KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Bariatric Surgery

- Adjustable gastric banding, Laparoscopic or Open (Lap Band)
- EndoGastric Solutions StomaphyX™ Endoluminal Fastener
- Gastric Bypass for GERD
- Gastric Electrical Stimulator
- Intragastric Balloons
- Laparoscopic Sleeve Gastrectomy
- Roux-en-Y Gastric Bypass (RYGB)
- Vertical Banded Gastroplasty (VBG)
- Vertical Sleeve Gastrectomy (VSG)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Billing and Coding: Bariatric Surgery Coverage (A53028)

For Non-Medicare Members

Procedure	Kaiser Permanente Commercial plans (including SEBB)
Adjustable gastric banding, Laparoscopic or Open (Lap Band) -Not covered for Federal Plans Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity Roux-en-Y Gastric Bypass (RYGB) Vertical Sleeve Gastrectomy (VSG) **Effective 3/1/2022** **Vertical Banded Gastroplasty (VBG) will no longer be considered medically necessary.** Vertical Banded Gastroplasty (VBG)	The qualifying age in criteria will change to 18 years of age or older. See Bariatric Surgery (KP-516 v2 eff 11.01.2021) MCG*. *Please see MCG Guideline Index for access to criteria: https://kpwa.access.mcg.com/index. **If requesting this service, please send the following documentation to support medical necessity:** • Last 2 years of gastroenterology notes • Most recent clinical note from requesting provider • Documentation of patient height, weight & comorbid conditions

Back to Top

Procedure	Kaiser Permanente Commercial plans (including SEBB)
EndoGastric Solutions StomaphyX™ Endoluminal Fastener Gastric Bypass for GERD Gastric Electrical Stimulation (GES) for Obesity	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist
Intragastric Balloon Device	MCG* A-0970 This is not covered per MCG **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist *Please see MCG Guideline Index for access to criteria: https://kpwa.access.mcg.com/index.

The following procedures are not covered (benefits are varied and need to be verified): Biliopancreatic bypass, Distal gastric bypass, Duodenal switch (Single-Anastomosis Duodenal Switch), Mini-gastric bypass.

Effective March 1, 2022
The vertical banded gastroplasty (VBG) is no longer a standard of care and is therefore considered not medically necessary and not covered.

CDC Adult Body Mass Index (BMI) Calculator View Chart
https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html
Percent of Excess Body Weight Loss Formula
(Initial Weight – Postop Weight)/ (Initial weight – Ideal Weight*) Ideal weight is defined by the weight corresponding to a BMI of 25 for the person in question.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

EndoGastric Solutions
Gastric Bypass for GERD
Gastric Electrical Stimulator for Obesity
Intragastric Balloons
Laparoscopic Sleeve Gastrectomy
Vertical Sleeve Gastrectomy (VSG)

Background

Back to Top

The NIH has defined overweight as a BMI between 25 kg/m2 and 29.9 kg/m2, and obesity as a BMI of > 30 kg/m2. According to national survey data, an estimated one-third of adults in the United States are overweight. Overweight and obesity are associated with an increased risk of mortality. Individuals with a BMI > 30 have a 50-100% increased risk of premature death compared to individuals with a BMI between 20 and 25. In addition, overweight and obesity are associated with an increased risk of coronary heart disease, type 2 diabetes, hypertension, certain cancers and musculoskeletal disorders such as knee osteoarthritis (Surgeon General report: USPSTF).

Lifestyle changes, including diet, exercise, and behavior modification, are generally considered first-line therapy for overweight and obesity. Pharmacotherapy can be used as an adjunctive therapy when lifestyle changes alone are ineffective. Medical management of obesity has been found to be less effective with individuals who are morbidly obese (BMI > 35) than for those with lower BMI, particularly in terms of sustained weight loss. The NIH has stated that bariatric surgery is an option for patients with a BMI > 40 or a BMI > 35 with comorbid conditions, who have failed medical treatment (Fisher and Schauer, 2002; NIH, 1998).

There are two main strategies for surgically inducing weight loss, gastric restriction and intestinal malabsorption. Restrictive procedures mechanically reduce the size of the stomach. This limits the amount of food a patient can consume at a single meal and causes early satiety. Substantial dietary compliance is required, because individuals are still able to consume high-calorie liquids or soft foods. Malabsorption procedures involve bypassing a portion of the intestines which decreases the proportion of nutrients that are absorbed from food. Some types of surgeries use elements of both strategies (Fisher and Schauer, 2002; Southern California-RAND EBPC 2004).

Two currently accepted bariatric surgery methods are Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB). VBG is a restrictive procedure that uses staples to create a narrow gastric inlet or pouch and a non-adjustable band is placed around the new inlet to prevent enlargement. RYGB includes both restrictive and malabsorptive elements. The stomach is reduced to a small gastric pouch, and this pouch is connected to a segment of the jejunum, bypassing the duodenum and proximal small intestine. RYGB can be performed as open surgery or laparoscopically.

Adjustable gastric banding is a restrictive technique, using the Lap-Band System® (Inamed). A small gastric pouch is formed by laparoscopically placing a silicone ring (the Lap-Band) around the upper part of the stomach just below the gastro-esophageal junction. The band is connected via tubing to an access port that is secured beneath the skin of the abdomen. The band has a reservoir that is accessed percutaneously and filled with saline. The size of the band can be adjusted by adding or removing saline. The Lap-Band is removable, either laparoscopically or via an open procedure. In the clinical study presented by the manufacturer to the FDA, 60% of the band removal procedures were laparoscopic. The Lap-Band has been used in Europe and Australia since early 1990s and was approved by FDA in June 2001 (manufacturer's Web site).

Medical Technology Assessment Committee (MTAC)

Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)

2/10/1999: MTAC REVIEW

Evidence Conclusion: The published scientific evidence consists of several large case series and one randomized controlled trial from multiple institutions published over a 10-year period of time. Vertical Banded Gastroplasty (VBG) Data from 4 case series and 1 RCT totaling 403 patients undergoing VBG with 75-100% follow up at 3 years demonstrates between 15 and 31% weight loss. Reoperation or revisional surgery was required in 3% of patients in one series and 36% in another series. Mortality was 1-3% overall. Roux-en-Y (REY)- Data from 2 case series and 1 RCT totaling 532 patients in the REY groups with 60-86% follow up at 3 years demonstrates that Roux-en-Y gastric restrictive surgery results in between 33 and 35% weight loss. Reoperation or revisional surgery was required in 6% of patients in one series and not reported in the other series. Mortality was 1% overall.

Articles: MacLean, LD et al. *Surgery*, 1993;113:380-388. See Evidence Table. Sugerman, HJ, et al. 1989: *Am J Surg.*;157 93-100. See Evidence Table.

Sjostrom CD, Peltonen M, Wedel H, Sjostrom L. Differentiated long-term effects of intentional weight loss on diabetes and hypertension. *Hypertension* 2000; 36: 20-25. See Evidence Table.

The use of gastric restrictive surgery (VBG or REY) meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/8/2006: MTAC REVIEW

Back to Top

Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)

Evidence Conclusion: There is some evidence that Lap-Band surgery is more effective than optimal non-surgical management for patients with BMI between 30-35 kg/m2 with co-morbidities. This evidence is not conclusive due to the size of the single RCT, and its limitations. Evidence from non-randomized studies suggests that gastric bypass surgery is more effective for weight loss than the Lap-Band technique for patients who meet standard eligibility criteria for bariatric surgery (BMI > 40 kg/m2 or > 35 kg/m2 with co-morbidities) and for the sub-set of patients with BMI > 50 kg/m2. Gastric surgery was not associated with more complications than the Lap-Band procedure, and studies generally found a higher reoperation rate after Lap-Band surgery. There may be residual confounding in the non-randomized studies. There are no randomized controlled trials comparing the safety and effectiveness of Lap-Band surgery to either gastric bypass or optimal non-surgical management for adults with BMI > 35 kg/m2. There is evidence from one randomized controlled trial that Lap-Band surgery is more effective for weight loss than a non-surgical intervention (i.e. supervised dieting, pharmacotherapy) for patients with BMI between 30-35 kg/m2 with co-morbidities (O'Brien et al., 2005). However, in the two years of follow-up 4 of the 39 patients who received the Lap-Band experienced prolapse of the posterior gastric wall. In addition, limitations of the study were that it was not blinded, follow-up was only two years, and the nonsurgical intervention was not well described beyond 6 months. The best evidence comparing the Lap-Band and Roux-en-Y gastric bypass comes from two non-randomized comparative studies (Weber et al., 2004; Cottam et al. 2006). Both matched patients who did and did not receive the Lap-Band according to age, sex and BMI. The Weber study included patients with BMI > 40 kg/m2 or BMI > 35 kg/m2 who had co-morbidities and the Cottam study did not specify eligibility criteria, but mean BMI was 47 kg/m2. Both studies found significantly more weight loss at 2-3 years and fewer co-morbidities in the group that underwent gastric bypass. In the Weber et al. study, the rate of reoperation was somewhat higher in the gastric bypass group than the Lap-Band group during the first 30 days (n=7 vs. n=1), but after 30 days the rate was higher in the Lap-Band group (n=26) than the gastric bypass group (n=4). The Cottam et al. study found a slightly higher rate of major reoperation in the gastric bypass group compared to the Lap-Band group (8% vs. 5%), but this difference was not statistically significant. A third non-randomized study compared the Lap-Band and laparoscopic Roux-en-Y gastric bypass in super morbidly obese patients (BMI > 50 kg/m2). Similar to the studies of patients with lower mean BMI, there was greater reduction in BMI and a higher proportion of excess weight loss in patients who received gastric bypass compared to the Lap-Band. There appeared to be a greater reduction in co-morbidities and fewer complications in the gastric bypass group, but numbers were too small to accurately compare the groups in these areas. Reoperations were necessary in 15% of the Lap-Band group and 6.5% of the gastric bypass group. In all of the non-randomized studies, there may be confounding variables, differences between groups that affect the outcome (such as differences in commitment to losing weight). A large case series conducted in Italy (n=1893) provides additional information on the safety of the Lap-Band technique. Reported post-operative mortality was 1 out of 200 procedures (0.5%) and was restricted to patients with preoperative cardiovascular complications. The most common post-operative complications were gastric pouch dilation (5%) and tube port complications (4%). The ideal study would be a randomized controlled trial comparing long-term outcomes of gastric surgery with the Lap-Band and commonly accepted bariatric surgery procedures or optimal non-surgical management. One randomized controlled trial was identified and critically appraised. It compared the Lap-Band to non-surgical treatment. Five non-randomized comparative studies were identified comparing the Lap-Band to gastric bypass. One study conducted in Sweden was excluded because it compared two case series of patients treated at different institutions. A second study was excluded because only preliminary findings were reported: there was 60% follow-up at 1 year and 15% at 2 years. The other three studies were critically appraised. A large case series from Italy (n=1863) was also reviewed to evaluate the long-term safety of Lap-Band surgery.

Articles: *Evidence tables were created for the following studies:* O'Brien PE, Dixon JB, Laurie C et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program. *Ann Intern Med* 2005; 144: 625-633. See Evidence Table. Weber M, Miller MK, Bucher T. Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity. *Ann Surg* 2004; 240: 975-983. See Evidence Table. Cottam DR, Atkinson J, Anderson A et al. A case-controlled matched-pair cohort study of laparoscopic Roux-en-Y gastric bypass and Lap-Band patients in a single US center with three-year follow-up. *Obesity Surg* 2006; 16: 534-540. See Evidence Table. Browne WB, Julliard K, Castro AE et al. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients. *Arch Surg* 2006; 141: 683-689. See Evidence Table. Angrisani L, Furbette F, Doldi SB et al. Lap-Band adjustable gastric banding system: The Italian experience with 1863 patients operated on over 6 years. *Surg Endosc* 2003; 17: 409-412. See Evidence Table.

The use of adjustable gastric banding and lap-band in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

12/15/2014: MTAC REVIEW

Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)

Evidence Conclusion: There is a lack of good quality RCTs with long-term follow-up that compared laparoscopic gastric banding versus Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy. The few published RCTs were small, with short follow-up duration, and methodological limitations. Colquitt and colleagues' 2014 systematic review and meta-analysis on surgery for morbid obesity was the last published update of previous Cochrane reviews and updates on that topic conducted by the same group of authors over the last decade. This last August 2014 update (Evidence table 1) included RCTs on bariatric surgery published through December 2013. The meta-analysis included 15 trials (N=1,180 participants) that compared different bariatric surgery procedures used for weight loss (seven additional trials compared surgery to non-surgical weight loss therapies). The meta-analysis had valid methodology and analysis, but the majority of the studies included had uncertain or high risk of bias. The overall results for the comparisons made among the three most commonly performed procedures were as follows: Laparoscopic gastric bypass (LRYGB) vs. laparoscopic adjustable gastric banding (LAGB)

The review found moderate quality evidence from 3 RCTs with uncertain risk of bias that LRYGB achieved significantly greater weight loss and BMI reductions up to 5 years after surgery vs. LAGB. Two trials reported longer duration of hospitalization with LRYGB, and one study showed that it was associated with larger number of late major complications vs. LAGB. On the other hand, one study showed that a large proportion of those undergoing LAGB required reoperation for band removal (the authors warned against generalizability of results of this study due to high drop-out rates). The evidence on QoL and co-morbidities was of very low quality. LAGB vs laparoscopic sleeve gastrectomy (LSG) One relatively small study (Himpens et al, 2006) with methodological limitations (reviewed earlier by MTAC) showed that reductions in weight and BMI were statistically significantly higher with LSG vs LABG. The study also showed that symptoms of GERD were resolved in a higher proportion among patients in the LSG group vs. LAGB (no tests of significance were provided). Open or LRYGB vs. LSG The RCTs included showed no statistically significant differences between the two procedures in the reductions in weight or BMI. Serious adverse events were reported in one trial and were higher in the LRYGB group. There were no statistically significant differences between the 2 procedures in their effect on comorbidities and complications except for one study that showed significantly more improvement in diabetes mellitus with LRYGB. The authors of the review concluded that the outcomes were similar between RYGB and LSG and that both procedures had better outcomes than LAGB. There was no good evidence from RCTs to determine whether any procedure was more effective than another in controlling comorbidities. The studies had relatively short-term follow-up durations, which was insufficient to study the long-term effects of the surgical procedures.

Wang et al, 2013 (Evidence table 2) conducted a meta-analysis of 11 randomised and non-randomized controlled studies (N=1,004 participants) that compared LAGB with LSG. The pooled results suggest that LSG is associated with greater excess with loss (EWL% mean difference -12.55 [95% CI, -15.66, -9.43] at 6 months and -4.97 [95% CI, -7.58, -2.36] at 12 months). LSG was also associated with better improvement in type 2 DM than LAGB (pooled OR of 0.34; 95 % CI 0.16-0.73). The meta-analysis combined the results of a small number of randomized and non-randomized studies with small sample sizes and short-term follow-up durations. The authors concluded that larger RCTs with long-term follow-up are needed to compare the efficacy of LSG, LAGB, and LRYGB.

Dogan and colleagues (2014) compared the safety and effectiveness of LAGB, LRYGB, and LSG in a matched retrospective cohort study involving 735 patients who underwent the procedures in two centers in the Netherlands between 2007 and 2010. The results showed that LRYGB was associated with a significantly higher excess weight loss compared to LSG in the first year after which there was no significant difference in weight loss between the two procedures. After 3 years of follow-up LAGB had a higher complication rate compared to the other two procedures. Revision surgery was needed in 21% of LAGB, and 9% of LSG underwent conversion to RYGB. The authors concluded that LRYGB is a safe and effective treatment in morbidly obese patients with good long-term outcomes. LSG was comparable to LRYGB regarding weight loss and complication rate; and that LAGB was inferior to both LRYGB and LSG. Arterburn, et al (2014) compared the short and long-term outcomes of LRYGB and LAGB in a retrospective cohort study of 7,457 adult patients who underwent laparoscopic bariatric surgery from January 2005 through December 2009 in 10 health care systems (including Kaiser Permanente) in the US. 1,507 underwent LAGB and 5,950 underwent RYGB. The primary outcomes were change in BMI, composite of 30-day rate of major adverse outcomes, subsequent hospitalization, and subsequent intervention. The results indicate that RYGB led to a significantly greater loss in BMI than LAGB (14.8 loss with RYGB vs. 8.0 LAGB, $p<0.001$). RYGB was associated with a higher rate of short-term complication, and long-term subsequent hospitalization. LAGB on the other hand was associated with a higher risk of long-term subsequent interventions procedures. The study was large and included a diverse group of patients but was retrospective and not randomized. Data were obtained from records which did not included all required information, and the subsequent interventions and hospitalizations may have been due to causes unrelated to the bariatric procedures. Trastulli et

Back to Top

al (2013) conducted a systematic review to evaluate the safety and effectiveness of LSG in terms of weight loss, comorbidity remission, and efficacy for the management of patients with type 2 diabetes mellitus. The review included 15 RCTs, 6 of which compared LSG with LGB and 2 vs. LAGB. Three of these studies were judged by the authors to have good quality and the rest were of fair quality. The authors could not perform a meta-analysis due to the heterogeneity of the studies but performed some cumulative analyses when suitable. The results of these analyses indicate that the complication rate was 12.1% (range 10-32%) with LSG vs. a mean of 20.9% (range 10-26.4%) with LGB. Only two trials compared LSG with LAGB, one reported 0% hospital morbidity for both procedures, and the other (Himpens 2006) a total of 7 (17.5%) complications with LAGB (all were late) vs. 2 (5%) complications with SLG (all were postoperative). The percentage of excess weight loss (%EWL) ranged from 49% to 81% in the LSG group, 62.1% to 94.4% in the LGB group, and 28.7%-48% in the LAGB group) in a follow-up duration ranging from 3 months to 3 years. Type 2 DM remission ranged from 26.5% to 75% with LSG and 42%-93% with LGB. Buchwald and colleagues (2009) performed a systematic review and meta-analysis of 621 experimental and observational studies (N=136,134 participants) on bariatric surgery that were published in English between 1990- 2006, and that reported on the resolution of type 2 diabetes. Nineteen studies with 43 treatment arms and 11,175 patients reported on both weight loss and diabetes resolution separately for diabetic patients (N=4,070). The analysis indicated that overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion/duodenal switch, followed by gastric bypass, and least for banding procedures. Insulin levels declined significantly postoperatively, as did hemoglobin A1C and fasting glucose values. Conclusion: The limited published evidence comparing LAGB to LRYGB or LSG suggest that LAGB is not the most effective surgical procedure for the morbidly obese patients. The literature indicates that LAGB may have shorter operative time, shorter length of hospital stays, and lower rate of early complications; but it is also associated with higher rates of late complications and risk of surgical interventions compared to other bariatric surgery procedures. There is no good published quality evidence to date, to determine the comparative effectiveness of LAGB to LSG or LRYGB on the resolution of co-morbidities and improvement of health-related quality of life.

Articles: The literature search for studies published after the 2006 MTAC review, revealed over 500 publications, many of which were unrelated to the current review. Very few small randomized controlled trials compared the effects of one surgical bariatric procedure versus another. The search identified a recently updated Cochrane review (Colquitt et al, 2014) on surgery for weight loss in adults; a meta-analysis that compared LAGB with LSG (Wang et al, 2013), a multicenter retrospective matched cohort study (Dogan et al, 2014) that compared gastric bypass, LAGB and LSG in morbidly obese patients; three systematic reviews with no meta-analyses of RCTs on bariatric surgeries; a comparative effectiveness study of laparoscopic adjustable gastric banding vs. laparoscopic gastric bypass; as well as several cohort studies with no control or comparison groups that reported on short and long-term outcomes of gastric banding and LSG procedures. The two most recent meta-analyses were selected for critical appraisal.

Colquitt JL, Pickett K, Loveman E, et al. Surgery for weight loss in adults. Cochrane Database Syst Rev. 2014 Aug 8;8:CD003641. DOI: 10.1002/14651858.CD003641.pub 4. See Evidence Table 1

Wang S, Li P, Sun XF, et al. Comparison between laparoscopic sleeve gastrectomy and laparoscopic adjustable gastric banding for morbid obesity: a meta-analysis. Obes Surg. 2013 Jul; 23(7):980-986. See Evidence Table 2

The use of LAGB in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

EndoGastric Solutions Stomaphy X™ Endoluminal Fastener

BACKGROUND

Obesity Surgery the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system is a sterile, single-use device for use in transoral tissue approximation and ligation in the GI tract. The system consists of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants. The device is introduced into the body through the mouth under endoscopic visualization. Once inside the stomach, the stomach wall is suctioned into the tissue port on the StomaphyX™ creating a large plication. Non-resorbable polypropylene fasteners are then deployed across the fold to hold the tissue in place. Typically, 10 to 20 folds are required depending on the patient's anatomy. The pleats created in the stomach will reduce its size, which would potentially lead to early satiety and weight loss. According to the manufacturer, the StomaphyX™ procedure is incisionless, adjustable, and revisable. It is usually performed as an outpatient procedure, and is intended for individuals who want an alternative to invasive weight loss surgery, or those who have had previous gastric bypass surgery and are regaining weight. The EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system was cleared for marketing by the FDA in February 2007 for use in endoluminal trans-oral tissue approximation and ligation in the GI tract. The InScope™ Tissue Apposition System is a sterile, single patient

Back to Top

used disposable suture system for approximating and securing soft tissue within the gastrointestinal tract. It is intended to perform suturing in conjunction with endoscopes having a working channel of 2.8 mm or larger. The system can be used to treat variety of defects endoscopically including ulcers and perforations (FDA Web site). The InScope™ Tissue Apposition System was cleared by the FDA for marketing in January 2007 to be used for the placement of sutures and approximation of soft tissue. GERD According to the Montreal Consensus, gastroesophageal reflux disease (GERD) is defined as a condition which develops when the reflux of stomach contents cause troublesome symptoms and/or complications. GERD is a mechanical disorder that is caused by a defective lower esophageal sphincter, a gastric emptying disorder, or failed esophageal peristalsis. Typical symptoms of GERD include heartburn and regurgitation; however, overtime reflux can cause ulceration, Barrett's esophagus, airway disease, and esophageal cancer. It is estimated that 40% of individuals in the United States suffer from GERD on a monthly basis. Current treatment options for GERD include long-term use of acid suppression medications or surgical intervention. While treatment with acid suppressing medications such as proton pump inhibitors and histamine 2-receptor blockers are effective, they do not treat the underlying mechanical disorder. Additionally, not all patients respond to these therapies (Zagol 2011, Stefanidid 2010). Surgery is another treatment option for patients with GERD. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), surgical therapy should be considered in patients with a diagnosis of reflux who (Stefanidid 2010): Have failed medical management (due to inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side-effects). Opt for surgery despite medical management (due to quality-of-life considerations, lifelong need for medication intake, expense of the medication, etc.). Have complications of GERD (e.g., Barrett's esophagus, peptic stricture). Have extra-esophageal manifestations (asthma, hoarseness, cough, chest pains, aspiration). There are a variety of surgical procedures used for the treatment of GERD. Currently, there is no consensus on the best procedure for all patients. The choice of procedure is often based on anatomic considerations and expertise; however, the laparoscopic Nissen fundoplication has emerged as one of the most widely used techniques. With fundoplication, the gastric fundus is wrapped around the lower end of the esophagus to reduce gastric reflux. The fundal wrap can be either total (360°) or partial (less than 360°). Studies suggest that approximately 90% of patients who undergo Nissen fundoplication achieve symptom relief. Side effects of this procedure include dysphagia, hyperflatulence, inability to belch, bloating, and postsurgery bowel symptoms (AGA 2008, Stefanidid 2010). Transoral incisionless fundoplication using the EsophyX device (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. This procedure attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. The EsophyX device is inserted transorally, under direct endoscopic visualization, into the stomach and is positioned at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The result is an omega shaped valve 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are less than 2 cm in size through the use of a built-in vacuum invaginator. As this procedure is incisionless and can often be performed on an outpatient basis it is an attractive alternative to conventional surgical procedures (Jafri 2009, Louis 2010). The EsophyX system had been cleared by the FDA for use in transoral tissue approximation, full-thickness plication and ligation in the gastrointestinal tract for the treatment of GERD in patients with symptomatic chronic GERD who require and respond to pharmacological therapy. This device may also be used to narrow the gastroesophageal junction and reduce hiatal hernia ≤2 cm in size in patients with symptomatic chronic GERD. The EsophyX system has not been previously reviewed by the Medical Technology Assessment Committee and is being review based on request from bariatric surgery and a member appeal.

04/09/2008: MTAC REVIEW
EndoGastric Solutions Stomaphy X™ Endoluminal Fastener
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the EndoGastric Solutions StomaphyX™ endoluminar fastener for weight loss. There is insufficient published evidence to determine the efficacy and safety of the InScope™ Tissue Apposition System for endoscopic gastric sutures.
Articles: The literature search did not reveal any published studies, on the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system, or on the InScope™ Tissue Apposition System. Information about the systems was obtained from the FDA and the manufacturer's Web sites.

The use of endoluminar fasteners in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Vertical Sleeve Gastrectomy (VSG)
BACKGROUND

Back to Top

Obesity is a rapidly growing health problem in the United States and worldwide. According to data from the National Health and Nutrition Examination Survey (NHANES), over two thirds of the adults in the US are overweight or obese. Overweight is defined as Body Mass Index [BMI] between 25 and 29 kg/m2, and obesity is defined as BMI of 30.0 kg/m2 or higher. Obesity can be further subdivided into class 1: (BMI 30 to less than 35), class 2: (BMI 35 to less than 40), class 3: severe or morbid obesity (BMI of 40 or higher), and class IV: super obese or super morbid (BMI >50 kg/m2). Obesity leads to substantial morbidity, lower social functioning and quality of life, as well as premature mortality. It is associated with development and /or aggravation of many chronic conditions including cardiovascular diseases, hypertension, type 2 diabetes mellitus, sleep apnea, some forms of cancer, depression, and osteoarthritis (Duval 2006, Ogden 2006, Sturm 2007, Flegal 2012). Diet, behavioral modification, and exercise are the primary recommended treatments for obesity, but were found to have limited success among the morbidly obese. Drug therapy may be indicated for some, but has its side effects, and the majority regain the lost weight over time. Bariatric surgery is considered as an alternative therapy for morbidly obese individuals. Studies showed that bariatric surgery was more effective than behavioral and medical therapy, had long-term control of obesity, and improved comorbidities as type 2 diabetes. There are several surgical techniques for weight loss, but the Roux-en-Y gastric bypass (RYGB) and the adjustable gastric banding (AGB) are the two most commonly performed procedures across the world. However, surgery is a major intervention and may be associated with risk of complications and perioperative mortality. The morbidly obese individuals usually have a higher incidence of co-existing medical problems and are more likely to develop short and long-term complications after bariatric surgery (Karamanakos 2008, Almogy 2004, Fuks 2009). Sleeve gastrectomy (SG), also known as vertical sleeve gastrectomy (VSG), vertical gastrectomy (VG), greater curvature gastrectomy, parietal gastrectomy or vertical gastroplasty, was initially described in the late 1980s, as a first step procedure performed before RYGB or biliopancreatic diversion-duodenal switch in the super obese patients with severe comorbidities. It was intended to achieve a significant weight loss prior to performing a more restrictive and malabsorption operation among those at high surgical or anesthesiologic risk. After a period of initial weight loss, the surgical risk would be reduced, and the second definitive surgery could be performed. More recently, SG have been increasingly used as stand-alone operation for the morbidly obese patients due to its technical simplicity and short-term outcomes in weight loss (Lee 2007, Rubin 2008, Akkary 2008, Mellissas 2008, Keuper 2008, Kehagias 2011). Sleeve gastrectomy is a purely restrictive operation with no malabsorptive effects. It involves removing the fundus and greater curvature portion of the stomach leaving a narrow tubular stomach that is approximately the size and shape of a banana. It preserves the integrity of the pylorus and does not include intestinal bypass as part of the technique. The technique is simple, but some components of the surgery can result in serious complications if not performed correctly (Peterli 2009, Gill 2010, Brethauer 2011). There are several mechanisms contributing to the weight loss with SG; removing 80-90% of the stomach and leaving behind only a sleeve restricts the amount of the food that can be ingested and gives the sensation of fullness with minimal oral intake. Hormonal change represented by the decrease in the ghrelin level due to resection of the fundus may be another factor for the weight loss, as well as the accelerated gastric emptying, and the behavioral modification of the patients. The exact underlying mechanism is still unknown, and the long-term effects of the surgery are still under investigation (Rubin 2008, Akkary 2008, Moy 2008, Karamanakos 2008, Brethauer 2011). Sleeve gastrectomy has many potential advantages. Preservation of gastric function including the pylorus eliminates dumping, and being purely restrictive, SG does not result in malabsorption. Moreover, it can be performed laparoscopically (laparoscopic sleeve gastrectomy or LSG) even in the super-obese patients. SG does not require implantation of any artificial device or adjustments as the laparoscopic adjustable gastric band. It can also be performed in patients with disorders which preclude intestinal bypass e.g. anemia or Crohn’s disease. However, the procedure is irreversible and has potential complications associated with the relatively long staple line such as bleeding and leakage. Leakage is the most concerning complication after SG and may result from the placement of the final staple line across the gastroesophageal junction or distal esophagus resulting in a staple line disruption. It may also result from mid-sleeve stenosis due to stenosis in the lumen or twisting or kinking of the sleeve at the incisura. Other reported complications associated with the sleeve gastrectomy include pulmonary embolism, subphrenic abscess, liver failure, stricture, wound infection, and need for reoperation. On the long-term, sleeve gastrectomy may potentially lead to gastroesophageal reflux disease due to an increase in the gastric pressure associated with the procedure (Moy 2008, Fuks 2009, Brethauer 2011). The First Report form the American College of Surgeons Bariatric Surgery Center Network indicates that obesity is a life-long disease, and thus short-term safety and efficacy of bariatric surgery should not be the deciding factor for selection of the procedure, and long-term follow-up beyond 1 year is needed; more importantly 5 years or longer. The report also notes that specifically longer-term assessment of the sleeve gastrectomy is critical as the gastric pouch enlargement over time may limit its ultimate effectiveness (Hutter 2011).

04/06/2009: MTAC REVIEW
Vertical Sleeve Gastrectomy (VSG)

Back to Top

Evidence Conclusion: The evidence consists of two RCTs (Himpens et al 2006, and Karamanakos et al (2008), and several case series. Himpens and colleagues compared laparoscopic sleeve gastrectomy to gastric banding in 80 patients with a median BMI 38 kg/m2 and Karamanakos and colleagues compared it with laparoscopic Roux-en-Y gastric bypass in 32 patients with mean BMI of 46 kg/m2. The longest follow-up duration reported was 3 years in Himpen's study. The two trials were randomized and controlled but had their limitations. The authors did not discuss specific inclusion criteria e.g. the BMI threshold and other characteristics. In addition, there was no standardized technique for performing sleeve gastrectomy, no standardized size or design for the gastric sleeve, and no optimal dilator size to create the lesser curvature conduit. All these variables could affect weight loss and make it difficult to compare sleeve gastrectomy with other established bariatric procedure. Himpen and colleagues found that the weight loss after 1 and 3 years was more significant with sleeve gastrectomy vs. gastric banding. However, the late weight loss after the two procedures was insufficient; it ranged from 1 to 48 kg with sleeve (median 29.5 kg), and 0 to 40 kg with gastric banding (median 17 kg). The number of reported adverse events associated with sleeve gastrectomy was small. However, some events were severe and required re-operations as intraperitoneal bleed, ischemia of the sleeve, anastomosis leak, and insufficient weight loss. Other reported complications of SG included pulmonary embolism, GERD, gastric erosion, gastric pain, vomiting, and others. Karamanakos and colleagues' trial showed no significant difference in the weight loss at 12 months between the two procedures. However, the study was too small, and had insufficient power to detect significant differences between the two study groups. In conclusion, there is insufficient published scientific literature to date to determine the long-term efficacy, safety, and durability of the weight loss associated with sleeve gastrectomy procedure as a stand-alone treatment option for obese patients. There is also insufficient evidence to determine the optimum BMI threshold where SG would be recommended or encouraged.
Articles: The search yielded over 130 articles. Many were reviews and opinion pieces. There were three randomized controlled trials; one compared SG with adjustable gastric banding, another compared it with Roux-en-Y gastric bypass, and the third compared two different techniques for sleeve gastrectomy. There were also a number of case series with different population sizes and follow-up durations. Only four were relatively large with sample sizes over 100, one was conducted in the US and three were conducted overseas. The US series (Lee et al 2007) had the largest sample size, longest follow-up duration, and non-randomized comparison groups.
The two RCTs that compared SG with alternative bariatric surgeries were selected for critical appraisal as well as the Lee et al's case series. The citations for the critically appraised studies are:
Himpens J, Dapri G, Cadiere GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy. Results after 1 and 3 years. Obesity Surgery 2006; 16:1450-1456. See Evidence Table Karamanakos SN, Vagenas K, Kalfarentzos F, et al. Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide –YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy. A prospective, double blind study. Ann Surg 2008; 247:401-410. See Evidence Table
Lee CM, Cirangle PT, Jossart GH. Vertical gastrectomy for morbid obesity in 216 patients: Report of two-year results. Surg Endosc 2007; 21:1810-1816. See Evidence Table

The use of Vertical Sleeve Gastrectomy for the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

2/11/2013: MTAC REVIEW
Vertical Sleeve Gastrectomy (VSG)
Evidence Conclusion: There is some evidence from very few small RCTs, and non-randomized prospective studies that laparoscopic sleeve gastrectomy performed as a stand-alone surgery, leads to short to mid-term significant weight loss, and improvement in comorbidities in obese patients. However, there is insufficient evidence to determine whether the weight loss and resolution of comorbidities will be sustained long-term. There is insufficient evidence to determine the long-term comparative effectiveness and safety of sleeve gastrectomy and Rou-en-Y gastric bypass or adjustable gastric banding for the treatment of obesity and obesity-related comorbidities. There is insufficient evidence to determine the long-term net health outcomes of laparoscopic sleeve gastrectomy. The studies that reported on long-term outcomes were small case series with no comparison or control group. Himpens and colleagues (2010) reported on the results of 6 years follow-up of 53 patients who underwent laparoscopic SG (different population from that in the RCT published by the same group of investigators in 2006). The results showed that after the sixth postoperative year weight gain was observed in 31 cases (75.6%). The mean BMI in this group of patients was 39.9± 5.9 at baseline, 26.6 ± 4.3 at 3 years, and 31.1 ± 6.2 at 6 years. New gastroesophageal reflux symptoms were also reported after 6 years; 18% of the patients in the stand-alone SG group reported occasional vomiting, and 23% reported frequent episodes of GERD. In another follow-up of a case series, D'Hondt and colleagues (2012) also reported a trend towards decrease in weight loss by time (median % excess weight loss [EWL] was 78.5% at 12 months, 72% at 24 months, and 54.4% at 72 months). When % EWL above 50% was considered, the total success rate of SG was 92.9% at 1 year,

Back to Top

89.5%, 87%, 85.7%, 64.3% and 54.5% after 2, 3, 4, 5, and 6 years respectively. There is also insufficient evidence to establish criteria for patient selection or an optimum BMI threshold where SG is recommended or encouraged.
Articles: The search for studies published after the 2009 MTAC review revealed one RCT comparing laparoscopic sleeve gastrectomy versus laparoscopic Roux-en-Y gastric bypass in patients with BMI <50 kg/m2, another very small RCT that compared the effects of the two procedures on the glucose metabolism, two non-randomized prospective comparative studies, and one case control study that compared the outcomes of SG to one or more other bariatric surgery. The literature search also revealed one network meta-analysis and two systematic reviews without meta-analyses that evaluated the different procedures for bariatric surgery, as well as a number of prospective and retrospective case series with or without comparison groups.
The two RCTs and two prospective comparative studies were selected for critical appraisal. The network meta-analysis was not selected for further critical appraisal as it compared changes of BMI levels with different bariatric surgeries vs. standard care and included only two earlier studies on SG. The following studies were critically appraised: Peterli R, Wölnerhanssen B, Peters T, 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; 50:234-241. See Evidence Table Kehagias I, Karamanakos SN, Argentou M, et al. Randomized clinical trial of laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the management of patients with BMI<50 kg/m2.Obes Surg. 2011;21:1650-1656. See Evidence Table Leyba JL, Aulestia N, Llopis SN. 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; 21:212-216. See Evidence Table Varela JE. Laparoscopic sleeve gastrectomy versus laparoscopic adjustable gastric banding for the treatment severe obesity in high risk patients. JSLS 2011; 15:486-491. See Evidence Table

The use of Vertical Sleeve Gastrectomy for the treatment of obesity does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity

BACKGROUND
Individuals with BMI >60 are considered to be “super obese.” Super obesity is associated with an increased risk of multiple health problems including arthritis, breathing problems, cancer, depression, diabetes, heart disease, hypertension, venous disorders and death. In addition, surgical treatment for obesity, such as a Roux-en-Y gastric bypass, is believed to be more dangerous in super obese than less obese patients, particularly for individuals who carry their weight in the belly area. Laparoscopic sleeve gastrectomy (LSG) is a bariatric procedure that involves the laparoscopic removal of 70-80% of the left side of the stomach. This results in a stomach that is approximately the size and shape of a banana. LSG is technically simpler than other bariatric procedures including gastric bypass surgery, since it does not require re-routing of the intestines. In addition, the procedure does not require implantation of any artificial device as with other obesity treatments such as the Lap-Band. LSG is most commonly used as the first stage in a two-stage procedure. Patients may be able to lose 80 or more pounds after an LSG, reducing their BMI to the point that a Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch can be done more safely. The second operation is generally performed 8-12 months after the LSG. LSG is sometimes performed as a stand-alone procedure, but this application is not yet recognized by the American Society for Bariatric Surgery (ASDS). LSG has not been reviewed previously by MTAC.

04/02/2007: MTAC REVIEW
Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity
Evidence Conclusion: There is insufficient evidence on the safety and efficacy of laparoscopic sleeve gastrectomy for obesity. Only case series were available; there are no randomized controlled trials or cohort studies. The case series were generally small, and the largest series (Cottam et al., 2006) was compromised by a low follow-up rate. Follow-up data 12 months after the stage-one LSG were available for fewer than half of the treated patients. Mean weight loss in 46% of patients with follow-up data was 45± 17%.
Articles: The search yielded 6 case series; all but one included fewer than 50 patients. The only published case series with a sample size of >100 patients was critically appraised for MTAC: Cottam D, Qureshi FG, Mattar G et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. Surg Endosc 2006; 20: 859-863.

The use of laparoscopic sleeve gastrectomy in the treatment of severe morbid obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

Gastric Electrical Stimulator for Obesity

BACKGROUND

Gastric electric stimulation is a new technique that has been proposed as a treatment for obesity. It involves the application of a small electrical current to the stomach through leads that are implanted in the muscular layer of the gastric wall. Although the exact mechanism of action is not fully understood, it is thought that electrical stimulation of the stomach wall can induce early satiety and reduce appetite. It may also have an effect on hormones related to satiety and/or appetite (Mizrahi 2012, Stamin 2012, Verdam 2012). Currently, no gastric electric stimulation devices are FDA approved for the treatment of obesity. This technology was previously reviewed by the Medical Technology Assessment Committee (MTAC) in 2001 for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. It did not meet MTAC criteria for this indication. It has not been previously reviewed for the treatment of obesity. It is being reviewed based on a request from Kaiser Permanente Bariatric Surgery.

2/11/2013: MTAC REVIEW

Gastric Electrical Stimulator for Obesity

Evidence Conclusion: A recent RCT that included 190 obese subjects evaluated the effects of gastric electric stimulation on weight loss. All patients underwent implantation with the gastric electric stimulator. Patients were instructed to consume a diet with a 500 kcal per day deficit and were required to attend monthly support group meetings. Patients in the treatment group had their devices activated. The devices for patients in the control group were kept inactive. After 12 months, there was no significant difference in the percent of excess weight lost between the treatment and the control group. The mean percent of excess weight loss was 11.7 in the treatment group and 11.8 in the control group (P=0.71). Adverse events included: endoscopy-detected gastric lumen lead penetration during the 2-lead implantation procedure (N=26), low battery between month 10 and month 12 (N=22), lead dislodgement (N=2), and pocket infection (N=1). There were no deaths or major complications. Medtronic/Transeuronix sponsored the study (Shikora 2009). An earlier study conducted by the same author also found no significant difference in the percent of excess weight loss between treatment (device on) and control (device off) subjects at 6 months; however, due to methodological limitations results from this study should be interpreted with caution (Shikora 2004). Conclusion: Evidence from a RCT suggests that there is no significant difference in the percent of excess weight lost between patients who received treatment with gastric electric stimulation plus a lifestyle intervention and patients who were treatment with lifestyle intervention alone.
Articles: The literature search revealed several small, case-series and two randomized controlled trials (RCTs) that evaluated the safety and efficacy of gastric electric stimulation for the treatment of obesity. The RCTs were selected for review. The following studies were selected for review: Shikora SA, Bergenstal R, Bessler M, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. Surg Obes Relat Dis 2009; 5:31-7. See Evidence Table Shikora SA. "What are the yanks doing?" the U.S. experience with implantable gastric stimulation (IGS) for the treatment of obesity - update on the ongoing clinical trials. Obes Surg 2004;14 Suppl 1: S40-8. See Evidence Table

The use of Gastric Electric Stimulation for the Treatment of Obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Bypass for GERD

BACKGROUND

Obesity is a rapidly growing health problem in the United States and worldwide. According to the National Health and Nutrition Examination Survey (NHANES), more than one third of the adults and almost 17% of the youths in the US are obese defined as Body Mass Index [BMI] 30.0 kg/m2 or higher. It is estimated that at least 5% of the total population are morbidly obese (i.e. with BMI >40 kg/m2). Obesity is associated with the development and /or aggravation of many chronic conditions including cardiovascular diseases, hypertension, type 2 diabetes mellitus, sleep apnea, some forms of cancer, depression, and osteoarthritis. Obesity may also be a predisposing factor for gastroesophageal reflux disease (GERD); obese patients are nearly three times as likely to experience GERD symptoms as those with normal BMI. However, researchers have found that the prevalence of GERD, even in the setting of severe obesity is <50%, which suggests that severe obesity itself is not sufficient to cause GERD. The mechanism by which obesity may increase gastroesophageal reflux is not fully understood, but several pathophysiologic mechanisms have been proposed to explain the association between the two conditions. Obese individuals may experience extrinsic gastric compression by surrounding adipose tissue leading to the increase in intragastric pressure and subsequent relaxation of the lower esophageal sphincter (LES), as well as anatomical disruption of the gastroesophageal junction. The latter may result in the formation of hiatal hernia which was found to be more prevalent in obese individuals than in those with normal weight (Ortega 2004, Nelson 2005, Duval 2006, Ogden 2012, Sturm 2007, Tai 2009, Prachand 2010, Flegal 2012).

Back to Top

The initial treatment of GERD symptoms involves lifestyle and dietary modification, which are often combined with acid inhibiting therapy. These generally alleviate GERD symptoms, but are usually unsuccessful in morbidly obese patients. If conservative measures fail, surgery is often considered as an alternative approach. Laparoscopic Nissen fundoplication has been the standard operation for these cases with medically refractory GERD. However, its use is controversial among obese patients due to conflicting results concerning its long-term effectiveness and sustainability. Fundoplication affects only the LES and lower gastroesophageal junction without addressing weight. Bariatric operations, which are intended primarily to induce weight loss in the morbidly obese, are considered as a potential alternative approach for treating GERD in obese patients. The success of these surgeries depends on the technique used. Restrictive techniques such as laparoscopic adjustable gastric banding and sleeve gastrectomy result in weight reduction by reducing the stomach volume leading to early satiety. However, some patients reported persistence or worsening acid reflux symptoms after these surgeries. Malabsorptive techniques such as jejuno-ileal bypass and biliopancreatic diversion result in weight reduction by functional shortening of the digestive tract and /or by diverting gastric juices. The Roux-en-Y gastric bypass (RYGB), a more technically complex operation, has both restrictive and malabsorptive properties and is described by some as a reliable procedure for treating severe GERD in obese individuals. It does not directly affect the cardio-esophageal competence but may prevent GERD through weight loss and physically altering the anatomy of the gastrointestinal tract and preventing acid reflux into the esophagus (Nelson 2005, El-Serag 2008, Ikramuddin 2008, De Groot 2009, Prachand 2010, Reavis 201).

2/11/2013: MTAC REVIEW
Gastric Bypass for GERD
Evidence Conclusion: There is insufficient published evidence from randomized controlled trials to determine the comparative effectiveness and safety of Roux-en-Y gastric bypass (RYGB) surgery and Nissen fundoplication for the treatment of GERD in obese patients. The methodological quality of the published studies is low due to non-randomization of the patients, small population sizes, differences in definitions of obesity and evaluation of GERD symptoms, lack of objective outcome assessment, as well as other inherent limitations of observational studies. In a non-randomized trial, Braghetto and colleagues (2012) evaluated postoperative results after fundoplication, RYGB, or a combination of the two procedures for the treatment of 139 obese patients with GERD and Barrett's esophagus. The authors did not explain why and how they selected the patients for each operation, and patients were not equally distributed among the different procedures. They noted however, that those with BMI >35 kg/m2 were selected for RYGB. Compared to the other two groups, patients in the RYGB had significantly higher BMI and weight. Patients underwent careful clinical assessment of symptoms and endoscopic/histological studies at baseline, and at 3-5 years after surgery. Manometric studies and 24-intra-esophageal pH studies were performed in all patients at baseline and among 116 (83%) after surgery. Overall the results of the study showed that the reflux symptoms and erosive esophagitis improved after all three surgeries compared to baseline. The improvement observed was significantly higher in the two approaches that included gastric bypass versus fundoplication alone. The gastric bypass surgery alone did not modify the lower esophageal sphincter (LES) pressure but led to the highest reduction in body weight and BMI. In an earlier very small (N=12) study with data obtained from a prospectively maintained database, Patterson and colleagues (2003) also showed that laparoscopic Roux-en-Y gastric bypass and laparoscopic Nissen Fundoplication were both effective in treating heartburn symptoms and acid reflux in obese patients. The LES resting pressure increased significantly after the fundoplication but not after the RYGB surgeries. Results from a number of other case series show that RYGB resulted in weight loss, improvement of GERD symptoms, regression of esophagitis, and reduction of number of antireflux medications used in obese patients with GERD. The studies did not evaluate the effect of lifestyle and dietary habits of the patients after the surgery, and do not provide sufficient evidence to determine the long-term benefits of gastric bypass in these obese patients with GERD.
Articles: The literature search did not reveal any randomized controlled trial that compared gastric bypass surgery to other standard medical or surgical treatment for severe GERD in obese patients. There was one non-randomized prospective study that compared outcomes of three different laparoscopic procedures for the treatment of obese patients with GERD and Barrette's esophagus, a very small study that compared bypass surgery to fundoplication, and another small study that compared vertical banded gastroplasty vs. Roux-en-Y gastric bypass in patients with GERD and morbid obesity. Other published studies on bypass surgery for GERD were all case series with population sizes ranging from less than ten to just over 200 patients. The study that included fundoplication as a comparative surgery as well as 4 relatively large and/or more recent case series were selected for critical appraisal. Braghetto I, Korn O, Csendes A, et al. Laparoscopic treatment of obese patients with gastroesophageal reflux disease and Barrett's esophagus: a prospective study. Obes Surg 2012; 22:764-772. See Evidence Table Frezza EE, Ikramuddin S, Gourash W, et al. Symptomatic improvement in gastroesophageal reflux disease (GERD) following laparoscopic Roux-en-Y gastric bypass. Surg Endosc 2002; 16:1027-1031. See Evidence Table Nelson LG, Gonzalez R, Haines K, et al. Amelioration of gastroesophageal

Back to Top

reflux symptoms following Roux-en-Y gastric bypass for clinically significant obesity. Am Surg 2005; 71:950-953. See Evidence Table Ortega J, Escudero MD, Mora F, yet al. Outcome of esophageal function and 24-houir esophageal pH monitoring after vertical banded gastroplasty and Roux-en-Y gastric bypass. Obes Surg 2004; 14:1086-1094. See Evidence Table Tai CM, Lee YC, Wu MS, et al. The effect of Roux-en-Y gastric bypass on gastroesophageal reflux disease in morbidly obese Chinese patients. Obes Surg 2009; 19:565-570. See Evidence Table

The use of gastric bypass surgery for treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/20/2016: MTAC REVIEW
Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD)
Evidence Conclusion: The literature search did not identify any published randomized controlled trials to date, that compared gastric bypass surgery to Nissen fundoplication, or other standard medical or endoscopic procedures used for the treatment of severe GERD in morbidly obese patients. The studies published after the last MTAC reviews were all case series, and retrospective analyses of registered data in a database with no control or comparison groups. Due to their inherent biases, particularly selection bias; and lack of control groups, case series represent a level IV of evidence in the hierarchy of evidence. Case series cannot prove a cause and effect relationship but may only generate hypotheses for future research. Overall, the results the published case series suggest that gastric bypass leads to significant weight loss in obese patients, and is associated with improvement in GERD symptoms, and/or reduction of number of anti-reflux medications used by obese patients with severe GERD. These series generally relied on subjective outcomes, did not evaluate the effect of confounding factors, lifestyle and dietary habits of the patients after the surgery, and do not provide sufficient evidence to determine the long-term durability of the observed outcomes. Madalosso and colleagues, 2016 (Evidence table 1), recently published 3-years results of a prospective case series to assess the impact of Roux-en-Y gastric bypass (RYGB) on gastroesophageal reflux disease (GERD) in morbidly obese patients. The study did not compare gastric bypass to Nissen fundoplication, sham procedure, or any other surgical or medical therapy. In addition, the 39 months follow-up data were available for only 53 of the 94 (56%) patients recruited. The authors compared the postoperative outcomes to the baseline values and had the advantage of including objective measures. The overall results of the analysis suggest that RYGB surgery was associated with a significant weight loss, reduction in GERD symptoms, and decrease in esophageal acid exposure. These results have to interpreted with caution due to the nature of the study, potential selection bias, confounding, lack of a control group, and high dropout rate. Dupree, et al (2014) retrospectively analyzed data from the Bariatric Outcomes Longitudinal Database (BOLD)*, focusing on patients with pre-existing GERD. 33,876 patients underwent LRYGB, and 4,832 underwent LSG from 2007-2010. The results of the analysis showed that LRYGB was associated with complete resolution of GERD symptoms in 62.8% of the patients (symptoms were stable in 17.6% and worse in 2.2 %). For those who underwent LSG, 84.1% continued to have GERD symptoms, and 9.0% reported worsening of symptoms. Pallati and colleagues (2014) also used the same database (BOLD) to compare the efficacy of various bariatric procedures on the improvement of GERD symptoms, 36,938 patients out of 116,136 registered in the database from 2007–2009), had evidence of GERD before undergoing a bariatric surgery. After excluding patients undergoing concomitant hernia repair or fundoplication, 22,870 patients with 6 months follow-up were included in the analysis. 14,078 of these patients underwent RYGB, 8,207 LAGB, and 585 underwent LSG procedures. The analysis showed that GERD symptom score was significantly improved with the three surgeries, with the highest improvement reported with RYGB (56.5%) followed by AGB (46%) and SG (41%). Worsening of symptoms occurred in 2% of patients undergoing RYGB (4.6% with SG, and 1.2% with LAGB). The remainder of patients had no change in their GERD status. The study did not show any objective measure of GERD improvement. The results of Dupree et al and Pallati et al's analyses of data obtained from the Bariatric Outcomes Longitudinal Database should be interpreted cautiously. These were retrospective analyses influenced by the quality of the database and the extent of variables/patient characteristics it includes, such as alcohol consumption, cigarette smoking and other factors that have a potential impact on GERD. In addition, according to the authors the documented data on GERD was only based on the use of acid suppression medication with no objective data to confirm the gastroesophageal reflux e.g. 24-hour pH monitoring. Varban and colleagues (2015), retrospectively analyzed data from the Michigan Bariatric Surgery Collaborative (MBSC) registry to assess the use of acid-reducing medication (ARM) at one year after bariatric surgery in morbidly obese patients. Approximately 50% of the patients were reported to have GERD at baseline. 51% of those who underwent RYGB had GERD, and 40.6% of them were using an ARM at baseline, compared to 29.2% at 1-year after surgery. It was also reported that 19.2% of the patients not using ARM at baseline started using one after RYGB.

Back to Top

Conclusion:

- Due to the nature of the published studies, lack of comparison groups and objective outcome assessment, it is hard to determine whether the observed improvement of GERD symptoms were due to a direct effect of gastric bypass and reduction of abdominal pressure, or due to a placebo effect, masking of GERD by the change in diet after surgery, or undervaluation of the disease due to satisfaction with weight loss.
- There is insufficient published evidence to determine the comparative effectiveness and safety of gastric bypass surgery to Nissen fundoplication or other standard medical or endoscopic procedures used for the treatment of severe GERD in morbidly obese patients.
- There is insufficient published evidence to determine the long-term safety and efficacy of gastric bypass surgery in reducing GERD symptoms morbidly obese patients.
- There is insufficient published evidence to determine the effect gastric bypass surgery on the progression or regression of Barrett's esophagus in morbidly obese patients with GERD

Articles: The literature search did not reveal any randomized controlled trial that compared gastric bypass surgery to other standard medical or surgical treatment for severe GERD in obese patients with or without Barrett's esophagus. The empirical studies on gastric bypass surgery for patients with GERD were all observational studies that assessed the impact of RGYB on GERD in morbidly obese patients that underwent the surgery either as an initial operation or after a failed fundoplication surgery. The search also identified an analysis using a prospective database (Bariatric Outcomes Longitudinal Database) for patients who underwent bariatric surgery by a participant in the American Society of Metabolic and Bariatric surgery center of Excellence program; a recent meta-analysis that compared RYGB versus laparoscopic sleeve gastrectomy to treat morbid obesity-related comorbidities including GERD; and a number case series on the role of RYGB for failed antireflux surgery. The use of bypass surgery for a failed fundoplication as well as the comparison of different bariatric surgeries were outside the scope of the current review. The largest observational study with the longer follow-up duration was selected for critical appraisal. Madalosso CA, Gurski RR, Callegari-Jacques SM, et al. The Impact of Gastric Bypass Gastroesophageal Reflux Disease in Morbidly Obese Patients. Ann Surg. 2016 Jan; 263(1):110-116. See Evidence Table 1.

The use of Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Intragastric balloons for the treatment of obesity or morbid obesity

BACKGROUND

Obesity is a chronic disease that is strongly associated with numerous conditions including cardiovascular disease (heart failure, stroke, hypertension), diabetes mellitus, sleep apnea, cancers, osteoarthritis and disability [1]. The prevalence of obesity has been increasing and it is projected that, by the year of 2030, 20% of the world's adult population will be obese [1]. Obesity can be categorized based on body mass index (BMI). A body mass index (BMI) between 25 kg/m2 and 29 kg/m2 is considered overweight while obesity is defined as BMI greater than 30 kg/m2 [1]. Moderate and morbid obesity are defined as BMI between 30 to 39.9 kg/m2 and BMI >40 kg/m2 respectively [2]. The cause of obesity is multifactorial [3]. First, the chronic imbalance between energy intake and energy expense leads to obesity. Second, interactions between genetic, behaviors, social and environmental factors play a crucial role in the pathogenesis of obesity[3].

Management of obesity includes conservative therapy such as diet modification, physical exercise, psychosocial interventions, pharmacotherapy such as orlistat and bariatric surgery[4]. A study investigating the effect of diet on weight loss [5] showed that hypocaloric diet and exercise alone led to a non-sustainable weight reduction (5%). Similarly, pharmacotherapy results in additional benefits. Bariatric surgery seems to be an alternative method for long term management [6] but can be associated with adverse events. Despite the benefits of these approaches, some patients might not be able to lose weight or sustain weight loss.

For patients who have failed weight reduction with diet and exercise alone, intragastric balloon (IGB) may be an alternative. Performed for the first time in 1980s [7], IGB is a minimally invasive procedure that diminishes the capacity of the stomach resulting in premature satiation and prolonged satiety and subsequently induces weight loss; Other mechanism resides in the regulation of hormone-mediated signal transduction [4, 8]. IGB insertion is a restrictive procedure in which a spherical, saline-filled balloon is endoscopically positioned in the stomach under mild sedation and left inflated for six months [9]. One or two balloons can be inserted and different fill volumes (400-700ml) and fill media have been described. These include air, fluid, combination of air and fluid. Some balloons can be swallowed and do not need to be endoscopically inserted.

Back to Top

Early designs were removed from the market due to severe complication such as migration resulting in intestinal obstruction but the introduction of the dual-balloon from ReShape Medical (San Clemente, CA) is believed to reduce the risks of obstruction and perforation. The ReShape Integrated Dual Balloon System (Reshape Dual Balloon) and ORBERA Intragastric Balloon System were approved by the Food and Drug Administration (FDA) in 2015.

03/21/2016: MTAC REVIEW
Intragastric balloons for the treatment of obesity or morbid obesity
Evidence Conclusion: Zheng et al., 2015 [4]: Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis (Evidence table 1) This meta-analysis aimed to confirm the safety and efficacy of intragastric balloon (IGB). The outcomes measured were weight loss, BMI, percent excess weight loss and safety. 11 RCTs were included after searching MEDLINE, EMBASE, CENTRAL plus other sources through December 2014. The quality of included studies was assessed, and weighted mean differences were determined from the analysis. Modest efficacy for intragastric balloon as a conjunction therapy to conservative therapy was achieved in six months group (SMG). The incidences of the adverse events were higher in the intervention group (IGB plus conservative therapy). The authors concluded that short-term efficacy for 6 months treatment of intragastric balloon in association with conservative therapy is clinically significant. However, the findings should be interpreted with cautious due to several limitations. Ponce et al., 2015 [10] The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity (Evidence table 2): This is a RCT, multicenter, sham controlled which aimed to investigate the safety and effectiveness of a dual balloon system plus diet and exercise in the treatment of obesity compared to diet and exercise alone. The study measured the percent excess weight loss (%EWL), the proportion of DUO patients achieving at Least a 25% EWL as primary outcomes. 326 patients were randomized to dual gastric balloon plus diet and exercise (Duo) or Sham endoscopy plus diet and exercise (Diet) and followed up for 48 weeks. The %EWL was greater in Duo arm compared to Diet arm. The response rate among DUO was 48.8 in the intention to Treat ($p<0.0001$). Improvements in comorbid conditions were observed. The authors concluded that the reshape duo balloon had an excellent safety profile and was significantly more effective than diet and exercise. However, the results should be interpreted with cautious due to many limitations. Other small sample size RCTs [11-14] with short follow-up duration and meta-analysis [15], suggested that IGB may be safe and effective on the short term. Conclusion: The results indicate that intragastric balloon in combination with diet and exercise may have a short-term effect in reducing weight in obese patients. The findings also indicate that intragastric balloon may be temporarily more effective than diet and exercise. However, the follow-up duration was insufficient to determine the safety and durability of the outcomes. There is insufficient data to determine whether intragastric balloon is safer and more effective than standard weight loss surgeries or pharmacotherapy. Intragastric balloon was reviewed by Interregional New Technology Committee (INTC) which concluded that “based on low-quality evidence of benefit as compared to conventional weight-loss management and lack of long-term evidence regarding safety and efficacy, it could not be concluded whether or not the benefit of intragastric balloon outweigh the harms at this time”.
Articles: The search identified a meta-analysis [4] and RCTs comparing IGB to diet and exercise and or sham balloon. However, the search did not identify RCTs making direct comparison between IGB and standard weight loss surgeries or pharmacotherapy. The following studies were selected for critical appraisal: Zheng, Y., M. Wang, et al. (2015). "Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis." Journal of translational medicine 13(1): 1-9. See Evidence Table 1. Ponce, J., G. Woodman, et al. (2015). "The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity." Surgery for Obesity and Related Diseases 11(4): 874-881. See Evidence Table 2.

The use of Intragastric balloons for the treatment of obesity or morbid obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Intragastric Balloons for Treatment of Obesity. Lansdale, PA: Hayes, Inc; 3/2018

Applicable Codes

Adjustable Gastric Banding--

Back to Top

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® /HCPC Codes	Description
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
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Gastroplasty--

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
***Effective March 1, 2022: 43842 will be considered not medically necessary for Medicare and non-Medicare.**

CPT® Codes	Description
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)

Sleeve Gastrectomy--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)

Lap Band Port Revision--

Back to Top

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

Gastric Bypass (including Roux-en-Y)--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
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
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)

Gastric Electrical Stimulation (GES) for Obesity--

Considered Not Medically Necessary:

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Intragastric Balloon--

Back to Top

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No Specific Codes – *often submitted as 43999 Unlisted procedure, stomach*	

Gastric Bypass for GERD--

Considered Not Medically Necessary:

CPT® Codes	Description
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
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)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
02/01/1999	07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC], 03/5/2013[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC] 01/06/2015 [MPC], 05/05/2015 [MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC]	01/07/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2015	KP-516: Medical policy has been revised to highlight treatment for bariatric complications and repeat bariatric surgical procedure criteria.
09/01/2015	Revised Laparoscopic Sleeve Gastrectomy L34166 and L34157
04/05/2016	Added MTAC Review for Intragastric Balloons
06/20/2016	Added MTAC Review for Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD)
09/28/2017	Added Gastric Electrical Stimulation codes
11/02/2017	PEBB criteria updated
02/14/2017	Added non-covered procedures from CWQI
03/27/2018	Added LCA A53028
04/17/2018	Added Hayes review – Intragastric Balloons for Treatment of Obesity
10/06/2020	MPC approved the MCG 24th ed. guideline for Intragastric Balloon Device: A-0970

Back to Top

06/01/2021	MPC approved the updated recommendations to the current hybrid criteria for Bariatric Surgery to lower the qualifying age from 20 to 18 years or older. Requires 60-day notice, effective date 11/01/2021.
08/19/2021	Noted that PEBB is adopting Kaiser Permanente Commercial clinical review criteria for bariatric surgery procedures effective 01/01/2022.
09/07/2021	Removed reference to retired Noridian LCD L34157 as its content was added to LCA A53028 in 2016.
10/05/2021	MPC approved the removal of Vertical Banded Gastroplasty (VBG) from covered procedures. Requires 60-day notice, effective date 03/01/2022.
01/07/2022	Removed PEBB criteria from the commercial plan. PEBB will be using KP criteria effective 01/01/2022.

Back to Top