess the efficacy of the intragastric balloon (IGB) found studies had very short follow-up and when compared to conventional management, IGB outcome data did not provide convincing evidence of a greater weight loss. More recent studies (e.g., REDUCE trial by Ponce, et al. 2015) found promising short-term (up to 48 weeks) results of weight loss when balloon insertion was compared to diet and exercise alone. Further studies are needed to demonstrate the long-term effects of utilizing intragastric balloon as a weight loss strategy.

Literature related to transoral gastroplasty for the treatment of obesity is limited; data is insufficient to provide conclusions on its safety and efficacy. The results of two studies (n=21, BMI range 35-53) were presented at the 2007 SAGES Annual Scientific Session. Follow-up for six patients at six months demonstrated an average weight loss of 31 pounds and an EWL of 24.9%. Sham-controlled trials are needed to further evaluate the utility of the EndoCinch device in obesity. Well-designed studies with long-term follow-up will be needed to measure the durability of the observed weight loss. Particularly, the stability of the gastric sutures remains unproven given the lack of long-term data.

There is not sufficient data published in the medical literature to draw conclusions about the safety and effectiveness of the mini-gastric bypass (also called loop gastric by-pass) procedure.

While preliminary data show that gastric plication 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; Abelbaki, et al. 2012), additional well-designed comparative studies with established bariatric procedures are needed to determine its overall safety, efficacy and impact on health outcomes.

Transoral outlet reduction is being evaluated as an endoscopic revisional surgery in patients with weight regain following their primary bariatric procedure (e.g., gastric bypass). Preliminary results are promising with feasibility, safety and short-term efficacy being demonstrated in case series (Jirapino, et al. 2013; Thompson, et al. 2013, Kumar, et al. 2014). However, the long-term durability of the procedure still needs to be proven in larger studies.

Twelve months of abstinence is usually required for patients with a history of drug/alcohol abuse as liver toxins need to be avoided due to the higher rate of liver disease post bariatric surgery.

CODES: Number Description

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.

<u>CPT:</u>	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 band (gastric band and subcutaneous port components)
	43771	revision of adjustable gastric band component only
	43772	removal of adjustable gastric band component only
	43773	removal and replacement of adjustable gastric band component only
	43774	removal of adjustable gastric band and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 8 OF: 23
---	---

- | | |
|-------|--|
| 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 bowel reconstruction to limit absorption |
| 43848 | Revision of gastric restrictive procedure for morbid obesity |
| 43886 | Gastric restrictive procedure, open; revision of subcutaneous port components only |
| 43887 | removal of subcutaneous port component only |
| 43888 | removal and replacement of subcutaneous port component only |

Copyright © 2015 American Medical Association, Chicago, IL

- | | | |
|----------------------|---------------|--|
| <u>HCPCS:</u> | S2083 | Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline |
| | C9724 (E/I) | Endoscopic full thickness plication of stomach using endoscopic plication system (EPS); includes endoscopy |
| <u>ICD9:</u> | 278.01 | Morbid obesity |
| | V85.30-.45 | Body Mass Index between 30-39.9 for obese adults over 20 years old (code range) |
| <u>ICD10:</u> | E66.01 | Morbid (severe) obesity due to excess calories |
| | Z68.30-Z68.45 | Body mass index (BMI), 30.0-69.9, adult (code range) |

REFERENCES:

- *Aashiem ET, et al. Vitamin status after bariatric surgery: a randomized study of gastric bypass and duodenal switch. Am J Clin Nutr 2009 Jul;90(1):15-22.
- Abbatini F, et al. Long-term effects of laparoscopic sleeve gastrectomy, gastric bypass, and adjustable gastric banding on type 2 diabetes. Surg Endosc 2010 May;24(5):1005-10.
- 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.
- Abdelbaki TN, et al. Gastric plication for morbid obesity: a systematic review. Obes Surg 2012 Oct;22(10):1633-8.
- *Abu-Abeid S, et al. Bariatric surgery in adolescence. J Pediatr Surg 2003 Sep;38(9):1379-82.
- Abu-Gazala S, et al. Conversion of failed gastric banding into four different bariatric procedures. Surg Obes Relat Dis 2011;doi:10.1016/j.soard.2011.01.009.
- Abu-Jaish W, et al. Sleeve gastrectomy: a new surgical approach for morbid obesity. Expert Rev Gastroenterol Hepatol 2010 Feb;4(1):101-19.
- *Adams TD, et al. Long-term mortality after gastric bypass surgery. NEJM 2007 Aug 23;357(8):753-61.
- Adegbola S, et al. Systematic review of laparoscopic adjustable gastric banding in patients with body mass index < 35 kg/m². Surg Obes Relat Dis 2013 Jun 2 [Epub ahead of print].

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 9 OF: 23
---	---

Agency for Healthcare Research and Quality (AHRQ). Comparative effectiveness review number 82. Bariatric surgery and nonsurgical therapy in adults with metabolic conditions and a body mass index of 30.0-34.9 kg/m². 2013 Jun [www.qhrq.gov] accessed 10/2/15.

*Aggarwal S, et al. Laparoscopic sleeve gastrectomy for morbid obesity: a review. Surg Obes Dis 2007 Mar-Apr;3(2):189-94.

Aikenhead A, et al. Effectiveness and cost-effectiveness of paediatric bariatric surgery: a systematic review. Clin Obes 2011 Feb;1(1):12-25.

*Alami RS, et al. Is there a benefit in preoperative weight loss in gastric bypass patients? A prospective randomized trial. Surg Obes Relat Dis 2007 Mar-Apr;3(2):141-5.

Alexandrou A, et al. What is the actual fate of super-morbid-obese patients who undergo laparoscopic sleeve gastrectomy as the first step of a two-staged weight-reduction operative strategy? Obes Surg 2012 Oct;22(10):1623-8.

Alfredo G, et al. Long-term multiple intragastric balloon treatment- a new strategy to treat morbid obese patients refusing surgery: prospective 6-year follow-up study. Surg Obes Relat Dis 2014 Mar-Apr;10(2):307-11.

Alley JB, et al. Quality of life after sleeve gastrectomy and adjustable gastric banding. Surg Obes Relat Dis 2012 Jun;8(3):31-40.

*American Society for Bariatric Surgery. Rationale for surgical management of severe obesity. [http://www.obesity-online.com/guidelines_asbs.htm] updated 2001 Nov 29. accessed 10/2/15.

American Society for Metabolic and Bariatric Surgery. Position statement on emerging endosurgical interventions for the treatment of obesity. [http://asmbs.org/2012/01/emerging-endosurgical-interventions-for-treatment-of-obesity/] assessed 10/2/15.

American Society for Metabolic and Bariatric Surgery. Updated position statement on sleeve gastrectomy as a bariatric procedure. [http://asmbs.org/2012/06/sleeve-gastrectomy-as-a-bariatric-procedure-update/] assessed 10/2/15.

Anderin C, et al. Weight loss before bariatric surgery and postoperative complications: data from the Scandinavian Obesity Registry (SOREg). Ann Surg 2015 May;261(5):909-13.

*Angrisani L, et al. Lap Band adjustable gastric banding system: the Italian experience with 1863 patients operated on 6 years. Surg Endosc 2003 Mar;17(3):409-12.

*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.

Arapis K, et al. Long-term results of adjustable gastric banding in a cohort of 186 super-obese patients with a BMI > 50 kg/m². J Visc Surg 2012 Apr;149(2):e143-52.

Apers JA, et al. perioperative outcomes of revisional laparoscopic gastric bypass after failed adjustable gastric banding and after vertical banded gastroplasty: experience with 107 cases and subgroup analysis. Surg Endosc 2013 Feb;27(2):558-64.

*Arias E, et al. Mid-term follow-up after sleeve gastrectomy as a final approach for morbid obesity. Obes Surg 2009 19(9):544-8.

ASMBS Clinical Issues Committee. Updated position statement on sleeve gastrectomy as a bariatric procedure. Surg Obes Relat Dis 2012 Jun;8(3):e21-6.

ABMBS Clinical issue Committee. ASMBS policy statement on gastric plication. Surg Obes Relat Dis 2011 May-Jun;7(3):262.

Becouarn G, et al. Weight loss prior to bariatric surgery is not a pre-requisite of excess weight loss outcomes in obese patients. Obes Surg 2010 May;20(5):574-7.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 10 OF: 23
---	--

*Belachew M, et al. Long-term results of laparoscopic adjustable gastric banding for the treatment of morbid obesity. Obes Surg 2002 Aug;12(4):564-8.

Bellanger DE, et al. Laparoscopic sleeve gastrectomy, 529 cases without a leak: short-term results and technical considerations. Obes Surg 2011;21:146-50.

Benaiges D, et al. Laparoscopic sleeve gastrectomy and laparoscopic gastric bypass are equally effective for reduction of cardiovascular risk in severely obese patients at one year of follow-up. Surg Obes Relat Dis 2011 Mar 3 [Epub ahead of print].

*Benotti PN, et al. Preoperative weight loss before bariatric surgery. Arch Surg 2009 Dec;144(12):1150-5.

*Biertho L, et al. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding: a comparative study of 1,200 cases. J Am Coll Surg 2003 Oct;97(4):537-47.

Biertho L, et al. Transoral endoscopic restrictive implant system: a new endoscopic technique for the treatment of obesity. Surg Obes Relat Dis 2010 Mar 4;6(2):203-5.

*Blackburn GL, et al. Expert panel on weight loss surgery: executive report update. Obesity 2009 May;17(5):842-62.

BlueCross BlueShield Association. Blue Distinction Centers of Bariatric Surgery. [<http://www.bcbs.com/why-bcbs/blue-distinction/blue-distinction-bariatric/>] accessed 10/2/15.

BlueCross BlueShield Association. Bariatric surgery. Medical Policy Reference Manual. Policy #7.01.47. 2013 Oct 10.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Newer techniques in bariatric surgery for morbid obesity. 2003 Sep;18(10).

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Newer techniques in bariatric surgery for morbid obesity: laparoscopic adjustable gastric banding, biliopancreatic diversion, and long-limb gastric bypass. 2005 Aug;20(5).

BlueCross BlueShield Association Technology Evaluation Center (TEC). Laparoscopic adjustable gastric banding in patients with body mass index less than 35 kg/m² with weight-related comorbidity. 2012 Oct;27(3).

BlueCross BlueShield Association Technology Evaluation Center (TEC). Bariatric surgery in patients with diabetes and body mass index less than 35 kg/m². 2012 Oct;27(3).

Bohdjalian A, et al. Sleeve gastrectomy as sole and definitive bariatric procedure: 5-year results for weight loss and ghrelin. Obesity Surg 2010 May;20 (5):535-40.

Bolton J, et al. Endoscopic revision (StomaphyX) versus formal surgical revision (gastric bypass) for failed vertical band gastroplasty. J Obes 2013;2013:1108507.

*Bowne WB, et al. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients: A prospective, comparative analysis. Arch Surg 2006 Jul;141(7):683-9.

Boza C, et al. Laparoscopic Roux-en-y gastric bypass versus laparoscopic sleeve gastrectomy: a case-control study and 3 years of follow-up. Surg Obes Relat Dis 2012 Jun;8(3):243-9.

Brethlauer S. ASMBS position statement on preoperative supervised weight loss requirements. Surg Obes Relat Dis 2011 May-Jun;7(3):257-60.

Brethlauer S. ASMBS position statement: bariatric surgery in class I Obesity (BMI 30-35 kg/m²). Surg Obes Relat Dis 2012 [<http://asmbs.org/2012/09/bariatric-surgery-in-class-1-obesity-bmi-30-35-kgm2/>] accessed 10/2/15.

Brethlauer S, et al. Transoral gastric volume reduction as intervention for weight management: 12-month follow-up of TRIM trial. Surg Obes Relat Dis 2012 Jun;8(3):296-304.

Brethauer SA, et al. Can diabetes be surgically cured? Long-term metabolic effects of bariatric surgery in obese patients with type 2 diabetes mellitus. Ann Surg 2013 Oct;258(4):628-37.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 11 OF: 23
---	--

*Brolin RE. Bariatric surgery and long-term control of morbid obesity. JAMA 2002 Dec;288(22):2793-6.

*Braghetto I, et al. Laparoscopic sleeve gastrectomy: surgical technique, indications and clinical results. Obes Surg 2007 Nov;17(11):1442-50.

*Brethauer SA, et al. Systematic review of sleeve gastrectomy as staging and primary bariatric procedure. Surg Obes Relat Dis 2009; 5(4):469-75.

*Cadiere GB, et al. Laparoscopic adjustable gastric banding. Semin Laparosc Surg 2002 Jun;9(2):105-14.

California Technology Assessment Forum. Sleeve gastrectomy as a stand-alone bariatric procedure for obesity. 2011 Oct 13 [http://www.ctaf.org/assessments/sleeve-gastrectomy-stand-alone-bariatric-procedure-obesity] accessed 10/2/15.

Campos GM, et al. Improvement in peripheral glucose uptake after gastric bypass surgery is observed only after substantial weight loss has occurred and correlates with the magnitude of weight loss. J Gastrointest Surg 2010 Jan;14(1):15-23.

Campos GM, et al. Better weight loss, resolution of diabetes, and quality of life for laparoscopic gastric bypass vs banding. Arch Surg 2011 Feb;146(2):149-55.

Carlin AM, et al. The comparative effectiveness of sleeve gastrectomy, gastric bypass, and adjustable gastric banding procedures for the treatment of morbid obesity. Ann Surg 2013 May;257(5):791-7.

Chakravarty PD, et al. Comparison of laparoscopic adjustable gastric banding (LAGB) with other bariatric procedures; a systematic review of the randomized controlled trials. Surgeon 2012 Jun;10(3):172-82.

Chang SH, et al. The effectiveness and risks of bariatric surgery: an updated systematic review and meta-analysis, 2003-2012. JAMA Surg 2014 Mar;149(3):275-87.

Chao SH. Gastric clipping for morbid obesity: the initial results of a clinical trial. World J Surg 2010 Feb;34(2):303-8.

Chopra A, et al. Laparoscopic sleeve gastrectomy for obesity: can it be considered a definitive procedure? Surg Endosc 2012 Mar;26(3):831-7.

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 Mar 8 [Epub ahead of print].

*Clegg AJ, et al. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. Health Technology Assessment (Winchester, England) 2002 Jul;6(12):1-153.

*Clinical Issues Committee of American Society for Metabolic and Bariatric Surgery. Sleeve gastrectomy as a bariatric procedure. Surg Obes Relat Dis 2007 Nov-Dec;3(6):573-7.

Coblijn UK, et al. Laparoscopic Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy as revisional procedure after adjustable gastric band- a systematic review. Obes Surg 2013 Nov;23(11):1899-1914.

*Collins J, et al. Initial outcomes of laparoscopic Roux-en-Y gastric bypass in morbidly obese adolescents. Surg Obes Relat Dis 2007 Mar-Apr;3(2):147-52.

*Colquitt J, et al. Surgery for morbid obesity (Cochrane Review). Cochrane Database Syst Rev. 2005;(2):CD003641. updated Apr 15 2009.

Colquitt JL, et al. Surgery for weight loss in adults. Cochrane Database Syst Rev 2014 Aug 8;8:CD003641.

*Cote` GA, et al. Emerging technology: endoluminal treatment of obesity. Gastrointest Endosc 2009 Nov;70(5):991-9.

*Cottam D, et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. Surg Endosc 2006 Jun;20(6):859-63.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 12 OF: 23
---	--

Courcoulas AP, et al. Surgical vs medical treatments for type 2 diabetes mellitus: a randomized clinical trial. JAMA Surg 2014 Jul;149(7):707-15.

Crea N, et al. Long-term results of biliopancreatic diversion with or without gastric preservation for morbid obesity. Obes Surg 2011;139-45.

Cywes R, et al. Interim results at 48 weeks of LAP-BAND AP experience (APEX) study: prospective, multicenter, open-label longitudinal patient observational study. Surg Obes Dis 2012 Nov-Dec;8(6):741-6.

Dakin GF, et al. Endoluminal revision of gastric bypass for weight regain—a systematic review. Surg Obes Relat Dis 2013 May-Jun;9(3):335-42.

*Daniels SR, et al. American Heart Association Childhood Obesity Research Summit: executive summary. Circulation 2009 Apr 21;119(15):2114-23.

*Davila-Cervantes A, et al. Open versus laparoscopic vertical banded gastroplasty: a randomized controlled double blind trial. Obes Surg 2002 Dec;12(6):812-8.

*de Cspel J, et al. Conversion to a laparoscopic biliopancreatic diversion with a duodenal switch for failed laparoscopic adjustable silicone gastric banding. J Laparoendosc Adv Surg Tech A 2002 Aug;12(4):237-40.

*DeMaria EJ, et al. High failure rate after laparoscopic adjustable silicone gastric banding for treatment of morbid obesity. Ann Surg 2001;233:809-18.

DeMaria EJ, et al. Baseline data from American Society for Metabolic and Bariatric Surgery-designated bariatric surgery centers of excellence using bariatric outcomes longitudinal database. Surg Obes Relat Dis 2010 Jul-Aug;6(4):347-55.

*De Paula AL, et al. Laparoscopic sleeve gastrectomy with ileal interposition (“neuroendocrine brake”) - pilot study of a new operation. Surg Obes Relat Dis 2006 Jul-Aug;2(4):464-7.

D’Hondt M, et al. Laparoscopic sleeve gastrectomy as a single 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 Feb 27 [Epub ahead of print].

Dimick JB, et al. Bariatric surgery complications before vs after implementation of a national policy restricting coverage to centers of excellence. JAMA 2013 Feb 27;309(8):792-9.

Dixon JB, et al. Impact of laparoscopic adjustable gastric banding on type 2 diabetes. Obes Rev 2012 Jan;13(1):57-67.

Edholm D, et al. Long-term results 11 years after primary gastric bypass in 384 patients. Surg Obes Relat Dis 2012 Mar 23 [Epub ahead of print].

Eid GM, et al. StomaphyX vs sham procedure for revisional surgery to reduce regained weight in Roux-en-Y gastric bypass patients: a randomized clinical trial. JAMA Surg 2014 Apr;149(4):372-9.

*Ellsmere JC, et al. Endoscopic interventions for weight loss surgery. Obesity 2009 May;17(5):929-33.

Elnahas A, et al. Revisional surgery after failed laparoscopic adjustable gastric banding: a systematic review. Surg Endosc 2013 Mar;27(3):740-5.

*Emerging Technologies and Clinical Issues Committee of the ASMBS. American Society for Metabolic and Bariatric Surgery position statement on emerging endosurgical interventions for treatment of obesity. Surg Obes Relat Dis 2009 May-Jun;5(3):297-8.

Escalona A, et al. Initial human experience with restrictive duodenal-jejunal bypass liner for treatment of morbid obesity. Surg Obes Relat Dis 2010 Mar 4;6(2):126-31.

*Evans J, et al. Laparoscopic adjustable gastric banding for the treatment of morbid obesity. Am J Surg 2002;184:97-102.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 13 OF: 23
---	--

Executive summary: Guidelines (2013) 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 published by the Obesity Society and American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Based on a systematic review from the Obesity Expert Panel, 2013. Obesity 2014 Jul;22 Suppl 2:S5-39.

*Farrell TM, et al. Clinical application of laparoscopic bariatric surgery: an evidenced-based review. Surg Endosc 2009 May;23(5):930-49.

*Feng JJ, et al. Effect of standard vs extended Roux limb length on weight loss outcomes after laparoscopic Roux-en-Y gastric bypass. Surg Endosc 2003;17:1055-60.

*Fernandez AZ, et al. Multivariate analysis of risk factors for death following gastric bypass for treatment of morbid obesity. Ann Surg 2005;239(5):698-703.

*Fernandes M, et al. Intra gastric balloon for obesity. Cochrane Database Syst Rev. 2007 Jan 24;(1):CD004931.

Fitch A, et al. Institute for Clinical Systems Improvement. Prevention and Management of Obesity for Adults. Updated May 2013 [https://www.icsi.org/_asset/s935hy/Obesity-Interactive0411.pdf] accessed 10/2/15.

Franco JV, et al. A review of studies comparing three laparoscopic procedures in bariatric surgery: sleeve gastrectomy, Rou-en-Y gastric bypass and adjustable gastric banding. Obes Surg 2011 Sep;21(9):1458-68.

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.

*Frutos MD, et al. Intra gastric balloon reduces liver volume in super-obese patients, facilitating subsequent laparoscopic gastric bypass. Obes Surg 2007 Feb;17(2):150-4.

*Fox SR, et al. The Lap-Band system in a North American population. Obes Surg 2003 Apr;13(2):275-80.

*Garb J, et al. Bariatric surgery for the treatment of morbid obesity: a meta-analysis of weight loss outcomes for laparoscopic adjustable gastric banding and laparoscopic gastric bypass. Obes Surg 2009 Oct;19 (10):1447-55.

Gehrer S, et al. Fewer nutrient deficiencies after laparoscopic sleeve gastrectomy (LSG) than after laparoscopic Roux-en-Y gastric bypass (LRYGB)- a prospective study. Obes Surg 2010 Apr;20(4):447-53.

*Geloneze B, et al. Surgery for nonobese type 2 diabetic patients: an interventional study with duodenal-jejunal exclusion. Obes Surg 2009 Aug;19(8):1077-83.

*Genco A, et al. BioEnterics Intra gastric Balloon: The Italian experience with 2,515 patients. Obes Surg 2005 Sep;15(8):1161-4.

*Gentileschi P, et al. Evidence-based medicine: open and laparoscopic bariatric surgery. Surg Endosc 2002;16:736-44.

Gersin KS, et al. Open-label, sham-controlled trial of an endoscopic duodenojejunal bypass liner for preoperative weight loss in bariatric surgery candidates. Gastrointest Endosc 2010 May;71(6):976-82.

Gianos M, et al. Outcomes of bariatric surgery in patients with body mass index < 35 kg/m2. Surg Obes Relat Dis 2012 Jan-Feb;8(1):25-30.

Gill RS, et al. Sleeve gastrectomy and type 2 diabetes mellitus: a systematic review. Surg Obes Relat Dis 2010 Nov-Dec;6(6):707-13.

*Goergen M, et al. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic vertical banded gastroplasty: results of a 2-year follow-up study. Surg Endosc 2007 Apr;21(4):659-64.

Goyal V, et al. Gastric pouch reduction using stomaphyX in post Roux-en-Y gastric bypass patients does not result in sustained weight loss: a retrospective analysis. Surg Endosc 2013 Sep;27(9):3417-20.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 14 OF: 23
---	--

*Gravante G, et al. Laparoscopic adjustable gastric bandings: a prospective randomized study of 400 operations performed with 2 different devices. Arch Surg 2007 Oct;142(10):958-61.

*Greenway SE, et al. Effects of obesity surgery on non-insulin-dependent diabetes mellitus. Arch Surg 2002 Oct;137:1109-17.

Halperin F, et al. Roux-en-Y gastric bypass surgery or lifestyle with intensive medical management in patients with type 2 diabetes: feasibility and 1-year results of a randomized clinical trial. JAMA Surg 2014 Jul;149(7):716-26.

Hedberg J, et al. Long-term follow-up in patients undergoing open gastric bypass as a revisional operation for previous failed restrictive procedures. Surg Obes Relat Dis 2011;doi:10.1016/j.soard.2011.06.011.

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.

Helmio M, et al. SLEEVEPASS: a randomized prospective multicenter study comparing laparoscopic sleeve gastrectomy and gastric bypass in the treatment of morbid obesity: preliminary results. Surg Endosc 2012 Sep;26(9):2521-6.

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.

*Holterman AX, et al. Short-term outcome in the first 10 morbidly obese adolescent patients in the FDA-approved trial for laparoscopic adjustable gastric banding. J Pediatr Gastroenterol Nutr 2007 Oct;45(4):465-73.

Holterman AX, et al. A prospective trial for laparoscopic adjustable gastric banding in morbidly obese adolescents: an interim report of weight loss, metabolic and quality of life outcomes. J Pediatr Surg 2010 Jan;45 (1):74-87.

Hoogerboord M, et al. laparoscopic sleeve gastrectomy: perioperative outcomes, weight loss and impact on type 2 diabetes mellitus over 2 years. Can J Surg 2014 Apr;57(2):101-5.

Huang CK, et al. Novel bariatric technology: laparoscopic adjustable gastric banded plication: technique and preliminary results. Surg Obes Relat Dis 2012 Jan-Feb;8(1):41-5.

Hutter MM, et al. First report from the American College of Surgeons Bariatric Surgery Center Network. Laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the Band and the Bypass. Ann Surg 2011 Sep;254(3):410-22.

Ibrahim M, et al. Endoscopic options for the treatment of obesity. Gastroenterol 2010 Jun;138(7):2228-32.

Ikramuddin S, et al. Roux-en Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial. JAMA 2013 Jun 5;309(21):2240-9.

*Inge TH, et al. Bariatric surgery for pediatric extreme obesity: now or later? Int J Obes (Lond) 2007 Jan;31(1):1-14.

*Inge TH, et al. Teen-longitudinal assessment of bariatric surgery: methodological features of the first prospective multicenter study of adolescent bariatric surgery. J Pediatr Surg 2007 Nov;42(11):1969-71.

*Jan JC, et al. Laparoscopic adjustable gastric banding versus laparoscopic gastric bypass for morbid obesity: a single institution comparison study of early results. J Gastrointest Surg 2005 Jan;9(1):30-9.

*Jan CJ, et al. Comparative study between laparoscopic adjustable gastric banding and laparoscopic gastric bypass: single-institution; 5-year experience in bariatric surgery. Surg Obes Relat Dis 2007 Jan-Feb;3(1):42-50.

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. Circulation 2014 Jun 24;129(25 Suppl 2):S102-38.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 15 OF: 23
---	--

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.

*Johnson WH, et al. Surgical revision of loop("mini") gastric bypass procedure: multicenter review of complications and conversions to Roux-en-gastric bypass. Surg Obes Relat Dis 2007 Jan-Feb;3(1):37-41.

*Kalfarentzos F, et al. A prospective comparison of the vertical banded gastroplasty and Roux-en-Y gastric bypass in a non-superobese population. Obes Surg 2006 Feb;16(2):151-8.

*Kaminski DL. Gastric restrictive procedures to treat obesity: reasons for failure and long-term evaluation of the results of operative revision. In J Surg Investig 2001;2(5):413-21.

Kashyap SR, et al. Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized controlled trial comparing surgery with intensive medical treatment. Diabetes Care 2013 Aug;36(8):2175-82.

*Keating CL, et al. Cost-efficacy of surgically induced weight loss for the management of type 2 diabetes: a randomized controlled trial. Diabetes Care 2009 Apr;32(4):580-4.

Kelly AS, et al. Severe obesity in children and adolescents: identification, associated health risks, and treatment approaches: a scientific statement from the American Heart association. Circulation 2013 Oct 8;128(15):1689-712.

*Kothari SN, et al. Lap-band failures: conversion to gastric bypass and their preliminary outcomes. Surg 2002 Jun;131(6):625-9.

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.

Kumar N and Thompson CC. Transoral outlet reduction for therapy of weight regain after gastric bypass: long-term follow-up. Gastrointest Endosc 2015 Sep 4 [Epub ahead of print].

Lakdawala MA, et al. Comparison between the results of laparoscopic sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass in the Indian population: a retrospective 1 year study. Obes Surg 2010 Jan;20(1):1-6.

*Latzer, Y, et al. Managing childhood overweight: behavior, family, pharmacology, and bariatric surgery interventions. Obesity 2009 Mar;17(3):411-23.

Laurenus A, et al. laparoscopic biliopancreatic diversion/duodenal switch or laparoscopic Roux-en-Y gastric bypass for super-obesity-weight loss versus side effects. Surg Obes Relat Dis 2010 Jul-Aug;6(4):408-14.

Lee DY, et al. Outcomes of laparoscopic Roux-en-Y gastric bypass versus laparoscopic adjustable gastric banding in adolescents. Obes Surg 2012 Dec;22(12):1859-64.

*Lee WJ, et al. Laparoscopic versus open vertical banded gastroplasty for the treatment of morbid obesity. Surg Laparosc Percutan Techniq 2001;11(1):9-13.

*Lee WJ, et al. Laparoscopic Roux-en-Y versus mini-gastric bypass for the treatment of morbid obesity: a prospective randomized controlled clinical trial. Ann Surg 2005 Jul;242(1):20-8.

Lee WJ, et al. Laparoscopic sleeve gastrectomy for diabetes treatment in nonmorbidly obese patients: efficacy and change of insulin secretion. Surgery 2010 May;147(5):664-9.

Lee WJ, et al. Gastric bypass vs sleeve gastrectomy for type 2 diabetes mellitus: a randomized controlled trial. Arch Surg 2011 Feb;146(2):143-8.

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.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 16 OF: 23
---	--

Li JF, et al. Comparison of laparoscopic Roux-en-Y gastric bypass with laparoscopic sleeve gastrectomy for morbid obesity or type 2 diabetes mellitus: a meta-analysis of randomized controlled trials. Can J Surg 2013 Dec;56(6):E158-64.

*Livhits M, et al. Does weight loss immediately before bariatric surgery improve outcomes: a systematic review. Surg Obes Relat Dis 2009 Nov-Dec;5(6):713-21.

Lynch J, et al. Bariatric surgery is effective and safe in patients over 55: a systematic review and meta-analysis. Obes Surg 2012 Sep;22(9):1507-16.

Maciejewski ML, et al. Survival among high-risk patients after bariatric surgery. JAMA 2011 Jun 15;305(23):2419-26.

Maciejewski ML, et al. Health expenditures among high-risk patients after gastric bypass and matched controls. Arch Surg 2012 Jul;147(7):633-40.

Magee CJ, et al. Laparoscopic sleeve gastrectomy for high-risk patients: weight loss and comorbidity improvement-short-term results. Obes Surg 2011;21:547-50.

*Maggard MA, et al. Meta-analysis: surgical treatment of obesity. Ann Intern Med 2005 Apr 5;142(7):547-59.

Maggard-Gibbons M, et al. Bariatric surgery for weight loss and glycemic control in nonmorbidly obese adults with diabetes. JAMA 2013 Jun 5;309(21):2250-61.

Maglione MA, et al. Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m² [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Jun. Report No.: 12(13)-EHC139-EF. AHRQ Comparative Effectiveness Reviews.

*Marceau P, et al. Duodenal switch: long-term results. Obes Surg 2007 Nov;17(11):1421-30.

Marin-Perez P, et al. Outcomes after laparoscopic conversion of failed adjustable gastric banding to sleeve gastrectomy or Roux-en-Y gastric bypass. Br J Surg 2014 Feb;101(3):254-60.

*Marshall JS, et al. Roux-en-Y gastric bypass leak complications. Arch Surg 2003 May;138(5):520-3.

*Mathus-Vliegen EM, et al. Intragastric balloon for treatment-resistant obesity: safety, tolerance, and efficacy of 1-year balloon treatment followed by a 1-year balloon-free follow-up. Gastrointest Endosc 2005 Jan;61(1):19-27.

Mechanick JI, et al. Clinical guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patients- 2013 update: cosponsored by American Association of Clinical Endocrinologists, the Obesity Society, and American Society for metabolic & Bariatric Surgery. Surg Obes Relat Dis 2013 Mar-Apr;9(2):159-91.

*Melissas J, et al. The intragastric balloon- smoothing the path to bariatric surgery. Obes Surg 2006 Jul;16(7):897-902.

Michaelson R, et al. LAP-BAND® for lower BMI: 2-year results from the multicenter pivotal study. Obesity 2013 Jun;21(6):1148-58.

Michalsky MP, et al. Cardiovascular recovery following bariatric surgery in extremely obese adolescents: preliminary results using cardiac magnetic resonance (CMR) imaging. J Pediatr Surg 2013 Jan;48(1):170-77.

*Miller K, et al. Gallstone formation prophylaxis after gastric restrictive procedures for weight loss: a randomized double-blind placebo controlled trial. Ann Surg 2003 Nov;238(5):697-702.

*Miller K, et al. Vertical Banded gastroplasty versus adjustable gastric banding: prospective long-term follow-up study. Surg Obes Relat Dis 2007 Jan-Feb;3(1):84-90.

Mingrone G, et al. Bariatric surgery versus conventional medical therapy for type 2 diabetes. New Engl J Med 2012 Apr 26;366(17):1577-85.

*Morino M, et al. Laparoscopic adjustable gastric banding versus vertical banded gastroplasty in morbidly obese patients: a prospective randomized controlled clinical trial. Ann Surg 2003 Dec;238(6):835-42.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 17 OF: 23
---	--

Moon RC, et al. Conversion of failed laparoscopic adjustable gastric banding: sleeve gastrectomy or Roux-en-Y gastric bypass? Surg Obes Relat Dis 2013 Nov-Dec;9(6):901-7.

Muller-Stich BP, et al. Surgical versus medical treatment of type 2 diabetes mellitus in nonseverely obese patients: a systematic review and meta-analysis. Ann Surg 2015 Mar;261(3):421-9.

Mukherjee S, et al. Sleeve gastrectomy as a bridge to a second bariatric procedure in super-obese patients- a single institution experience. Surg Obes Relat Dis 2011;doi:10.1016/j.soard.2011.04.232

*Nadler EP, et al. Short-term results in 53 US obese pediatric patients treated with laparoscopic adjustable gastric banding. J Pediatr Surg 2007 Jan;42(1):137-41.

Nanni G, et al. Effectiveness of the Transoral Endoscopic vertical Gastroplasty (TOGa®): a good balance between weight loss and complications, if compared with gastric bypass and biliopancreatic diversion. Obes Surg 2012 Dec;22(12):1897-902.

*National Heart, Lung, and Blood Institute and the National Institute of Health. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in Adults. 1998 Jun.

*National Institutes of Health, National Heart, Lung and Blood Institute, Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. Executive Summary. Bethesda, MD: National Institutes of Health; September 1998. [http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm] accessed 10/2/15.

National Institute for Health and Care Excellence. Implantation of a duodenal-jejunal bypass sleeve for managing obesity. IPG 471. Nov 2013 [www.nice.org.uk] accessed 10/2/15.

*Nehoda H, et al. Laparoscopic gastric banding in older patients. Arch Surg 2001;136:1171-286.

*Nelson WK, et al. The malabsorptive very, very long limb Roux-en-Y gastric bypass for super obesity: results in 257 patients. Surgery 2006 Oct;140(4):517-22.

*Nguyen NT, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. Ann Surg 2001;234:279-91.

*Nguyen NT, et al. Result of a national audit of bariatric surgery performed at academic centers: a 2004 University HealthSystem Consortium Benchmarking project. Arch Surg 2006 May;141(5):445-9.

Nguyen NT, et al. Outcome of laparoscopic adjustable gastric banding and prevalence of band revision and explantation at academic centers: 2007-2009. Surg Obes Relat Dis 2012 Nov-Dec;8(6):724-7.

Nguyen NT, et al. Changes in the makeup of bariatric surgery: a national increase in use of laparoscopic sleeve gastrectomy. J Am Coll Surg 2013 Feb;216(2):252-7.

Niazi M, et al. Short-term outcomes of laparoscopic gastric plication in morbidly obese patients: importance of postoperative follow-up. Obes Surg 2013 Jan;23(1):87-92

Nijhawan S, et al. Laparoscopic gastric bypass for the adolescent patient: long-term results. Obes Surg 2012 May;22(5):1445-9.

*Nilsell K, et al. Prospective randomised comparison of adjustable gastric banding and vertical banded gastroplasty for morbid obesity. Eur J Surg 2001;167:504-9.

Nocca D, et al. Impact of laparoscopic sleeve gastrectomy and laparoscopic gastric bypass on HbA1c blood level and pharmacological treatment of Type 2 Diabetes mellitus in severe or morbidly obese patients. Results of a multicenter prospective study at 1 year. Obes Surg 2011;21:738-43.

*Nocca D. Laparoscopic adjustable gastric banding and laparoscopic sleeve gastrectomy: which has a place in the treatment of diabetes in morbidly obese patients? Diabetes Metab 2009 Dec;35(6 Pt 2):524-7.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 18 OF: 23
---	--

*O'Brien P, et al. The laparoscopic adjustable gastric band (Lap-Band®): A prospective study of medium-term effects on weight, health and quality of life. Obes Surg 2002 Oct;12:660-2.

*O'Brien PE, et al. A rational approach to cholelithiasis in bariatric surgery: its application to laparoscopically placed adjustable gastric banding. Arch Surg 2003 Aug;138(8):908-12.

*O'Brien PE, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. Ann Intern Med 2006 May 2;144(9):625-33.

O'Brien PE, et al. Laparoscopic adjustable gastric banding in severely obese adolescents. JAMA 2010 Feb 10;303(6):519-26.

O'Brien PE, et al. Long-term outcomes after bariatric surgery: fifteen-year follow-up of adjustable gastric banding and a systematic review of the bariatric surgical literature. Ann Surg 2013 Jan;257(1):87-94.

Ochner CN, et al. Effectiveness of a pre-bariatric surgery insurance-required weight loss regimen and relation to postsurgical weight loss. Obesity 2010 Feb;18(2):287-92.

O'Keefe K, et al. Bariatric surgery outcomes in patients aged 65 years and older at an American Society for Metabolic and Bariatric Surgery Center of Excellence. Obes Surg 2010;20:1199-205.

*Oliak D, et al. Short-term results of laparoscopic gastric bypass in patients with BMI > 60. Obes Surg 2002 Oct;12:643-7.

Ong'uti SK, et al. Effective weight loss management with endoscopic gastric plication using StomaphyX device: is it achievable? Surg Obes Relat Dis 2011 Nov 9 [Epub ahead of print].

Orci L, et al. Short versus long Roux-limb length in Roux-en-Y gastric bypass for the treatment of morbid and super obesity: a systematic review of the literature. Obes Surg 2011 Jun;21(6):797-804.

Owers C, et al. A study examining the complications associated with gastric banding. Obes Surg 2013 Jan;23(1):56-9.

Pallati P, et al. Trends in adolescent bariatric surgery evaluated by UHC database collection. Surg Endosc 2012 Nov;26(11):3077-81.

*Parikh MS, et al. Laparoscopic bariatric surgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. Obes Surg 2005 Jun-Jul;15(6):858-63.

Parikh M, et al. Laparoscopic "gastrojejunal sleeve reduction" as a revision procedure for weight loss failure after Roux-en-Y gastric bypass. Obes Surg 2011;21:620-54.

Pataky Z, et al. Psychological factors and weight loss in bariatric surgery. Curr Opin Gastroenterol 2011 Mar;27(2):167-73.

Peacock JC, et al. An assessment of patient behavioral requirements pre- and post-surgery at accredited weight loss surgical centers. Obes Surg 2011 Feb 21 [Epub ahead of print].

*Perugini RA, et al. Predictors of complications and suboptimal weight loss after laparoscopic Roux-en-Y gastric bypass: a series of 188 patients. Arch Surg 2003 May;138:541-6.

*Peterli R, et al. Improvement in glucose metabolism after bariatric surgery: comparison of laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy: a prospective randomized trial. Ann Surg 2009 Aug;250(2):234-41.

Peterli R, et al. Early results of the Swiss Multicentre Bypass or Sleeve Study (SM-BOSS): a prospective randomized trial comparing laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass. Ann Surg 2013 Nov;258(5):690-4.

*Picot J, et al. The clinical effectiveness and cost effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess 2009 Sep;13(41):1-190.

Pilone V, et al. Improvement in health-related quality of life in first year after laparoscopic adjustable gastric banding. Surg Obes Relat Dis 2012 May-Jun;8(3):260-8.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 19 OF: 23
---	--

*Podnos YD, et al. Complications after laparoscopic gastric bypass: a review of 3464 cases. Arch Surg 2003;138(9):57-961.

Ponce J, et al. prospective, randomized, multicenter study evaluating safety and efficacy of intragastric dual-balloon in obesity. Surg Obes Relat Dis 2013 Mar-Apr;9(2):290-5.

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

Pories WJ, et al. Beyond BMI: The search for better guidelines for bariatric surgery. Obesity 2010 May;18(5):865-71.

*Pratt JS, et al. Best practice updates for pediatric/adolescent weight loss surgery. Obesity 2009 May;17(5):901-10.

Pull CB. Current psychological assessment practices in obesity surgery programs: what to assess and why. Curr Opin Psychiatry 2010 Jan;(23)1:30-6.

*Puzziferri N, et al. Three-year follow-up of a prospective randomized trial comparing laparoscopic versus open gastric bypass. Ann Surg 2006 Feb;243(2):181-8.

Puzziferri N, et al. Long-term follow-up after bariatric surgery: a systematic review. JAMA 2014 Sep 3;312(9):934-42.

Radtka J, et al. Revisional bariatric surgery: who, what, where, and when? Surg Obes Relat Dis 2010;6:635-42.

*Ramos AC, et al. Laparoscopic duodenal-jejunal exclusion in the treatment of type 2 diabetes mellitus in patients with BMI < 30 kg.m2 (LBMI). Obes Surg 2009 Mar;19(3):307-12.

Rawlins L, et al. Sleeve gastrectomy: 5 year outcomes of a single institution. Surg Obes Relat Dis 2012 [http://dx.doi.org/10.1016/j.soard.2012.08.014] accessed 10/5/15.

Raziel A, et al. Mid-term follow-up after laparoscopic sleeve gastrectomy in obese adolescents. Isr Med Assoc J 2014 Jan;16(1):37-41.

*Regan JP, et al. Early experience with two-stage laparoscopic Rou-en-Y gastric bypass as an alternative in the super-obese patient. Obes Surg 2003 Dec;13(6):861-4.

*Ren CJ, et al. US experience with the LAP-BAND system. Am J Surg 2002 Dec;184(6B):46S-50S.

Risstad H, et al. Five-year outcomes after laparoscopic gastric bypass and laparoscopic duodenal switch in patients with body mass index of 50-60: a randomized clinical trial. JAMA Surg 2015 Apr;150(4):352-61.

*Roa PE, et al. Laparoscopic sleeve gastrectomy as treatment for morbid obesity: technique and short-term outcome. Obes Surg 2006 Oct;16(10):1323-6.

*Rubenstein RB. Laparoscopic adjustable gastric banding at a U.S. center with up to 3-year follow-up. Obes Surg 2002 Jun;12:380-4.

*Rubin M, et al. Prospective study of 250 patients undergoing laparoscopic gastric banding using the two-step technique. Surg Endosc 2003 Jun;17(6):857-60.

Rubino F, et al. The Diabetes Surgery Summit consensus conference: recommendations for the evaluation and use of gastrointestinal surgery to treat type 2 diabetes mellitus. Ann Surg 2010 Mar;251(3):399-405.

*Sanchez-Santos R, et al. Short-and mid-term outcomes of sleeve gastrectomy for morbid obesity: the experience of the Spanish National Registry. Obes Surg 2009 Sep;19(9):1203-10.

*Sarker S, et al. Three-year follow-up weight loss results for patients undergoing laparoscopic adjustable gastric banding at a major university medical center: does weight loss persist? Am J Surg 2006 Mar;191(3):372-6.

*Schauer PR, et al. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. Ann Surg 2001;232:515-29.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 20 OF: 23
---	--

Schauer PR, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med 2012 Apr 26;366(17):1467-576.

Schauer PR, et al. Bariatric surgery versus intensive medical therapy for diabetes-3 year outcomes. N Engl J Med 2014 May 22;370(21):2002-13.

Schimizu H, et al. Revisional bariatric surgery for unsuccessful weight loss and complications. Obes Surg 2013 Jul 5 [Epub ahead of print].

Schouten R, et al. A multicenter, randomized efficacy study of the EndoBarrier Gastrointestinal Liner for presurgical weight loss prior to bariatric surgery. Ann Surg 2010 Feb;251(2):236-43.

Schouton R, et al. Long-term results of bariatric restrictive procedures: a prospective study. Obes Surg 2010 Dec;20(12):1617-26.

*Scopinaro N, et al. Laparoscopic standard biliopancreatic diversion: technique and preliminary results. Obes Surg 2002 Jun;13:362-5.

*Scozzari G, et al. Laparoscopic adjustable silicone gastric banding vs laparoscopic vertical banded gastroplasty in morbidly obese patients: long-term results of a prospective randomized clinical trial. Obes Surg 2009 Aug;19 (8):1108-15.

Shi X, et al. A review of laparoscopic sleeve gastrectomy for morbid obesity. Obes Surg 2010 Aug;20(8):1171-7.

*Silecchia G, et al. Effectiveness of laparoscopic sleeve gastrectomy (first stage of biliopancreatic diversion with duodenal switch) on co-morbidities in super-obese high-risk patients. Obes Surg 2006 Sep;16(9):1138-44.

Singhal R, et al. Medium-term outcomes of patients with insulin-dependent diabetes after laparoscopic adjustable gastric banding. Surg Obes Relat Dis 2013 Jan-Feb;9(1):42-7.

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

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.

Slegtenhorst BR, et al. Effect of primary versus revisional Roux-en-Y gastric bypass: inferior weight loss of revisional surgery after gastric banding. Surg Obes Relat Dis 2013 Mar-Apr;9(2):253-8.

Spiegel HU, et al. From longitudinal gastric resection to sleeve gastrectomy- revival of a previously established surgical procedure. J Gastrointest Surg 2011 Jan;15(1):219-28.

*Spivak H, et al. Weight loss and improvement of obesity-related illness in 500 U.S. patients following laparoscopic adjustable gastric banding procedure. Am J Surg 2005 Jan;189(1):27-32.

*Solomon H, et al. Benefits to patients choosing preoperative weight loss in gastric bypass surgery: new results of a randomized trial. J Am Coll Surg 2009 Feb;208(2):241-5.

Sovik TT, et al. Randomized clinical trial of laparoscopic gastric bypass versus laparoscopic duodenal switch for superobesity. Br J Surg 2010 Feb;97(2):160-6.

*Stanford A, et al. Laparoscopic Roux-en-Y gastric bypass in morbidly obese adolescents. J Pediatr Surg 2003 Mar;38(3):430-3.

Stimac D, et al. Intra gastric balloon treatment for obesity: results of a large single center prospective study. Obes Surg 2011;21:551-5.

*St Peter SD, et al. Impact of advanced age on weight loss and health benefits after laparoscopic gastric bypass. Arch Surg 2005 Feb;140(2):165-8.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 21 OF: 23
---	--

*Strain GW, et al. Comparison of weight loss and body composition changes with four surgical procedures. Surg Obes Relat Dis 2009 Sep-Oct;5(5):582-7.

*Stroh C, et al. Results of sleeve gastrectomy-data from a nationwide survey on bariatric surgery in Germany. Obes Surg 2009 May;19(5):632-40.

*Sugerman HJ, et al. Diabetes and hypertension in severe obesity and effects of gastric bypass-induced weight loss. Ann Surg 2003 Jun;237(6):751-8.

*Sugerman HJ, et al. Bariatric surgery for severely obese adolescents. J Gastrointest Surg 2003 Jan;7(1):102-7.

Sultan S, et al. Five-year outcomes of patients with type 2 diabetes who underwent laparoscopic adjustable gastric banding. Surg Obes Relat Dis 2010;6(3):373-6.

*Suter M, et al. European experience with laparoscopic Roux-en-Y gastric bypass in 466 obese patients. Br J Surg 2006 Jun;93(6):726-32.

Sysko R, et al. Psychological outcomes and predictors of initial weight loss outcomes among severely obese adolescents receiving laparoscopic adjustable gastric banding. J Clin Psychiatry 2012 Oct;73(10):1351-7.

Taha O. Efficacy of laparoscopic greater curvature plication for weight loss and type 2 diabetes: 1-year follow-up. Obes Surg 2012 Oct;22(10):1629-32.

Tai CM, et al. Effectiveness of intragastric balloon treatment for obese patients: one-year follow-up after balloon removal. Obes Surg 2013 Dec;23(12):2068-74.

Talebpour 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.

*Tarnoff M, et al. Open label, prospective, randomized controlled trial of an endoscopic duodenal-jejunal bypass sleeve versus low calorie diet for pre-operative weight loss in bariatric surgery. Surg Endosc 2009 Mar;23(3):650-6.

*Taylor CJ, et al. Laparoscopic adjustable gastric banding in patients > or = 60 years old: is it worthwhile? Obes Surg 2006 Dec;16(12):1579-83.

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.

*Thomusch O, et al. Risk factors for the intermediate outcome of morbid obesity after laparoscopically placed adjustable gastric banding. Am J Surg 2005 Feb;189(2):214-8.

Todkar JS, et al. Long-term effects of laparoscopic sleeve gastrectomy in morbidly obese subjects with type 2 diabetes mellitus. Surg Obes Relat Dis 2010 Mar 4;6(2):142-5.

Topart P, et al. Comparative early outcomes of three laparoscopic bariatric procedures: sleeve gastrectomy, Roux-en-Y gastric bypass, and biliopancreatic diversion with duodenal switch. Surg Obes Relat Dis 2012 May-Jun;8(3):250-4.

Topart P, et al. Weight loss is more sustained after biliopancreatic diversion with duodenal switch than Roux-en-Y gastric bypass in superobese patients. Surg Obes Relat Dis 2012 Mar 3 [Epub ahead of print].

*Torchia F, et al. LapBand System ® in super- superobese patients (>60 kg.m2): 4-year results. Obes Surg 2009 Sep;19(9):1211-15.

Tran TT, et al. Revisional weight loss surgery after failed laparoscopic gastric banding: an institutional experience. Surg Endosc 2013 Nov;27(11):4087-93.

*Tsai WS, et al. Bariatric surgery in adolescents: recent national trends in use and in-hospital outcome. Arch Pediatr Adolesc Med 2007 Mar;161(3):217-21.

Valle E, et al. Frequency of adjustments and weight loss after laparoscopic adjustable gastric banding. Obes Surg 2012 Dec;22(12):1880-3.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 22 OF: 23
---	--

Van de Laar A. Bariatric outcomes longitudinal database (BOLD) suggests excess weight loss and excess BMI loss to be inappropriate outcome measures, demonstrating better alternatives. Obes Surg 2012 Aug;22(8):1843-7.

*Van Dielen FM, et al. Laparoscopic adjustable gastric banding versus open vertical banded gastroplasty: a prospective randomized trial. Obes Surg 2005 Oct;15 (9):1292-98.

Van Nieuwenhove Y, et al. Long-term results of a prospective study on laparoscopic adjustable gastric banding for morbid obesity. Obes Surg 2011;21:582-7.

Van Rutte PW, et al. Outcomes of sleeve gastrectomy as a primary bariatric procedure. Br J Surg 2014 May;101(6):661-8.

Varela JE, et al. Laparoscopic sleeve gastrectomy versus laparoscopic adjustable gastric banding for the treatment severe obesity in high risk patients. JSLs 2011 Oct-Dec;15 (4):486-91.

Verdam FJ, et al. An update on less invasive and endoscopic techniques mimicking the effect of bariatric surgery. J Obes 2012;2012:597871 [Epub 2012 Aug 21].

Vijgen GH, et al. Revision of laparoscopic adjustable gastric banding: success or failure? Obes Surg 2012 Feb;22(2):287-92.

Wang MC, et al. Laparoscopic Roux-en-Y gastric bypass versus sleeve gastrectomy for obese patients with Type 2 diabetes: a meta-analysis of randomized controlled trials. Am Surg 2015 Feb;81(2):166-71.

Wang GF, et al. Predictive factors of type 2 diabetes mellitus remission following bariatric surgery: a meta-analysis. Obes Surg 2015 Feb;25(2):199-208.

*Weiner R, et al. Outcome after laparoscopic adjustable gastric banding- 8 years experience. Obes Surg 2003 Jun;13(3):427-34.

Weiner JP, et al. Impact of bariatric surgery on health care costs of obese persons: a 6-year follow-up of surgical and comparison cohorts using health plan data. JAMA Surg 2013 Jun;148(6):555-62.

*Westling A, et al. Roux-en-Y gastric bypass after previous unsuccessful gastric restrictive surgery. J Gastrointest Surg 2002 Mar-Apr; 692:206-11.

Yip S, et al. Gastric bypass and sleeve gastrectomy for type 2 diabetes: a systematic review and meta-analysis of outcomes. Obes Surg 2013 Dec;23(12):1994-2003.

Young MT, et al. Use and outcomes of laparoscopic sleeve gastrectomy vs laparoscopic gastric bypass: analysis of the American College of Surgeons NSIP. J Am Coll Surg 2015 May;220(5):880-5.

Zellmer JD, et al. Is laparoscopic sleeve gastrectomy a lower risk bariatric procedure compared with laparoscopic Roux-en-Y gastric bypass? A met-analysis. Am J Surg 2014 Dec;208(6):903-10.

*Zinzindohoue F, et al. Laparoscopic gastric banding: a minimally invasive surgical treatment for morbid obesity. Ann Surg 2003 Jan;237(1):1-9.

*key article

KEY WORDS:

Adjustable gastric band, Bariatric, Endobarrier, Gastric bypass, Gastric plication, Imbrication, intragastric balloon, Lap Band, ROSE, Roux-en-Y, Sleeve gastrectomy, transoral outlet reduction.

SUBJECT: SURGICAL MANAGEMENT OF OBESITY POLICY NUMBER: 7.01.29 CATEGORY: Technology Assessment	EFFECTIVE DATE: 05/18/00 REVISED 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 PAGE: 23 OF: 23
---	--

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for bariatric surgery and an article from NGS specific for sleeve gastrectomy. Please refer to the following NCD and LCD websites for Medicare Members:

NCD:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAAA%3d%3d&>

NGS article:

http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/a51967/!ut/p/a1/xVNNb8IwDP0rvXC4n6XYisMFoKjA3aCwppBoE27aBiH79-KSCNTRrbNE3LKc92nu1nByVohhJB9nxJKl4lktU4secm7nU0zYN-1NYcwH1zCN1JBL7loClKULIje0aLYsNZjWjGyPYNjtt-LxocHKIqqxWKxXKXs5RTspWvRMVEJdhjA87MB1wWGafPDchoulOISJWjQSHbisscO0VV8pIqJ4oGEEtr2k6dqKQ8RfGC2bZhNkGlzRRUs0kslVA9VZlm6QudpcRhVh0dRC0UDyWr0pL9xrJf-ORg-JYc70KMyAVsXrXa7dHQ8Fv6KeBCiljW4LwxuF7fA-wFw3Bw5QGMHHTzwx4vE9rmkXDqhfPRbWcso8_mKdH5PCU8zVPezoX7VUUfdAycf6_InYylRv0wuLvtuQb4Pxf9-qtVkaumb0MvXEpaUq1ULu4LNDstsXTy9cNDguWvqff7qUKzv_02Zb4Z-66RqzNYW-X-ZYJxN58PQozZwgXDyvYBfgUf__Zb/dl5/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=®ION=&LOB=Part%20B