

Medical Policy Manual

Topic: Bariatric Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Morbid obesity is defined as a body mass index (BMI) >40 kg/m² (normal BMI range: 19-25 kg/m²)

Note: BMI may be calculated by using the [BMI calculator](#).

Individuals with morbid obesity are at high risk for developing weight-related complications such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (colon, prostate, breast, uterus, and ovaries). In addition, morbid obesity is associated with a shortened life span.^[1]

The first-line treatment of morbid obesity involves dietary and lifestyle changes. Although this strategy may be effective in some patients, a majority of morbidly obese patients do not achieve significant weight loss through lifestyle modifications. In addition, the weight loss may not be durable, as only a small number of patients are able to comply with the changes on a long-term basis. When conservative measures fail, some patients may consider surgery for morbid obesity (bariatric surgery).

Several bariatric procedures have been developed, but based on the underlying mechanism of weight loss, all fall into one or both of the following categories:

Restrictive procedures

- Decrease the size of the stomach and limit food intake

Malabsorptive procedures

- Limit the absorption of calories and nutrients by altering the way food moves through the intestinal track
- Multiple variants exist, differing in the reconfiguration of the small intestines and consequently the extent of malabsorption.

The following table briefly summarizes different bariatric procedures:

Procedure	CPT Code	Description
Gastric Bypass with Roux-en-Y Anastomosis (RYGBP) AKA: Proximal or Short Limb Gastric Bypass	43846 43644	<ul style="list-style-type: none"> • Currently considered “gold-standard” for weight loss surgery • Involves both restrictive and malabsorptive components: <ul style="list-style-type: none"> ○ A small gastric pouch is created from the upper part of the stomach by segmentation or resection to restrict the amount of food that can be ingested ○ The mid portion of the jejunum is divided and the cut end of the distal limb (≤ 150 cm) is attached to the gastric pouch outlet (Roux limb). The cut end of the proximal limb (the limb consisting of the duodenum and proximal jejunum) is attached to the side of the Roux limb (the limb connected to the pouch). This creates the Y configuration of the small intestine, allowing food to bypass the duodenum and proximal jejunum, resulting in malabsorption.
<u>Distal (Long Limb) Gastric Bypass</u>	43847	<ul style="list-style-type: none"> • The procedure involves both restrictive and malabsorptive components and is a variant of the standard gastric bypass with the longer (>150 cm) Roux limb. The longer the Roux limb, the greater the bypass of the small intestine and consequently the degree of malabsorption.
<u>Biliopancreatic Diversion (Bypass) Procedure</u> AKA Scopinaro procedure	43847	<ul style="list-style-type: none"> • Involves both restrictive and malabsorptive components: <ul style="list-style-type: none"> ○ Subtotal (distal) gastrectomy creates small gastric pouch at the top of the stomach to limit food intake ○ A long limb Roux-en-Y anastomosis (>150 cm) results in the biliopancreatic juices being diverted into the distal ileum, significantly increasing malabsorption • Designed to preferentially inhibit the absorption of fat • Only partially reversible
<u>Biliopancreatic Diversion (Bypass) with Duodenal Switch (BPD-DS)</u>	43845	<ul style="list-style-type: none"> • This procedure is an adaptation of the standard biliopancreatic bypass: <ul style="list-style-type: none"> ○ The restrictive component involves subtotal gastrectomy resulting in a tube or sleeve-like stomach remnant that leaves the pyloric valve and the initial segment of duodenum intact. ○ The long limb Roux-en-Y anastomosis (>150 cm) provides malabsorption in this variant as well, but the distal ileum is connected to the duodenal segment leading from the stomach sleeve, instead of the stomach pouch itself.
<u>Mini-Gastric Bypass</u>	no specific code	<ul style="list-style-type: none"> • The procedure is a variant of the gastric bypass and involves both restrictive and malabsorptive components: <ul style="list-style-type: none"> ○ The stomach is segmented to create a small gastric pouch similar to traditional gastric bypass ○ Instead of creating a Roux-en-Y anastomosis, the loop of jejunum is anastomosed directly to the stomach pouch (similar to a Billroth II procedure)
<u>Sleeve Gastrectomy</u>	43775	<ul style="list-style-type: none"> • Greater curvature of the stomach is resected resulting in a gastric remnant shaped like a tube or sleeve. • The pyloric sphincter is preserved leaving stomach function unaltered. • Not reversible • Can be performed as: <ul style="list-style-type: none"> ○ A stand-alone procedure (restrictive) ○ The first part of a two-stage surgical procedure for the very high-risk patients ($\text{BMI} \geq 50 \text{ kg/m}^2$) who need to lose

Procedure	CPT Code	Description
		some weight before they can proceed with a malabsorptive procedure (most commonly BPD-DS or RYGBP)
<u>Adjustable Gastric Banding</u>	43770-43774 43886-43888	<ul style="list-style-type: none"> ● Restrictive procedure ● An adjustable, external, constrictive band is wrapped around the upper portion of the stomach to create a small stomach pouch ● The band can be adjusted through a subcutaneous access port, foregoing the need to enter the gastric cavity when adjusting the band ● The least invasive and least technically complex bariatric procedure ● Lap-Band® (Allergan, Inc.) and the REALIZE™ (Ethicon Endo-Surgery, Inc.) have received approval from the U.S. Food and Drug Administration (FDA).
<u>Vertical Banded Gastroplasty</u> AKA Vertically banded gastric partition or Gastric stapling	43842	<ul style="list-style-type: none"> ● Restrictive procedure ● Surgical stapling is used to create a small, vertical gastric pouch at the top of the stomach ● The pouch outlet (stoma) is reinforced with an external mesh collar
<u>Endoscopic (Endoluminal) Bariatric Procedures</u>		<ul style="list-style-type: none"> ● The access to the stomach is gained through the mouth, so no incisions are necessary. ● Endoluminal procedures being developed: <ul style="list-style-type: none"> ○ Primary bariatric procedure ○ Revision (e.g. for treatment of enlarged gastric stoma and/or enlarged gastric pouches that may be associated with weight gain after bariatric surgery) ● Examples of the endoscopic revision bariatric procedures include: <ul style="list-style-type: none"> ○ gastroplasty using an endoscopically guided stapler (reduces the size of the gastric pouch) ○ placement of gastric balloon (soft, silicone balloon inserted into the stomach and filled with sterile saline to induce feeling of satiety) ○ placement of duodenal-jejunal sleeve (sleeve placed inside duodenum and upper jejunum to prevent contact between food and the intestine). ● StomaphyX®, an endoscopically guided system intended for tissue plication and ligation, has received 510(k) FDA approval. The device is also being investigated for endoscopic treatment of gastroesophageal reflux.

MEDICAL POLICY CRITERIA

- I. Gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less, sleeve gastrectomy as a stand-alone procedure, or adjustable gastric banding, consisting of an adjustable external band placed around the stomach, may be considered **medically necessary** in the treatment of morbid obesity when **all** of the following criteria are met:
- A. At the start of the medically supervised, nonsurgical weight reduction program:
- BMI greater than or equal to 40 kg/m²; or
- BMI greater than or equal to 35 kg/m² either with a diagnosis of type 2 diabetes mellitus or with at least two of the following comorbid conditions which have not responded to medical management and which are generally expected to improve as a result of obesity surgical treatment:
- 1) Hypertension
 - 2) Dyslipidemia
 - 3) Coronary heart disease
 - 4) Sleep apnea
- B. Documentation of active participation for at least six months in a structured, medically supervised nonsurgical weight reduction program. A comprehensive commercial weight loss program is an acceptable program component, but it must be approved and monitored under the supervision of the healthcare practitioner providing medical oversight. Comprehensive weight loss programs generally address diet, exercise and behavior modification, e.g., Weight Watchers.
- Documentation from the clinical medical records must indicate that the structured medical supervision meets all of the following criteria:
1. Occur during at least 6 consecutive months within the 24 months prior to the request for surgery; and
 2. Include at least three visits for medical supervision, occurring at intervals of no longer than four months apart, e.g., at the start, middle and end of the 6-month weight loss program; and
 3. Be provided by an MD, DO, NP, PA or a registered dietitian under the supervision of an MD, DO, NP, or PA; and
 4. Include assessment and counseling concerning weight, diet, exercise, and behavior modification; and
- C. Preoperative evaluation to include both of the following:
1. Evaluation by a licensed psychologist, psychiatrist, or LCSW documents the absence of significant psychopathology that can limit an individual's understanding of the procedure or ability to comply with medical/surgical recommendations (e.g., active substance

- abuse, eating disorders, schizophrenia, borderline personality disorder, uncontrolled depression); and
2. Clinical documentation, by either a psychological or surgical evaluation, of willingness to comply with preoperative and postoperative treatment plan
- D. Age greater than or equal to 18 years.
- II. Adjustable gastric banding, gastric bypass using a Roux-en-Y anastomosis, and sleeve gastrectomy are considered **investigational** for the treatment of any condition other than morbid obesity, including but not limited to gastroesophageal reflux disease.
- III. The following surgical procedures are considered **investigational** for the treatment of any condition, including but not limited to morbid obesity and gastroesophageal reflux disease:
- A. Mini-gastric bypass (gastric bypass using a Bilroth II type of anastomosis)
 - B. Distal gastric bypass (long limb gastric bypass, i.e., >150 cm)
 - C. Biliopancreatic bypass (i.e., the Scopinaro procedure)
 - D. Biliopancreatic bypass with duodenal switch
 - E. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy followed by gastric bypass, sleeve gastrectomy followed by biliopancreatic diversion)
 - F. Adjustable gastric banding with existing gastric bypass or sleeve gastrectomy
- IV. The vertical banded gastroplasty is no longer a standard of care and is therefore considered **not medically necessary**.
- V. Reoperation
- A. Reoperation for the following documented significant complications of a bariatric procedure may be considered **medically necessary**:
 1. Band erosion or migration (slippage), that cannot be corrected with manipulation or adjustment
 2. Leak
 3. Obstruction
 4. Staple-line failure
 5. Weight loss to 80% or less of ideal body weight
 - B. Reoperation with removal of adjustable gastric band and conversion to a gastric bypass using a Roux-en-Y anastomosis or sleeve gastrectomy may be considered **medically necessary** AND criteria I. A-D are met. Note that criteria I. A-D must be met during the period after placement of the adjustable gastric band.
 - C. Reoperation which does not meet criteria V.A. or V.B. above, is considered **not medically**

necessary, including but not limited to reoperation for the following indications:

1. Early satiety
2. Nausea
3. Patient dissatisfaction
4. Gastroesophageal reflux disease (GERD)
5. Conversion of a prior procedure to a different procedure (e.g., laparoscopic adjustable banding to gastric bypass)

VI. Endoscopic procedures:

- A. Endoscopic procedures as the primary bariatric procedure are considered **investigational**.
- B. Endoscopic procedures, except for balloon dilatation of anastomotic strictures, are considered **investigational** to treat complications of primary bariatric surgery, including but not limited to weight gain due to a large gastric stoma or large gastric pouch and dumping syndrome.
- C. Examples of endoscopic devices/procedures include but are not limited to:
 1. StomaphyX™ (EndoGastric Solutions, Inc)
 2. ROSE procedure (Restorative Obesity Surgery, Endoscopic™)
 3. EndoCinch™ (Bard)
 4. EndoSurgical Operating System™ (EOS) (USGI Medical, Inc)
 5. Sclerotherapy of stoma

SCIENTIFIC EVIDENCE

Background

- Roux-en-Y Gastric Bypass (RYGBP)

The Roux-en-Y gastric bypass is the most commonly performed procedure with the most accumulated evidence in the published literature.^[2]

Consequently, in order to determine the safety and efficacy of other bariatric surgical procedures, they need to be compared to RYGBP in well-designed, well-executed randomized controlled trials (RCT).

- Laparoscopic Adjustable Gastric Banding (LAGB)

RCT data comparing the two procedures are limited, however:

- LAGB is reversible and the least invasive of all bariatric procedures.
- Weight loss following LAGB is less than what is usually seen following RYGBP.
- LAGB has low perioperative complications; however inadequate weight loss or long term complications of band erosion, slippage, or malfunction may require additional surgery.
- Sleeve Gastrectomy (SG)
 - Despite limited evidence, SG has been gaining increased acceptance in clinical practice.
 - SG offers an alternative to adjustable gastric banding with potentially greater weight loss but without the complications associated with malabsorptive procedures, such as RYGBP.
- Other Bariatric Surgical Procedures

Randomized Controlled Trials (RCTs)

Very few randomized controlled trials compared other bariatric procedures with RYBP. Overall, the trials were of poor quality and the findings unreliable due to at least one of the following design flaws:

- The trials had very small study populations, limiting the ability to rule out the role of chance as an explanation of findings.
- The randomization scheme was either inadequate or not explained. Inadequate randomization of study participants may result in unequal distribution of potential confounders, such as clinical characteristics, which in turn may affect the outcome.
- The studies have short follow-up times so there is no long-term (5-10 years or longer) evidence regarding:
 - durability of weight loss
 - complications (e.g. metabolic side effects, nutritional deficiencies, anastomotic ulcers, esophagitis, procedure-specific complications such as band erosion)
 - resolution of comorbidities (e.g. diabetes, hypertension, obstructive sleep apnea, increased cholesterol)
 - need for reoperations
- Short-term complications, adverse events, morbidity, resolution of comorbidities, and reoperation rates are inconsistently reported, limiting conclusions and comparisons across studies.
- There is limited understanding of appropriate patient selection criteria for each of the non-RYGBP bariatric procedures (e.g. superobese patients vs. morbidly obese patients).

Nonrandomized Studies

Although the published, peer-reviewed literature on non-RYGBP bariatric procedures is voluminous, it consists mostly of case series and retrospective, nonrandomized comparisons. Evidence from these studies is unreliable due to design flaws, such as non-random allocation of treatment, lack of adequate comparison groups, and short-term follow-up. In addition, the inconsistent reporting of weight loss, resolution of comorbidities, adverse events, morbidity, and reoperation rates further limit meaningful comparisons across these studies.

- Bariatric Surgery in the Pediatric Population

Overall, there is very little evidence on the role of bariatric surgery in treating morbidly obese pediatric patients. Moreover, the evidence mostly comes from small, non-randomized and therefore unreliable studies. Specifically:

- There is limited evidence that bariatric surgery leads to clinically significant, long-term sustained weight loss and resolution of obesity-related comorbidities in the pediatric population.
- The evidence does not permit conclusions regarding morbidity associated with and safety of any bariatric procedure in the pediatric population.
- There is no evidence regarding the long-term potential impact of bariatric procedures on growth and development in the pediatric population.

- Bariatric Surgery as a Treatment for Gastroesophageal Reflux Disease (GERD)

In order to determine the safety and efficacy of bariatric surgical procedures as treatments for GERD, they need to be compared to standard medical or surgical treatments of this condition in well-designed, well-executed randomized controlled trials. However, there are no published studies of this nature. In addition, there are no published evidence-based clinical practice guidelines that recommend any bariatric surgical procedure as a treatment of GERD.

- Endoscopic Bariatric Procedures

There is insufficient evidence to determine the safety and efficacy of any endoluminal procedure as either a primary bariatric procedure or a revision procedure. The published evidence is very limited and consists of only a few case series and one unreliable randomized trial.

- Multidisciplinary Approach to the Clinical Management of Bariatric Surgery Patients

The National Institutes of Health/National Heart, Lung, and Blood Institute (NIH/NHLBI) clinical practice guidelines state the importance of a multidisciplinary approach to the clinical management of bariatric surgery patients. Comprehensive programs should address nursing, nutrition, exercise, behavior modification, and psychological support, and they should provide lifelong follow-up for treated patients.^[1]

- Bariatric Surgery Centers of Excellence

The published evidence indicates that high volume bariatric centers are more likely to be successful in achieving optimal outcomes and lower complication and mortality rates than low volume bariatric centers.^[3-5] These data have led to national efforts to establish bariatric surgery centers of excellence by the American Society for Metabolic and Bariatric Surgery, the American College of Surgeons, and the BlueCross BlueShield Association.

Literature Appraisal

The following literature appraisal is based on randomized controlled trials (RCT), Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessments, Cochrane reviews, Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness reviews, Washington State Health Technology Assessment and evidence-based guidelines.

Distal (Long Limb) Gastric Bypass

TEC Assessment

The 2005 Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessment identified six comparative trials of long limb gastric bypass with Roux-en-Y anastomosis (LL-RYGBP) vs. standard RYGBP.^[2] However, only two were randomized controlled trials (RCT). The assessment determined that there was not sufficient evidence to reach conclusions on the efficacy and safety of LL-RYGBP compared to standard RYGBP:

1. In both RCTs, there was no significant difference in weight loss between the two groups at 1 year.
2. The evidence for the super obese (BMI ≥ 50 kg/m²) population was weak and did not allow conclusions concerning whether LL-GBRY is superior in this subgroup of patients
3. The adverse events were poorly reported in all comparative studies. Some of the reports contradicted one another.
4. There was no definite cut-off for “long” vs. “standard” limb, making comparisons even more challenging.

Randomized Controlled Trials (RCTs)

One RCT evaluated the effectiveness of the distal gastric bypass for weight loss and control of comorbidities.^[6] The study included only super obese patients (BMI ≥ 50 kg/m²). There was no significant difference in the control or improvement of hypertension, sleep apnea, or gastroesophageal reflux disorder between the patients who underwent long-limb (Roux limb = 250 cm) and short-limb gastric bypass (Roux limb = 150 cm). In addition, there was no difference in excess weight loss between the groups. Although the study reports better control of lipid disorders and diabetes in patients who underwent the long-limb gastric bypass, several design flaws undermine the reliability of the study findings:

- The small study population (n=105) limits the ability to rule out the role of chance as an explanation of findings.
- The randomization scheme was not explained. Inadequate randomization of study participants may result in unequal distribution of potential confounders, such as clinical characteristics.
- The short-term follow-up limits conclusions regarding the long-term complications and the effectiveness of the distal gastric bypass in controlling weight loss and comorbidities.
- The study included only super obese patients limiting the generalizability of the study findings to other patient populations (i.e. morbidly obese).
- The need for nutritional supplementation after the surgery was reported for the two treatment groups, but there was a failure to include statistical testing for this outcome.

Nonrandomized Trials

A number of nonrandomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing distal gastric bypass.^[2,7-9] As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable.

Conclusion

Evidence regarding long limb gastric bypass with Roux-en-Y anastomosis (LL-RYGBP) vs. standard RYGBP is limited to three RCTs which showed either no benefit to the LL approach compared to the RYGBP and/or had numerous methodological limitations. In addition, without a standardized cut-off for long vs. standard limb length, comprehensive assessment of the long limb procedure is unlikely. Therefore, current evidence is insufficient to recommend LL-RYGBP over standard RYGBP, including in the super obese.

Biliopancreatic Bypass and Biliopancreatic Bypass with Duodenal Switch

TEC Assessment

The 2005 BCBSA TEC Assessment identified only one comparative trial that compared RYGBP with biliopancreatic diversion with duodenal switch (BPD-DS).^[2] Although the trial included 237 RYGBP and 113 BPD-DS patients, it was not a randomized clinical study (the choice of the surgery was determined by surgeon and/or patient) and it followed participants for only one year. The TEC Assessment did not find this data sufficient to determine the risk/benefit ratio for this procedure or that it results in greater weight loss than RYGBP:

- The % estimated weight loss (EWL) at one year was the same for both the RYGBP and BPD-DS groups.
- Data on short-term adverse events was limited, except for the mortality and wound infection rates which were equivalent in both groups.
- More anastomotic leaks were reported in BPD-DS group.
- Long-term complications were not reported.
- Nutritional concerns were not adequately addressed. This is of concern because BPD-DS further reduces fat absorption, affecting the absorption of fat soluble vitamins.

Randomized Controlled Trials (RCTs)

Two prospective randomized trials compared the experiences of obese patients undergoing RYGBP vs. BPD.

The first trial compared weight loss, metabolic deficiencies, and resolution of comorbidities in morbidly obese patients undergoing RYGBP vs. a variant of BPD (BPD with RYGBP).^[10] The study reports comparable nutritional deficiencies between the two procedures. Although better weight loss and resolution of diabetes and hypercholesterolemia was reported in the BPD group, several design flaws undermine the reliability of the study findings:

- The study employed an inadequate randomization scheme: the report states that patients were chosen to undergo RYGBP or BPD, but fails to provide any further explanation of how the treatment was assigned. Inadequate randomization of study participants may result in unequal distribution of potential confounders, such as clinical characteristics.
- The RYGBP group had a significantly higher level of preexisting comorbidities ($p = 0.01$), suggesting a difference between the treatment groups that may have affected the outcome.
- The small study population (65 patients/surgery group) limits the ability to rule out the role of chance as an explanation of findings.

- The short-term follow-up (2 years) limits conclusions regarding the long-term metabolic complications and the long-term effectiveness of the BPD in controlling weight loss and comorbidities.

Another small randomized trial (n=60) compared laparoscopic RYGBP and BPD-DS for superobese patients (BMI 50-60 kg/m²).^[11] The study found comparable 30-day perioperative safety and greater weight loss following BPD-DS in the first year. However, several design flaws undermine the reliability of the study findings:

- It is not certain from the data presented whether the study was adequately powered to reliably observe the treatment differences, especially in the stratified sub-analyses.
- The short-term follow-up (one year) limits comparisons regarding the long-term complication rates and the long-term effectiveness of the two procedures in controlling weight loss.
- The effectiveness of the procedures in controlling comorbidities was not compared in this study.

Nonrandomized Trials

A number of non-randomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing biliopancreatic diversion with or without duodenal switch.^[12-29] As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable.

Conclusion

Studies that compared RYGBP with biliopancreatic diversion with duodenal switch (BPD-DS) are limited to three RCTs, all with methodological limitations, including inadequate power analysis, unequal distribution of preexisting comorbidities between groups, small sample size and short-term follow-up. Given these limitations, the efficacy of BPD-DS versus RYGBP as a treatment for obesity cannot be determined.

Sleeve Gastrectomy

Cochrane Review

The 2009 Cochrane review of bariatric surgery identified only one randomized controlled trial that compared sleeve gastrectomy to gastric bypass with Roux-en-Y anastomosis (RYGBP).^[30,31] This very small (n=32) and short trial that followed participants for only 1 year reported that:

- Weight loss and BMI were similar between the two procedures, but % excess weight loss was greater with sleeve gastrectomy.
- Two patients had diabetes at baseline, both in the RYGBP group. The condition was resolved at 1 year in both patients. The outcome of other comorbidities reported at baseline was not reported for the RYGBP or SG groups.
- Although the study reported no conversions to open surgery and no intraoperative and postoperative complications, the other complications and additional operative procedures were not reported.
- The study did not assess a two-stage approach using sleeve gastrectomy prior to another bariatric procedure and consequently no conclusions about the two-stage approach could be made.
- The short duration of the follow-up results in underestimation of the impact of late complications

and the need for revision surgery.

Randomized Controlled Trials (RCTs)

Evidence from RCTs that compared patients who underwent sleeve gastrectomy (SG) with standard RYGBP surgery is limited in quantity and quality. Five RCTs found SG and RYGBP to be overall comparable, however at least two major design flaws undermine the reliability of the reported study findings:^[32-36]

- The very small study populations (n=23, 27, and 60)^[32-34] in three of the studies limit the ability to rule out the role of chance as an explanation of findings.
- The very short follow-up durations (3 months, 1 year, 3 years^[35,36]) limit conclusions regarding medium- and long-term outcomes (e.g., weight loss, glucose metabolism, resolution of comorbidities, reoperation rates, and safety).

Nonrandomized Trials

A number of nonrandomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing sleeve gastrectomy.^[37-74] As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable.

Clinical Practice Guidelines^[75]

The 2011 American Society for Metabolic & Bariatric Surgery (ASMBS) Position Statement on Sleeve Gastrectomy as a Bariatric Procedure recognizes sleeve gastrectomy as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach. However, the ASMBS Statement does not include a critical appraisal of the reviewed evidence. The key publications cited in the statement^[31-34,49,68,69,73,74] have methodological limitations as noted above.

Conclusion

Although the evidence regarding sleeve gastrectomy (SG) with RYGBP compared to standard RYGBP is limited, SG has become a recognized surgical option in clinical practice for the treatment of morbid obesity.

Adjustable Gastric Banding

TEC Assessments

Although a 2007 Blue Cross Blue Shield TEC Assessment identified eight comparative trials of gastric bypass with Roux-en-Y anastomosis (RYGBP) vs. laparoscopic adjustable gastric banding (LAGB), none of the trials was a randomized controlled design that directly compared the two procedures.^[76] Three trials matched patients on key clinical characteristics, and the rest were comparisons of outcomes from separate clinical series of patients who had RYGBP or LAGB.

The assessment of the comparative trials found that there was a tradeoff in terms of safety and efficacy when comparing LAGB and RYGBP:

- LAGB was less invasive, required a shorter hospital stay, and was reversible.
- Short-term complications of LAGB were very low and mortality exceedingly rare.
- Weight loss for LAGB at one year was substantial, but inferior to RYGBP. The data on the longer-term weight loss was limited and the conclusions less definitive.
- The data on the longer-term complications was inadequate, but it suggested that a considerable minority of the LAGB patients may require reoperations and/or removal of the band.

In 2012, TEC conducted an updated Assessment, focusing on LAGB in patients with BMIs less than 35 kg/m².^[77] TEC made the following observations and conclusions:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There was only one small randomized, controlled trial, which had methodologic limitations, one nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence was sufficient to determine that weight loss following LAGB was greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss was large enough that improvements in weight-related comorbidities could be assumed.
- There was very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB was uncertain, thus it was not possible to determine whether the benefit of LAGB outweighed the risk for this population. TEC concluded that while the short-term safety of LAGB was well-established, the long-term adverse effects occur at a higher rate and are less well-defined.

Cochrane Review

The 2009 Cochrane review of bariatric surgery identified only one randomized controlled trial that compared laparoscopic adjustable gastric banding (LAGB) to laparoscopic gastric bypass with Roux-en-Y anastomosis (RYGBP).^[30,78] Both procedures were performed laparoscopically. This very small trial (n=51) which followed participants for five years reported that:

5. RYGBP was superior to LAGB on more than one measure of weight loss (% excess weight loss, mean BMI)
6. Early complications requiring reoperation were more present in the RYGBP patients, but numbers were small and no tests of statistical significance were reported.
7. Comorbidities and late complications were comparable but the numbers were very small and no tests of statistical significance were reported.

Randomized Controlled Trials (RCTs)

An updated literature search failed to identify any additional randomized controlled trials that compare LAGB with RYGBP.

Nonrandomized Trials

A number of non-randomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing LAGB.^[29,54,76,79-84] As noted at the beginning of the evidence section, conclusions cannot be reached as the evidence from these studies is considered unreliable.

Conclusion

Although the evidence regarding the laparoscopic adjustable gastric banding (LAGB) compared to standard RYGBP is limited, there appear to be benefits associated with LAGB in terms of the procedures reversibility and laparoscopic approach. Despite limited evidence, the LAGB has been gaining increased acceptance in clinical practice.

Mini-Gastric Bypass

Randomized Controlled Trials (RCTs)

One small RCT compared the safety and effectiveness of laparoscopic RYGBP and mini-gastric bypass (MGBP).^[85] The study found a comparable rate of late complications (>30 days post-op), weight loss, and comorbidity resolution. MGBP was associated with fewer early complications (<30 days post-op). However, the following design flaws undermine reliability of the study findings:

- The small study population (n=80) limits the ability to rule out the role of chance as an explanation of findings.
- Short-term follow-up (2 years) limits comparisons regarding the longer-term complications rates and the effectiveness of the two procedures in controlling weight loss and comorbidities

Nonrandomized Trials

Several non-randomized studies (retrospective comparisons, case series) describe experiences of patients undergoing MGBP.^[86-90] As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

Conclusion

Data regarding the mini-gastric bypass (MGBP) is limited to a small RCT, prohibiting conclusions regarding the efficacy of this procedure compared to RYGBP.

Vertical Banded Gastroplasty (VBG)

VBG has largely been abandoned in the United States due to insufficient weight loss and high reoperation rates (approximately 30%).^[30]

Two-Stage Bariatric Surgery Procedures

Bariatric surgeries that are performed in 2 stages have been proposed as a treatment option, particularly for patients with “super-obesity” defined as a BMI greater than 50. The rationale for a 2-stage procedure is that the risk of an extensive surgery is prohibitive in patients with extreme levels of obesity. Therefore, an initial procedure with low risk, usually a sleeve gastrectomy, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a biliopancreatic diversion (BD), is performed.

The evidence on 2-stage procedures consists of case-series of patients undergoing sleeve gastrectomy (SG) as the initial procedure. Many of these case series did not report on the second-stage operation, and in those that did, only a minority of patients undergoing the first stage actually proceeded to the second-stage surgery. For example, Cottam et al.^[45] reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first portion of a planned 2-stage procedure. A total of 36 patients (29%) proceeded to the second-stage procedure, which was laparoscopic gastric bypass. In a similar study, Alexandrou et al.^[91] reported on 41 patients who underwent SG as the first stage of a planned 2-stage procedure. After 1-year follow-up, 12 patients (29%) achieved a BMI less than 35 and were not eligible for the second-stage procedure. Of the remaining 28 patients, 10 (24% of total) underwent the second-stage procedure. The remaining 18 patients (44% of total) were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo 2-stage procedures are at risk for complications from both procedures. Silecchia et al.^[92] described the complication rates in 87 patients undergoing a stage I SG followed by a BPD in 27 patients. For the first stage of the operation, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, major complications occurred in 29.6% including bleeding, duodenoileal stenosis, and rhabdomyolysis.

Conclusion

The current evidence does not indicate that a 2-stage bariatric surgery procedure improves outcomes for patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. A majority of patients who received SG as the initial procedure lost sufficient weight during the first year such that a second procedure was no longer indicated. In addition, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is possible that overall complications are increased by this approach.

Endoscopic (Endoluminal) Bariatric Procedures

Nonrandomized Trials

A small number of non-randomized studies, primarily case series, describe experiences of patients undergoing different endoluminal procedures.^[93-100] As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

Bariatric Surgery in Patients with Diabetes with BMI < 35kg/m²

TEC Assessment

In 2012, TEC published an assessment evaluating the available literature on bariatric surgery in patients with diabetes and a BMI less than 35kg/m².^[77,101] TEC made the following observations and conclusions:

- There were no randomized trials comparing bariatric surgery to medical treatment for diabetic subjects with BMIs less than 35 kg/m². There was only one randomized trial comparing 2 bariatric procedures. Therefore, studies were categorized by procedure type and presented as case series, regardless of the underlying study type.

- Nine studies reported diabetes remission rates and other outcomes in subjects undergoing gastric bypass. Diabetes remission rates varied between 48% and 100% at follow-up times of 1 year and beyond. One of the studies was a randomized clinical trial of gastric bypass versus sleeve gastrectomy; in this study diabetes remission associated with gastric bypass was 93% versus 47% for sleeve gastrectomy at 1 year.
- Two studies reported outcomes of sleeve gastrectomy. The diabetes remission rates were 55% and 47% at 1 year.
- One study was selected that reported outcomes of ileal interposition. The diabetes remission rate at a mean follow-up time of 39.1 months was 78.3%.
- Two studies reported outcomes of gastric banding. The only measure of diabetes outcome was withdrawal of diabetes medication, which was not considered a clinically rigorous measurement. The reported remission rates were 27.5% and 50% at variable follow-up times.
- One study of biliopancreatic diversion reported a remission rate of 67% for subjects with BMI between 30 and 35 and 27% for subjects with BMI between 25 and 30 kg/m² at 12 months' follow-up.
- One study reported outcomes of duodenal-jejunal exclusion. The subjects in this study had more severe diabetes than the subjects enrolled in other studies; 100% were on insulin treatment and the duration of diabetes was between 5 and 15 years. The diabetes remission rate was 17% at 6 months.
- For procedures other than gastric bypass, TEC determined there was insufficient evidence to reach firm conclusions regarding the efficacy of bariatric procedures for the treatment of diabetes in patients with BMIs less than 35 kg/m².
- For gastric bypass, the TEC Assessment noted that it was the only procedure evaluated in more than two studies and resulted in 50% or greater remission of diabetes in all studies, with follow-up times up to two-years. In addition the assessment observed declines in LDL and triglyceride levels for diabetic patients who underwent gastric bypass, suggesting a reduction in cardiovascular risk.

Evidence from the TEC report was based upon 15 case series which were limited by sample size and short-term follow-up. Data from some of these studies was gathered from centers employing procedures considered investigational in the U.S. Despite this limited evidence, the TEC Assessment concluded that gastric bypass for diabetes in patients with BMIs less than 35 kg/m² should be considered and likened the risk/benefit profile to that of patients who are morbidly obese, noting the difficulty of diabetes remission with lifestyle and dietary changes. However, the assessment did note that no direct benefit of improved diabetic status with respect to long-term outcomes was observed in these studies.

Systematic Review and Meta-Analysis

In 2013, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review of bariatric surgery and nonsurgical therapy in adults with metabolic conditions, including diabetes, and a BMI of 30.0-34.9 kg/m².^[102,103] The report evaluated key issues which included the effectiveness of bariatric surgery compared to nonsurgical therapies, short and long-term effects in symptom control and racial and demographic disparities regarding benefits and harms of surgery in patients with metabolic conditions and a BMI of 30.0-34.9 kg/m².^[102] Evidence was gathered from global literature searches, reference mining and titles identified from external sources. A total of 24 studies reported bariatric surgery results, with a majority of studies evaluating RYGBP or LAGB procedures in diabetic patients with a BMI of 30-35 kg/m².^[102] The AHRQ report concluded that there was moderate strength evidence of efficacy for certain bariatric procedures as a treatment for diabetes in the short term. However, the report noted that the evidence contained many limitations, "(m)ost importantly, very few studies of this target population have long-term follow-up. Only two studies followed patients for more than 2 years; one has a followup rate of only 13.8 percent and the other

includes only seven patients. Thus, we have almost no data on long-term efficacy and safety.” In addition the AHRQ reported noted the lack of evidence on major clinical outcomes such as all-cause mortality, cardiovascular risks, or peripheral arterial disease. Although short-term studies suggest an improvement in glucose control, the AHRQ report points out that, “...the available evidence from the diabetes literature indicates it may be premature to assume that controlling glucose to normal or near normal levels completely mitigates the risk of microvascular and macrovascular events. Thus, claims of a “cure” for diabetes based on glucose control within 1 or 2 years require longer term data before they can be substantiated.”

Also in 2013, Parikh and colleagues reviewed the role of bariatric surgery as a treatment for type-2 diabetes in patients with a BMI < 35 kg/m².^[104] A total of 39 articles were identified for inclusion in the analysis, of which only 3 were RCTs. In 17 articles diabetes remission criteria was equal or stricter than the American Diabetes Association (ADA) criteria. Analysis of those 17 articles indicated that the overall rate of diabetes remission was 50.9% (95% CI, 40.3-61.5%) at 12 months. Data for diabetes improvement was available in 22 articles and estimated at 94.5% at 12 months. Data on the duration of diabetes, insulin use, or insulin resistance as predictors of remission were not reported due to incomplete and variable data. Although results from this study appear promising, the study is limited by a lack of available RCTs and short-term follow-up of only 1 year. Without long-term randomized trials which compare bariatric surgery to standard treatments for diabetes, questions regarding the ability of this procedure to durably control symptoms and improve health outcomes remain unanswered.

Randomized Controlled Trials (RCTs)

Since the publication of the AHRQ and TEC report, a single RCT has reported on bariatric surgery compared to medical therapy in diabetic patients with a BMI between 30-40 kg/m².

Ikramuddin et al. performed an unblinded RCT of gastric bypass versus intensive medical therapy on 120 patients with type II diabetes for at least 6 months and an HgbA1C of at least 8.0%.^[105] Patients were followed for 12 months with the primary endpoint being a composite of HgbA1C less than 7.0%, low-density lipoprotein (LDL) cholesterol less than 100 mg/dl and systolic blood pressure less than 130 mm Hg. A total of 28 patients in the surgery group achieved the primary outcome compared to 11 patients in the medical therapy group (odds ratio [OR]: 4.8, 95% CI: 1.9-11.7). The percent of patients achieving HgbA1C of less than 7.0% was 75% in the surgery group compared to 32% of patients in the medical therapy group (OR: 6.0, 95% CI: 2.6-13.9). There were 22 serious complications in the surgery group, including 4 perioperative complications, compared to 15 serious complications in the medical group. A limitation of this study was that results were not provided separately for patients who were above and below a BMI of 35 kg/m², thus restricting conclusions regarding the benefits of bariatric surgery compared to medical management in diabetic patients with a BMI < 35 kg/m².

Clinical Practice Guideline

- American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (AACE/ASM/Obesity Society)^[106]

In 2013, joint guidelines were published by AACE/ASM/Obesity Society regarding the perioperative nutritional, metabolic and nonsurgical support of the bariatric surgery patient. Recommendations regarding which patients should be offered bariatric surgery indicated the following:

“Patients with BMI of 30–34.9kg/m² with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.

There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.”

- Institute for Clinical Systems Improvement (ICSI)^[107]

In 2012, the ICSI published guidelines regarding the diagnosis and management of type 2 diabetes mellitus in adults and indicated:

“Bariatric surgery may be considered for adults with BMI >35 if diabetes or comorbidities are difficult to control with lifestyle and pharmacologic therapy.”

Conclusion

Evidence regarding the efficacy of bypass as a treatment for diabetes in patients with a BMI < 35 kg/m² primarily consists of small cases series with short-term follow-up as noted in the TEC assessment and AHRQ report. Since the publication of these reports a single RCT was identified which was limited by the inclusion of obese (BMI 35-40 kg/m²) and non-obese (BMI 30-34.9 kg/m²) patients, precluding conclusions regarding the clinically non-obese population. Only one clinical practice guideline was identified which recommended bariatric surgery in diabetic patients who do not meet the clinical definition of obesity; however, a lack of long-term data was noted. Overall, the current evidence does not demonstrate the safety and efficacy of bariatric surgery as a treatment for diabetes in patients with a BMI < 35 kg/m².

Adolescent and Pediatric Bariatric Surgery

Washington State Health Technology Assessment

The 2007 Washington State Health Technology Assessment evaluated the published, peer reviewed scientific literature describing bariatric surgery in the pediatric population.^[108] Data from 17 studies that enrolled a total of 553 pediatric patients were included. Only one study was clearly prospective. Eight studies reported outcomes after LAGB, six after RYGBP, two after VBG, and one after banded bypass. The report concluded that:

- The evidence that LAGB for morbidly obese pediatric patients leads to sustained and clinically significant weight loss compared to non-operative approaches was weak at the longest follow-up after surgery (1.7 to 3.3 years).
- The evidence that RYGBP for morbidly obese pediatric patients leads to sustained and clinically significant weight loss compared to non-operative approaches was weak at the longest follow-up after surgery (1 to 6.3 years).
- The evidence was insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
- The evidence was insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.

- The evidence was insufficient to permit any conclusions about weight loss in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.
- The evidence that LAGB for morbidly obese pediatric patients does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches was weak.
- The evidence that RYGBP for morbidly obese pediatric patients does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches was weak.
- The evidence was insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life improvement, or survival after any bariatric surgical procedure for pediatric patients.
- The evidence was insufficient to permit any conclusions about comorbidity resolution in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.
- The LAGB studies reported no in-hospital or postoperative death. However, the most commonly reported complication was band slippage. Reoperations were performed on 7.9% of the LAGB patients to correct various complications (band slippage, intragastric migration, port/tubing problems).
- The RYGBP studies reported one postoperative death. The most frequently reported complication was related to malnutrition and micronutrient deficiency. In addition, potentially life threatening complications (shock, pulmonary embolism, severe malnutrition, bleeding, gastrointestinal obstructions) were reported.
- The evidence was insufficient to permit any conclusions on potential impacts of bariatric surgery on growth and development of pediatric patients.
- The evidence was insufficient to permit any conclusions on potential harms in specific age groups (18-21, 13-17, 12 or less).

In summary, the assessment found that longer term, prospective collection of data on physical growth, quality of life, weight loss, persistence or resolution of comorbid conditions, and long-term survival are needed in order to fully understand the role of bariatric surgical procedures in treating morbidly obese pediatric patients.

Randomized Controlled Trials (RCTs)

One small randomized trial compared the outcomes of gastric banding with an optimal lifestyle program in adolescents 14-18 years of age with a BMI >35.^[109] Although the study reports that gastric banding resulted in greater percentage achieving a loss of 50% of excess weight, several flaws undermine the reliability of the study findings:

- The small study population (n=50) limits the ability to rule out the role of chance as an explanation of findings.
- The study had significant loss to follow-up suggesting a difference that may affect the outcome.
- Short-term follow-up (2 years) limits comparisons regarding the longer-term complications rates and the effectiveness of the procedure in controlling weight loss and comorbidities.

Nonrandomized Trials

Studies with short follow-up time

A small number of non-randomized comparative studies reported significant weight loss and resolution of some of the comorbidities in pediatric patients undergoing bariatric surgery.^[110-112] However, the studies were small and had a very short follow up time.

Studies with mid-term follow-up time

Two observational studies with mid-term follow-up times (≤ 10 and ≤ 8 years) reported experiences of pediatric patients undergoing LAGB (sample size 41 and 107 respectively).^[113,114] The first study found that weight loss was initially successful and resulted in resolution of some comorbidities, but it slowly increased over the time and ultimately was unsatisfactory in many patients. The second study reported 65.5% excess weight loss at eight years. Both studies reported high complication and reoperation rates (Lanthaler: 46% patients had complications that required reoperation; Mittermaier: 46% patients had complications and 29% required reoperation).

However, as noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

Clinical Practice Guidelines for Pediatric Bariatric Surgery

- American College of Physicians (ACP)

The 2005 ACP evidence-based guideline on use of bariatric surgery in adolescents and children states that the current evidence on surgical treatment of pediatric populations is limited to a few case series which do not permit quantitative analysis. Further, the guideline states that it is unclear whether extrapolation of adult data for bariatric surgery to the pediatric population is appropriate and that RCTs are needed (and feasible) to establish the role of bariatric surgery in this population.^[115]

- American Academy of Pediatrics (AAP)

In 2007, the AAP published, “Recommendations for Treatment of Child and Adolescent Overweight and Obesity^[116],” which stated that although there is increased use of bariatric surgery in adults:

“There is limited research on the safety, efficacy, and long-term outcomes of bariatric surgery for adolescents; therefore, data from adult studies must be considered as surrogate evidence.”

Ultimately, the AAP noted that additional trials are needed to determine whether bariatric surgery is acceptable in adolescents.

- American Heart Association (AHA)^[117]

In 2013, the AHA published a statement regarding severe obesity in children and adolescents which concluded:

“Current treatment approaches using lifestyle modification and medications to reduce BMI and improve chronic disease risk factors are insufficient for most patients and significant residual risk (unacceptably high BMI and risk factor levels) remains. Although experts recommend stepped intensification of interventions, the “step” after behavior-based and pharmaceutical interventions to the next established alternative, bariatric surgery, is unacceptably large because of its limited applicability and availability.”

The AHA indicated that the following evidence was needed before bariatric surgery could be widely recommended in children and adolescents:

“Generation of additional safety and efficacy data (especially long-term) on bariatric surgery, including studies describing improvements in vascular structure and function, insulin resistance, and β -cell function.”

- Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

The 2008 SAGES^[118] evidence-based guidelines state:

“RGB is well tolerated and produces excellent weight loss in patients younger than 18 years with 10-year follow-up... Well-designed prospective studies are just emerging to better define the place for adolescent bariatric surgery.”

This statement is based on eight publications of which six are retrospective studies, each with less than 35 participants and most with limited follow-up. Two of the supporting articles are opinion papers.

- Endocrine Society

In 2008 the Endocrine Society^[119] published clinical guidelines on the, “Prevention and Treatment of Pediatric Obesity”, which utilized the GRADE^[120] system to describe the quality of evidence and the strength of recommendations. The term ‘recommend’ was used for strong recommendations and the term ‘suggest’ for weak recommendations. Ultimately, the Endocrine Society’s guidelines are based upon expert opinion. The Endocrine Society suggests that bariatric surgery be considered for adolescents, but only after the following criteria have been met:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

- Institute for Clinical Systems Improvement (ICSI)^[121]

In 2011, ICSI^[121] published an information guideline for health professionals addressing the prevention and management of obesity in mature and adolescent adults. The group notes a limited number of randomized trials with long-term follow-up regarding the various bariatric procedures in adolescents. ICSI concluded that bariatric surgery in adolescents is highly controversial and should be carried out on a case-by-case basis at a high volume center. This statement, however, is based upon evidence from a randomized controlled trial of 80 adults.

In 2013, ICSI published updated guidelines regarding the prevention and management of obesity for children and adolescents. The group noted that, “there is limited information on the long-term efficacy and safety of bariatric surgery in children and adolescents.” However, ICSI concluded that bariatric surgery may be considered at centers of excellence when specific criteria were met and should not be considered in preadolescent children. These guidelines are primarily based upon review articles and consensus opinion.

- National Heart, Lung and Blood Institute (NHLBI)^[122]

In 2011 NHLBI published guidelines regarding cardiovascular health and risk reduction in overweight and obese children and adolescents which indicated bariatric surgery may be considered:

“For adolescents with BMI far above 35 kg/m² and associated comorbidities, bariatric surgery on a research protocol, in conjunction with a comprehensive lifestyle weight loss program, improved weight loss, BMI, and other outcomes—such as IR, glucose tolerance, and cardiovascular (CV) measures—in a small case series.”

This guideline is based on a Grade D recommendation which is defined as, “Expert opinion, case reports, or reasoning from first principles (bench research or animal studies).”

Conclusion

Despite evidence which suggest bariatric surgery may provide the benefits of weight reduction and improved comorbidities compared to non-surgical treatments in the obese children and adolescents, long-term data regarding the life-long impact of bariatric surgery on physical growth, nutrition status, weight loss, resolution of obesity-related comorbidities and long-term survival is lacking. Therefore, the efficacy of bariatric surgery in patients younger than 18 years of age is undetermined.

Gastroesophageal Reflux Disease (GERD)

Randomized Controlled Trials (RCTs)

No randomized controlled trials compared standard medical or surgical treatments of GERD with bariatric surgical procedures as a treatment of GERD.

Nonrandomized Trials

One retrospective study compared the in-hospital outcomes of morbidly obese patients who underwent laparoscopic fundoplication for the treatment of GERD versus laparoscopic gastric bypass for the treatment of morbid obesity and related conditions, including GERD.^[123] As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

Clinical Practice Guidelines

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)^[124]

In 2010, SAGES published clinical practice guidelines for the treatment of GERD and did not recommend any bariatric procedure as a surgical treatment option.

Conclusion

Data regarding bariatric surgery for the treatment of GERD is limited to a single nonrandomized study, prohibiting conclusions regarding the efficacy of these procedures as a treatment for GERD.

Safety of Bariatric Surgery

General Surgical Risks

Bariatric procedures are associated with all the potential risks of any major abdominal surgical procedure including but not limited to:

- Bleeding
- Death
- Infection
- Injury to internal organs or gastrointestinal tract
- Thromboembolic complications

Procedure-Specific Surgical Risks

The following table summarizes the most common procedure-specific risks. However, other adverse events are also possible.

RYGBP^[2]	LL-RYGBP^[2]	BPD/BPD-DS^[2,30]	SG^[30,42,125-127]	LAGB^[76]	MGB^[85]	Endoluminal Procedures
<ul style="list-style-type: none"> • Cholecystitis • Depression • Dilated stomach pouch • Dumping syndrome[†] • Gastritis • Leaks or obstructions at the anastomotic site • Marginal ulcer • Reoperations^{††} • Staple line failure • Vitamin/mineral deficiencies (iron, folate, B₁₂) 	<ul style="list-style-type: none"> • All RYGBP risks • Additional unknown risks associated with the greater bypass of the small intestine and consequent increase in malabsorption^{††} 	<ul style="list-style-type: none"> • Dilated stomach pouch • Gastric obstruction • GERD • Leaks or stenoses at anastomotic sites • Malnutrition and/or vitamin deficiencies • Nausea/vomiting • Wound dehiscence 	<ul style="list-style-type: none"> • Abscesses • Frequent vomiting • Gastric fistulas • GERD • Leaking from the stomach pouch • Reoperations^{†††} 	<ul style="list-style-type: none"> • Band slippage • Dilated stomach pouch • Erosion of the device through gastric wall • GERD • Malnutrition and vitamin deficiencies • Nausea and vomiting 	<ul style="list-style-type: none"> • Bile reflux • Gastrojejunostomy leak • Marginal ulcer • Reoperations^{†††} • Vitamin/mineral deficiency 	<p>The safety concerns are specific to the endoluminal procedure performed:</p> <p><u>Transoral circular stapler (SurgASSIST[®])</u>.^[128]</p> <ul style="list-style-type: none"> • Bowel obstruction • Intra-abdominal adhesions <p><u>Dduodenal-jejunal bypass sleeve (DJBS)</u>.^[96]</p> <ul style="list-style-type: none"> • Abdominal pain • Implant site inflammation • Nausea and vomiting <p><u>TOGa system endoscopic stapling</u>.^[97]</p> <ul style="list-style-type: none"> • Nausea • Vomiting • Pain • Transient dysphagia

[†] Abdominal pain, diarrhea, and/or vomiting shortly after eating due to reduced transit time in the intestine;

^{††} The evidence, especially from the studies with long-term follow-up, is limited and not much is known about the long-term complications of LL-RYGBP;

^{†††} Due to insufficient weight loss or technical issues;

Summary

Roux-en-Y Gastric Bypass (RYGBP), Adjustable Gastric Banding (AGB), and Sleeve Gastrectomy (SG)

- Roux-en-Y gastric bypass is well established in clinical practice, is the most studied bariatric procedure in the published literature, and is used as the gold standard against which other procedures are measured. Adjustable gastric banding is reversible, the least invasive of all bariatric procedures, and has low perioperative complications. Sleeve gastrectomy as a stand-alone procedure has been increasingly gaining acceptance in clinical practice despite the lack of reliable evidence. SG offers an alternative to AGB with potentially greater weight loss but without the complications associated with malabsorptive procedures. Therefore, RYGBP, AGB, and SG may be considered medically necessary in the treatment of morbid obesity.
- Due to insufficient evidence, Roux-en-Y gastric bypass, adjustable gastric banding, and sleeve gastrectomy are considered investigational for the treatment of any condition other than morbid obesity, including, but not limited to gastroesophageal reflux disease.

Mini-gastric bypass, distal gastric bypass, biliopancreatic bypass, biliopancreatic bypass with duodenal switch

Due to very limited scientific evidence and uncertainty about the long-term impact of these procedures on health outcomes, mini-gastric bypass, distal gastric bypass, biliopancreatic bypass, and biliopancreatic bypass with duodenal switch are considered investigational for the treatment of morbid obesity, gastroesophageal reflux disease or any other condition.

Vertical banded gastroplasty

Due to insufficient weight loss and high reoperation rates, vertical banded gastroplasty is no longer considered a standard of care and is therefore considered not medically necessary.

Endoscopic Bariatric Procedures

It is not possible to establish the safety and efficacy of any endoscopic bariatric procedure from the limited published scientific evidence. Therefore, endoscopic bariatric procedures are considered investigational for all indications.

Two-staged Bariatric Procedures

It is not possible to establish the safety and efficacy of any two-stage bariatric procedure from the limited published scientific evidence. Therefore, two-stage bariatric procedures are considered investigational for all indications.

Adolescent and Pediatric Bariatric Surgery

Current evidence regarding the safety and efficacy of bariatric surgery as a treatment for obesity in patients younger than 18 years of age is limited to short-term studies. Long-term, high-quality randomized trials are needed in order to evaluate the life-long impact of bariatric surgery on physical growth, nutrition status, weight loss, resolution of obesity-related comorbidities and overall survival in this population. Therefore, bariatric procedures in patients younger than 18 years of age are considered not medically necessary.

Bariatric Surgery in Patients with Diabetes with BMI < 35kg/m²

Evidence regarding the efficacy of bariatric procedures as a treatment for diabetes in patients with a BMI < 35 kg/m² primarily consists of small cases series with short-term follow-up. The majority of evidence-based clinical practice guidelines do not recommended bariatric surgery in diabetic patients who do not meet the clinical definition of obesity (BMI ≥ 35 kg/m²). Long-term, high-quality randomized trials are needed in order to evaluate the impact of bariatric surgery on health outcomes in this population. Therefore, bariatric procedures in diabetic patients with a BMI < 35 kg/m² are considered not medically necessary.

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CROSS REFERENCES

[Gastric Electrical Stimulation](#), Surgery, Policy No. 111

[Gastric Reflux Surgery](#), Surgery, Policy No. 186

CODES	NUMBER	DESCRIPTION
CPT	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (gastric band and subcutaneous port components)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical banded gastroplasty
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (less than 100 cm) Roux-en-Y gastroenterostomy

CODES	NUMBER	DESCRIPTION
	43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
	43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
	43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
	43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
	43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
HCPCS	S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline