

## ***Bariatric Surgery***

**Effective:** December 1, 2018

**Next Review:** December 2018

**Last Review:** November 2018

### **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**

Bariatric surgery is a major surgical intervention which aims to reduce weight, eliminate or improve comorbid conditions, and maintain weight loss in morbidly obese patients who have failed to achieve weight loss through lifestyle modifications.

## **MEDICAL POLICY CRITERIA**

**Note:** Member contracts for covered services vary. Member contract language takes precedence over medical policy.

- I. **All** of the following **general criteria** (I.A-D.) must be met for bariatric surgery to be considered for coverage:
  - A. At the start of the medically-supervised, nonsurgical weight reduction program, one of the following must be met:
    1. BMI greater than or equal to 40 kg/(meter squared); or
    2. BMI greater than or equal to 35 kg/(meter squared) with at least one of the following comorbid conditions:
      - a. Diabetes mellitus

- b. Hypertension
  - c. Coronary artery disease
  - d. Obstructive sleep apnea
- B. Documentation of active participation for a total of at least 3 consecutive 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 a total of at least 3 consecutive months within the 12 months prior to the request for surgery; and
  2. Include at least 2 visits for medical supervision, during the 3 consecutive months of program participation. One visit must occur at the initiation, and another at least 3 months later; and
  3. Be provided by an MD, DO, NP, PA, or RD under the supervision of an MD, DO, NP, or PA; and
  4. Include assessment and counseling concerning weight, diet, exercise, and behavior modification.
- C. Preoperative evaluation to include both of the following:
1. A licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters-level counselor, or NP in a behavioral health practice, 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. Procedures

- A. Sleeve gastrectomy as a stand-alone procedure, adjustable gastric banding (consisting of an adjustable external band placed around the stomach), or gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less may be considered **medically necessary** in the treatment of morbid obesity when **all** criteria I. (A-D) are met.
- B. Sleeve gastrectomy, adjustable gastric banding, gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less is **not medically necessary** in the treatment of morbid obesity when criteria II.A is not met.

III. The vertical banded gastroplasty is no longer a standard of care and is therefore considered **not medically necessary**.

- IV. Sleeve gastrectomy, adjustable gastric banding, or gastric bypass using a Roux-en-Y anastomosis are considered **investigational** for the treatment of any condition other than morbid obesity, including but not limited to gastroesophageal reflux disease or gastropareses.
- V. The following surgical procedures are considered **investigational** for the treatment of morbid obesity:
  - A. Distal (i.e. antrectomy) or partial (other than standard sleeve gastrectomy) gastrectomy performed with or without any of the following:
    - 1. Gastroduodenostomy
    - 2. Gastrojejunostomy
    - 3. Roux-en-Y reconstruction
  - B. Hiatal hernia repair, including repair of sliding or paraesophageal hernia
  - C. Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical banded gastroplasty or sleeve gastrectomy
- VI. 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 Billroth 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. Laparoscopic duodenal switch with single anastomosis
  - F. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy followed by gastric bypass, sleeve gastrectomy followed by biliopancreatic diversion, removal of gastric band followed by sleeve gastrectomy or gastric bypass)
  - G. Adjustable gastric banding with existing gastric bypass or sleeve gastrectomy, or other bariatric surgical procedure.
  - H. Parietal cell separating gastrojejunostomy
  - I. Laparoscopic gastric plication
- VII. 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. Examples of endoscopic devices/procedures include but are not limited to the following:
    - 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
6. Endoscopic gastroplasty
7. Endoscopically placed duodenal-jejunal sleeve
8. Endoscopic stoma revision
9. Gastric balloon systems
10. AspireAssist
11. OverStitch Endoscopic Suturing System (Apollo Endosurgery, Inc.)

VIII. Reoperation may be considered **medically necessary** when *either* criteria A. or B. are met:

- A. Reoperation with revision of a bariatric procedure (i.e. sleeve gastrectomy, adjustable gastric band, or gastric bypass) or adjustable gastric band removal may be considered **medically necessary** when one or more of the following documented significant complications is present:
  1. Bowel perforation, including band erosion
  2. Band migration (slippage), that cannot be corrected with manipulation or adjustment. Records must demonstrate that manipulation or adjustment to correct band slippage has been attempted.
  3. Leak
  4. Obstruction exceeding the inherent obstruction of the original bariatric procedure, documented by imaging.
  5. Staple-line failure (such as, Gastro-gastric fistula)
  6. Weight loss to 90% or less of ideal body weight
  7. Band infection
  8. Severe, clinically-objective esophagitis (including Barrett's esophagus), or Cameron lesion(s) unresponsive to optimal medical management. Medical management must have been documented for at least 4 months.
- B. Removal of adjustable gastric band and conversion to a gastric bypass using a Roux-en-Y anastomosis with an alimentary limb of 150 cm or less may be considered **medically necessary** when 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.

IX. Reoperation which does not meet criteria VIII. above, is considered **not medically necessary**, including but not limited to reoperation for the following indications:

- A. Early satiety
- B. Nausea
- C. Patient dissatisfaction
- D. Gastroesophageal reflux disease (GERD)

- E. Conversion, which does not meet criteria VIII.A. or VIII.B. above, of a prior procedure to a different procedure (such as, laparoscopic adjustable banding to gastric bypass or sleeve gastrectomy, sleeve gastrectomy to gastric bypass, or a gastric bypass to a sleeve gastrectomy)

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

### REQUIRED DOCUMENTATION:

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could our impact review and decision outcome:

1. Clinical documentation of a medically supervised nonsurgical weight reduction program or comprehensive commercial weight loss program approved and monitored under the supervision of the healthcare practitioner providing medical oversight, that includes:
  - A. BMI at the start of the program
  - B. Comorbid conditions
  - C. The program occurred during at least 3 consecutive months within the 12 months prior to request for surgery
  - D. At least 2 visits for medical supervision during the 3 consecutive months of program participation. One visit must occur at the initiation, and another at least 3 months later.
  - E. Assessment and counseling concerning weight, diet, exercise and behavior modification
  - F. Documentation the program was provided by an MD, DO, NP, PA, or RD under the supervision of an MD, DO, NP, or PA
2. Preoperative evaluation by a licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters-level counselor, or NP in behavioral health that includes:
  - A. Documentation of 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)
3. Preoperative evaluation by either a psychological or surgical evaluation, of willingness to comply with preoperative and postoperative treatment plan
4. History and Physical including current medications
5. For Reoperation, Revision or Removal requests:
  - A. Complication present
  - B. Interventions attempted. NOTE: For band migration (slippage), that cannot be corrected with manipulation or adjustment. Records must demonstrate that manipulation or adjustment to correct band slippage has been attempted.

- C. Imaging. NOTE: For obstruction, records must demonstrate that imaging has been performed.
- D. For severe esophagitis, documentation must demonstrate medical management has been tried for at least 4 months.

## CROSS REFERENCES

1. [Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease \(GERD\)](#), Surgery, policy No. 110
2. [Gastric Electrical Stimulation](#), Surgery, Policy No. 111
3. [Gastroesophageal Reflux Surgery](#), Surgery, Policy No. 186
4. [Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease](#), Surgery, Policy No. 190
5. [Vagus Nerve Blocking Therapy for Obesity](#), Surgery, Policy No. 200

## BACKGROUND

Morbid obesity is defined as a body mass index (BMI) >40 kg/m<sup>2</sup> (normal BMI range: 19-25 kg/m<sup>2</sup>)

**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.<sup>[1]</sup>

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
<b>Gastric Bypass with Roux-en-Y Anastomosis (RYGBP)</b> AKA: Proximal or Short Limb Gastric Bypass	43846 43644	<ul style="list-style-type: none"> <li>• Currently considered “gold-standard” for weight loss surgery</li> <li>• Involves both restrictive and malabsorptive components:               <ul style="list-style-type: none"> <li>○ 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</li> <li>○ The mid portion of the jejunum is divided and the cut end of the distal limb (<math>\leq 150</math> 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.</li> </ul> </li> </ul>
<a href="#">Distal (Long Limb) Gastric Bypass</a>	43847	<ul style="list-style-type: none"> <li>• The procedure involves both restrictive and malabsorptive components and is a variant of the standard gastric bypass with the longer (<math>&gt;150</math> cm) Roux limb. The longer the Roux limb, the greater the bypass of the small intestine and consequently the degree of malabsorption.</li> </ul>
<a href="#">Biliopancreatic Diversion (Bypass) Procedure</a> AKA Scopinaro procedure	43847	<ul style="list-style-type: none"> <li>• Involves both restrictive and malabsorptive components:               <ul style="list-style-type: none"> <li>○ Subtotal (distal) gastrectomy creates small gastric pouch at the top of the stomach to limit food intake</li> <li>○ A long limb Roux-en-Y anastomosis (<math>&gt;150</math> cm) results in the biliopancreatic juices being diverted into the distal ileum, significantly increasing malabsorption</li> </ul> </li> <li>• Designed to preferentially inhibit the absorption of fat</li> <li>• Only partially reversible</li> </ul>
<a href="#">Biliopancreatic Diversion (Bypass) with Duodenal Switch (BPD-DS)</a>	43845	<ul style="list-style-type: none"> <li>• This procedure is an adaptation of the standard biliopancreatic bypass:               <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ The long limb Roux-en-Y anastomosis (<math>&gt;150</math> 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.</li> </ul> </li> </ul>
<a href="#">Laparoscopic duodenal switch with single anastomosis</a> AKA Single loop duodenal switch	No specific CPT code	<ul style="list-style-type: none"> <li>• Restrictive and malabsorptive procedure</li> <li>• Simplified version of the BPD-DS procedure</li> <li>• Surgery consists of:               <ul style="list-style-type: none"> <li>○ Creation of a small gastric pouch by section the curvature of the stomach</li> <li>○ Duodenum is transected while keeping the pylorus intact</li> <li>○ A 1-loop duodenal switch is performed with creation of a 200-250 cm anastomosis</li> </ul> </li> </ul>
<a href="#">Mini-Gastric Bypass</a>	no specific code	<ul style="list-style-type: none"> <li>• The procedure is a variant of the gastric bypass and involves both restrictive and malabsorptive components:               <ul style="list-style-type: none"> <li>○ The stomach is segmented to create a small gastric pouch similar to traditional gastric bypass</li> <li>○ 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)</li> </ul> </li> </ul>
<a href="#">Sleeve Gastrectomy</a>	43775	<ul style="list-style-type: none"> <li>• Greater curvature of the stomach is resected resulting in a gastric remnant shaped like a tube or sleeve.</li> <li>• The pyloric sphincter is preserved leaving stomach function unaltered.</li> <li>• Not reversible</li> <li>• Can be performed as:               <ul style="list-style-type: none"> <li>○ A stand-alone procedure (restrictive)</li> </ul> </li> </ul>

Procedure	CPT Code	Description
		<ul style="list-style-type: none"> <li>○ The first part of a two-stage surgical procedure for the very high-risk patients (BMI <math>\geq 50</math> kg/m<sup>2</sup>) who need to lose some weight before they can proceed with a malabsorptive procedure (most commonly BPD-DS or RYGBP)</li> </ul>
<a href="#"><u>Adjustable Gastric Banding</u></a>	43770- 43774 43886- 43888	<ul style="list-style-type: none"> <li>● Restrictive procedure</li> <li>● An adjustable, external, constrictive band is wrapped around the upper portion of the stomach to create a small stomach pouch</li> <li>● The band can be adjusted through a subcutaneous access port, foregoing the need to enter the gastric cavity when adjusting the band</li> <li>● The least invasive and least technically complex bariatric procedure</li> <li>● Lap-Band® (original applicant, Allergan, Inc.; sold to Apollo Endosurgery, Inc.) and the REALIZE™ (Ethicon Endo-Surgery, Inc.) have received approval from the U.S. Food and Drug Administration (FDA).</li> </ul>
<a href="#"><u>Vertical Banded Gastroplasty</u></a> AKA Vertically banded gastric partition or Gastric stapling	43842	<ul style="list-style-type: none"> <li>● Restrictive procedure</li> <li>● Surgical stapling is used to create a small, vertical gastric pouch at the top of the stomach</li> <li>● The pouch outlet (stoma) is reinforced with an external mesh collar</li> </ul>
<a href="#"><u>Endoscopic (Endoluminal) Bariatric Procedures</u></a>	No specific CPT code	<ul style="list-style-type: none"> <li>● The access to the stomach is gained through the mouth, so no incisions are necessary.</li> <li>● Endoluminal procedures being developed: <ul style="list-style-type: none"> <li>○ Primary bariatric procedure</li> <li>○ Revision (e.g. for treatment of enlarged gastric stoma and/or enlarged gastric pouches that may be associated with weight gain after bariatric surgery)</li> </ul> </li> <li>● Examples of the endoscopic revision bariatric procedures include: <ul style="list-style-type: none"> <li>○ Gastroplasty using an endoscopically guided stapler (reduces the size of the gastric pouch)</li> <li>○ Placement of gastric balloon (soft, silicone balloon inserted into the stomach and filled with sterile saline to induce feeling of satiety)</li> <li>○ Placement of duodenal-jejunal sleeve (sleeve placed inside duodenum and upper jejunum to prevent contact between food and the intestine).</li> </ul> </li> <li>● 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.</li> <li>● OverStitch™ Endoscopic Suturing System is intended for endoscopic placement of sutures and approximation of soft tissue, and has received FDA approval. The system may be used as an incisionless revision surgery, with the intent to reduce the size of a stomach pouch that has stretched out following a previous bariatric procedure.</li> </ul>
<a href="#"><u>Laparoscopic Gastric Plication</u></a>	No specific CPT code	<ul style="list-style-type: none"> <li>● Sutures are laparoscopically placed over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach.</li> <li>● The procedure involves 2 main steps: <ul style="list-style-type: none"> <li>○ Mobilization of the greater curvature of the stomach, and</li> <li>○ Suture plication of the stomach to achieve gastric restriction</li> </ul> </li> </ul>



## EVIDENCE SUMMARY

- 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.<sup>[2]</sup> 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 (RCTs).

- Laparoscopic Adjustable Gastric Banding (LAGB)

RCT data comparing LAGB and RYGBP 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*

Very few randomized controlled trials compared other bariatric procedures with RYGBP. 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, nonrandomized 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.

- **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.<sup>[1]</sup>

- **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.<sup>[3-5]</sup> 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.

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**

### **SYSTEMATIC REVIEWS**

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.<sup>[2]</sup> 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:

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

### **RANDOMIZED CONTROLLED TRIALS**

One RCT evaluated the effectiveness of the distal gastric bypass for weight loss and control of comorbidities.<sup>[6]</sup> The study included only super obese patients (BMI  $\geq 50$  kg/m<sup>2</sup>). 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 STUDIES

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

## SECTION SUMMARY

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

### SYSTEMATIC REVIEWS

In 2013, Colquitt updated a 2009 Cochrane review<sup>[10]</sup> which compared outcomes for a variety of surgical weight loss procedures.<sup>[11]</sup> Two RCTs were identified which assessed outcomes of biliopancreatic diversion with duodenal switch (BPD-DS) compared to RYGBP. At a mean three year follow-up, data from the two trials were pooled (n= 107) and the following conclusions were reached:

- BPD-DS resulted in significantly greater weight loss than RYGBP.
- Quality of life measures were similar between the two groups.
- Reoperation rates were higher in the BPD-DS group (16.1%-27.6%) compared to the RYGBP group (4.3%-8.3%), with one death reported in the BPD-DS group.

The 2005 BCBSA TEC Assessment identified only one comparative trial that compared RYGBP with BPD-DS.<sup>[2]</sup> 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**

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).<sup>[12]</sup> 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 ( $BMI\ 50-60\ kg/m^2$ ).<sup>[13]</sup> 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 effectiveness of the procedures in controlling comorbidities was not compared in this study.

In 2015, long-term 5-year follow-up results were published on data from 55 patients (92%).<sup>[14]</sup> Results indicated a mean reduction of body mass index was greater with duodenal switch compared to bypass (mean between-group difference was 8.5 [95% CI, 4.9-12.2;  $P < .001$ ]); however, duodenal switch was associated with more surgical, nutritional and gastrointestinal adverse effects.

## **NONRANDOMIZED STUDIES**

A number of non-randomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing biliopancreatic diversion with or without duodenal switch.<sup>[15-33]</sup> As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable.

## **SECTION SUMMARY**

Studies that compared RYGBP with BPD-DS are limited by methodological limitations, including inadequate power analysis, unequal distribution of preexisting comorbidities between groups, small sample size and short-term follow-up. In addition, a recent Cochrane review reported higher reoperation rates with BPD-DS compared to RYGBP. Given these limitations and high reoperation rates, the efficacy of BPD-DS versus RYGBP as a treatment for obesity cannot be determined.

## SLEEVE GASTRECTOMY

There are various types of gastrectomy, which include distal, partial (including sleeve gastrectomy) or complete gastrectomy which may be performed with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction. There is insufficient evidence regarding the use of gastrectomy, other than sleeve gastrectomy, as a treatment of obesity. Numerous studies were identified which evaluated outcomes of these alternative gastrectomy methods as a treatment of other conditions, including gastric cancer; however, no studies or clinical practice guidelines were identified which evaluated the efficacy of these alternative types of gastrectomy as a treatment of obesity. Therefore, the following evidence review will focus on the use of sleeve gastrectomy as a treatment of obesity, in the context of systematic reviews and well-designed randomized controlled trials:

### SYSTEMATIC REVIEWS

In 2017, Juodeikis evaluated five-year results following sleeve gastrectomy in a systematic review of the literature through May 2016.<sup>[34]</sup> The review was conducted according to PRISMA guidelines. Twenty studies were included for evaluation, however, only one study was a randomized controlled trial. Of the 2,713 patients included amongst all the studies combined, 1,626 reached at least five years follow-up (duration ranged from 5-11 years follow-up). Although mean percentage excess weight loss of greater than 56% was achieved at each time point from 5 to 11 years time, the review was substantially limited by the lack of RCT data.

In 2016, Osland compared the efficacy of Roux-En-Y gastric bypass versus vertical sleeve gastrectomy in randomized controlled trials.<sup>[35]</sup> Six RCTs performed between 2005 and 2015 were included (N = 695; 347 for SG and 348 for RYGB). The authors summarized recent publications, without pooled analysis. Although the results stated comparable efficacy and improvement or resolution in comorbidities, the authors also noted the significant limitation of short follow-up time (one year, with significant loss of follow-up), and lack of blinding in five of the six studies included. In 2017, Osland published an additional meta-analysis, again comparing vertical sleeve gastrectomy in RCT's to LRYGB (N=865 patients; 437 for SG and 428 for LRYGB).<sup>[36]</sup> The authors concluded once again that a significant gap exists in the literature with respect to well-designed studies using intent-to-treat analysis.

In 2015, Zhang published a separate review comparing LSG to laparoscopic RYGBP (LRYGBP) which included 21 studies involving 18,766 morbidly obese patients.<sup>[37]</sup> Data regarding percentage of excess weight loss (%EWL), resolution or improvement of comorbidities, and adverse events were pooled. Although no difference in %EWL was observed between the two groups in the first 6 months-1.5 year follow-up, LRYGBP achieved higher %EWL compared to LSG ( $p < 0.05$ ). Except for improvements in type 2 diabetes, comorbidities did not differ significantly between the two groups. Adverse events were more frequent following Roux-en-Y bypass (OR for major complication: 1.29; 95% CI 1.22 to 3.22;  $P < 0.01$ ). Results of this review must be interpreted with caution as 13 of the 21 included studies were nonrandomized, limiting the ability to control for confounding factors.

A 2014 review by Zellmer compared complication rates of laparoscopic RYGBP to LSG in 61 publications which included 10,906 laparoscopic RYGBP patients and 4,816 LSG patients.<sup>[38]</sup> Authors reported similar leak and mortality rates in both groups; laparoscopic RYGBP (leak: 1.9%, mortality: 0.4%) vs. LSG (leak: 2.3%, mortality: 0.2%).

The 2013 Cochrane review of bariatric surgery identified only one randomized controlled trial that compared sleeve gastrectomy to gastric bypass with Roux-en-Y anastomosis (RYGBP).<sup>[10,11,39]</sup> 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.

In 2013, Trastulli published a systematic review of randomized trials that compared sleeve gastrectomy to other bariatric procedures.<sup>[40]</sup> A total of 15 RCTs with 1191 patients were included. In six trials laparoscopic sleeve gastrectomy (LSG) was compared to laparoscopic RYGBP. The authors reported mean complication rates with sleeve gastrectomy of 12.1% (range 10%-13.2) compared with 20.9% with laparoscopic gastric bypass (range 10%-26.4%). Percentage of excess weight loss ranged from 49%-81% with sleeve gastrectomy compared with 62.1%-94.4% with laparoscopic gastric bypass. Included studies which compared LSG to laparoscopic RYGBP were small<sup>[41-43]</sup> (n<60) and several contained a risk for bias which included unclear blinding, randomization methods and outcome data.

A 2013 meta-analysis by Li pooled data from five trials, four of which were included in the Trastulli review, to compare the impact of these procedures on type 2 diabetes rates.<sup>[44]</sup> Laparoscopic Roux-en-Y gastric bypass was associated with higher rates of type 2 diabetes remission and greater estimated weight loss, but higher rates of complications.

## **RANDOMIZED CONTROLLED TRIALS**

Additional RCTs aside from those addressed in the reviews, above, with adequate design (e.g., large study populations with long follow-up duration) were not identified.

## **CLINICAL PRACTICE GUIDELINES**

In 2012, the American Society for Metabolic & Bariatric Surgery (ASMBS) updated their position statement on *Sleeve Gastrectomy as a Bariatric Procedure*.<sup>[45]</sup> The ASMBS 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. In addition, the group noted that substantial comparative and long-term data have now been

published which demonstrate durable weight loss, improved medical comorbidities, long-term patient satisfaction, and improved quality of life after SG. However, the ASMBS Statement does not include a critical appraisal of the reviewed evidence.

## SECTION SUMMARY

Recent systematic reviews of existing trials indicate sleeve gastrectomy (SG) is a comparable procedure to RYGBP. Although the evidence regarding SG with RYGBP compared to standard RYGBP is limited by short-term follow-up, SG has become a recognized surgical option in clinical practice for the treatment of morbid obesity.

## ADJUSTABLE GASTRIC BANDING

### SYSTEMATIC REVIEWS

A 2017 systematic review by Kang reported results from a network meta-analysis of RCTs evaluating the three most commonly performed bariatric procedures – Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and laparoscopic adjustable gastric band (LAGB).<sup>[46]</sup> The review was conducted with literature through July 2016, and in accordance with PRISMA guidelines. Evidence was synthesized from 11 trials (8 RYGB vs SG; 2 RYGB vs LAGB; 1 SG vs LAGB) in order to evaluate the primary outcome of changes in weight loss, expressed as the mean difference in BMI reduction and in percentage excess weight loss (%EWL) following 1 year after the surgery. The smallest treatment effect was observed in LAGB (8 trials, totalling 656 patients). The mean %EWL for RYGB, SG, and LAGB were 67.3% (n=294), 71.2% (n=209), and 40.6% (n=153), respectively. Heterogeneity between studies was low (as evaluated by calculating the  $I^2$  statistic), and the studies were consistent between direct and indirect comparisons – both demonstrated strengths of the analysis. The study was limited by fewer trials evaluating LAGB, and inclusions of RCTs with a lack of blinding.

The 2013 Cochrane review of bariatric surgery identified three randomized controlled trial that compared laparoscopic adjustable gastric banding (LAGB) to laparoscopic gastric bypass with Roux-en-Y anastomosis (RYGBP).<sup>[10,11,47]</sup> At five-year follow-up, the review reported the following conclusions:

- RYGBP was superior to LAGB on more than one measure of weight loss (% excess weight loss, mean BMI).
- Quality of life measures and comorbidities were not assessed due to the low quality of the evidence.
- RYGBP resulted in a greater duration of hospitalization and a greater number of late major complications.
- One study reported high rates of reoperation for removal of LAGB (9 patients, 40.9%).

In 2012, TEC conducted an updated Assessment, focusing on LAGB in patients with BMIs less than 35 kg/m<sup>2</sup>.<sup>[48]</sup> 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.

## **RANDOMIZED CONTROLLED TRIALS**

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

## **NONRANDOMIZED STUDIES**

A number of non-randomized studies (retrospective comparisons, case series) describe the experiences of patients undergoing LAGB.<sup>[32,49-56]</sup> As noted at the beginning of the evidence section, conclusions cannot be reached as the evidence from these studies is considered unreliable.

## **SECTION SUMMARY**

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.

## **LAPAROSCOPIC DUODENAL SWITCH WITH SINGLE ANASTOMOSIS**

Several nonrandomized studies were identified which describe the experiences of patients undergoing laparoscopic duodenal switch with single anastomosis (LSDSA).<sup>[57-61]</sup> As noted at the beginning of the evidence section, conclusions cannot be reached from these studies as the evidence is considered unreliable. Well-designed RCTs which compare LSDSA with RYGBP are needed in order to evaluate the safety and efficacy of this procedure compared to accepted surgical treatments of morbid obesity.

## **MINI-GASTRIC BYPASS**

## **SYSTEMATIC REVIEWS**

In 2014, Georgiadou published a systematic review regarding the safety and efficacy of laparoscopic mini gastric bypass.<sup>[62]</sup> The review included a search of the literature through July 2013, and was conducted according to PRISMA guidelines. Ten articles with a total of 4,899 patients were included for review, of which three were comparative studies (two versus LRYGB and one versus LAGB). Excess weight loss at two years ranged from 64.4% ± 8.8% to 80%. Minor postoperative complication rates ranged from 3.6%-7.5%, and major early postoperative complication rates ranged from 0-7%. Authors noted a major concern for postoperative esophagitis and gastritis caused by bile reflux, and the risk for gastric cancer.

Overall, the study was limited by the limitations of the included studies (e.g., short term follow-up and noncomparative design).

## **RANDOMIZED CONTROLLED TRIALS**

One small RCT compared the safety and effectiveness of laparoscopic RYGBP and mini-gastric bypass (MGBP).<sup>[63]</sup> 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 STUDIES**

In 2017, Plamper reported a comparison of mini gastric bypass and sleeve gastrectomy in super-obese patients (i.e., BMI > 50 kg/m<sup>2</sup>) at a single institution.<sup>[64]</sup> At one-year follow-up, 90.8% (99 of 109) and 78.7% (74 of 94) of the MGB and SG patients were available for follow-up, respectively. Reasons for loss of follow-up were not discussed. One patient in the SG group died within 30 days of the operation due to multi-organ failure after staple line leakage. Percent excess weight loss was statistically significantly greater in the MGB group at 12 months. The authors cited limitations of their review to include the retrospective design, and short-term results.

Several other nonrandomized studies (retrospective comparisons, case series), describe experiences of patients undergoing MGBP.<sup>[65-69]</sup> As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

## **SECTION SUMMARY**

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%).<sup>[10,70]</sup>

## **HIATAL HERNIA REPAIR**

Numerous studies<sup>[71-74]</sup> were identified which evaluated outcomes of hiatal hernia repair performed in conjunction with other bariatric surgical procedures; however, no studies or clinical practice guidelines were identified which evaluated the efficacy of hiatal hernia repair and an independent treatment of obesity.

## **TWO-STAGE BARIATRIC SURGERY PROCEDURES**

Bariatric surgeries that are performed in two 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 two-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.

## **RANDOMIZED CONTROLLED TRIALS**

Coffin (2017) published results on the use of intragastric balloon (IGB) prior to a laparoscopic gastric bypass in patients with super-obesity.<sup>[75]</sup> Patients with BMI greater than 45 kg/m<sup>2</sup> were randomized to an IGB (n=55) or standard medical care (n=60) during the 6 months prior to a planned laparoscopic gastric bypass procedure. Five patients had the IGB removed earlier than 6 months due to complications (n=3) or patient request (n=2). Patients receiving IGBs during the first 6 months of the study experienced significantly more BMI reduction (2.8 kg/m<sup>2</sup>; range 1.7-6.2 kg/m<sup>2</sup>) than patients receiving standard care (0.4 kg/m<sup>2</sup>; range 0.3-2.2 kg/m<sup>2</sup>). Weight loss during months 6 through 12, after the laparoscopic gastric bypass procedure, was greater in the patients who received standard of care before the procedure. Duration of hospitalization after laparoscopic gastric bypass and quality of life did not differ between groups.

## **NONRANDOMIZED STUDIES**

Case series on two-stage procedures for patients undergoing sleeve gastrectomy (SG) as the initial procedure generally 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<sup>[76]</sup> reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first portion of a planned two-stage procedure. A total of 36 patients (29%) proceeded to the second-stage procedure, which was laparoscopic gastric bypass. In a similar study, Alexandrou<sup>[77]</sup> 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 two-stage procedures are at risk for complications from both procedures. Silecchia<sup>[78]</sup> 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.

## **SECTION SUMMARY**

The current evidence does not indicate that a two-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 two-

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

### SYSTEMATIC REVIEWS

Several systematic reviews of RCTs evaluating intragastric balloon (IGB) devices for the treatment of obesity have been published; none was limited to FDA-approved devices.<sup>[79-81]</sup>

The systematic review by Tate (2017) focused on recent RCTs, published between 2006 and 2016.<sup>[82]</sup> Additional inclusion criteria were: sham, lifestyle modification, or pharmacologic agent as a comparator; at least 1 outcome of body weight change; and study duration of 3 or more months. Eight RCTs were included in the review, with four contributing to the meta-analysis. The meta-analysis included 777 patients and showed a significant improvement in percent TBWL with IGB compared with control (5.5%; 95% CI, 4.3% to 6.8%). However, there was significant heterogeneity among the trials ( $I^2=62\%$ ), so interpretation of results is limited. The percent TBWL with IGB is lower than expected with RYGB (reported 27%) or with the most efficacious pharmacologic agent (reported 9%).

Saber (2017) identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention.<sup>[79]</sup> IGB was compared with sham in 15 trials, behavioral modification in 4 trials, and pharmacotherapy in 1 trial. In 17 trials, patients received lifestyle therapy in addition to other interventions. Studies were published between 1987 and 2015 and sample sizes varied from 21 to 326 participants. Outcomes were reported between 3 and 6 months. In a meta-analysis of 7 RCTs reporting BMI loss as an outcome, there was a significantly greater BMI loss in the IGB group than in the control group (mean effect size [ES], 1.59 kg/m<sup>2</sup>; 95% CI, -0.84 to 4.03 kg/m<sup>2</sup>;  $p<0.001$ ). Findings on other outcomes were similar. A meta-analysis of 4 studies reporting percent EWL favored the IGB group (ES=14.25%; 95% CI, 2.09% to 26.4%;  $p=0.02$ ). Also, a meta-analysis of 6 studies reporting absolute weight loss favored the IGB group (ES=4.6 kg; 95% CI, 1.6 to 7.6 kg;  $p=0.003$ ).

Although the review was not limited to FDA-approved devices, older devices were air-filled and newer devices, including the two approved by FDA in 2015, are fluid-filled. Sufficient data were available to conduct a sensitivity analysis of 3-month efficacy data. A meta-analysis of 4 studies did not find a significant difference in weight loss with air-filled IGB devices or a control intervention at 3 months (ES= 0.26; 95% CI, -0.12 to 0.64;  $p=0.19$ ). In contrast, a meta-analysis of 8 studies of fluid-filled devices found significantly better outcomes with the IGB than with control (ES=0.25; 95% CI, 0.05 to 0.45;  $p=0.02$ ).

In 2017, Vargas performed a systematic review of two observational studies with no comparator group combined with results from a multi-center study of 130 consecutive patients.<sup>[83]</sup> Between the three studies, 330 endoscopic transoral outlet reduction (TORe) cases were performed with the Apollo OverStitch system. TORe was performed in patients experiencing weight regain following RYGB. Study quality was evaluated using the Newcastle-Ottawa Quality Assessment Scale for cohort studies; all were rated to be of moderate overall quality. Using a random effects model, the pooled absolute weight loss at 6, 12, and 18–24 months was 9.5 kg (95% CI 7.9–11.1), 8.4 kg (95% CI 6.5–10.3), 8.4 kg (95% CI 5.9–10.9), respectively. Given the fluctuation of absolute weight loss reported between timelines by each of the three studies, longer term follow-up would aid in evaluating the overall efficacy of TORe.

A systematic review of the effect of EndoBarrier® on weight loss and diabetic outcomes was published in 2015.<sup>[84]</sup> There were five small RCTs included with a total of 235 individuals (range, 18-77) and follow-up ranging from 12 to 24 weeks. The comparators were diet and/or other lifestyle modifications, and 2 studies had sham controls. All studies were judged to be at high risk of bias using the Cochrane risk of bias tool. Combined results demonstrated that the EndoBarrier® group had 12.6% greater EWL (95% CI, 9.0 to 16.2) compared to medical therapy. For diabetic outcomes, there were trends toward greater improvement in the EndoBarrier® group that did not reach statistical significance. The mean difference in HgA1c was -0.8% (95% CI, -1.8 to 0.3) and the relative risk of reducing or discontinuing diabetic medications was 3.28 (95% CI, 0.54 to 10.73).

## **RANDOMIZED CONTROLLED TRIALS**

In June 2016 the AspireAssist (Aspire Bariatrics, King of Prussia, PA) weight loss therapy system was approved by the FDA to assist in weight reduction in adults aged 22 and older with a BMI of 35.0-55.0 kg/m<sup>2</sup> who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. Feasibility data for the AspireAssist was reported by Sullivan and colleagues in 2013.<sup>[85]</sup> Preliminary results from the ongoing PATHWAY Pivotal Trial (sponsored by Aspire Bariatrics) are included in the FDA Summary of Safety and Effectiveness Data, though results have not been published in peer-reviewed literature at this point in time.<sup>[86]</sup>

In 2014, Eid reported results from a single-center RCT of the StomaphX device compared with a sham procedure for revision procedures in patients with prior weight loss after Roux-en-Y gastric bypass at least two years earlier.<sup>[87]</sup> Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group after preliminary analysis failed to achieve the primary efficacy endpoint in at least 50% of StomaphyX patients. The primary efficacy end point (reduction in pre-Roux-en-Y gastric bypass excess weight by 15% or more, excess BMI loss, and BMI less than 35, at 12 months post-procedure) was achieved by 10/45 (22.2%) of the StomaphyX group and 1/29 (3.4%) of the sham control group (P<0.01). Conclusions regarding the use of the StomaphX device as a primary procedure for the treatment of obesity may not be drawn due to the discontinuation of the trial and the limited use of the device as a revision procedure in patients who had failed a prior bariatric surgery.

In 2014, Koehestanie published results from an RCT of duodenal-jejunal bypass liner (DJBL) treatment in comparison with dietary intervention for obesity and type 2 diabetes mellitus (T2DM).<sup>[88]</sup> A total of 77 patients were included in the trial with 38 patients randomized to 6 months DJBL in combination with dietary intervention and 39 patients were randomized to dietary interventions only. The total study duration for both groups was 12 months, including 6 months of post-DJBL removal follow-up. At 6 months follow-up, prior to DJBL removal, the DJBL group lost a higher percentage of excess weight compared to the dietary only group, 32% (22%-46.7%) vs. 16.4% (4.1%-34.6%) respectively. However, better HbA1c levels improvement was observed in the dietary only group compared to the DJBL at both 6 and 12 month follow-ups. Conclusions are limited in this study as both groups underwent dietary interventions limiting the isolation of the effects of DJBL upon obesity and type 2 diabetes.

In 2013, Sullivan reported results from a small feasibility pilot RCT (n=18) comparing the AspireAssist siphon assembly (Aspire Bariatrics, King of Prussia, PA) combined with lifestyle therapy (AT) versus lifestyle therapy (LT) alone.<sup>[85]</sup> Only fourteen subjects completed the 12-month trial (10 in the AT group and four in the LT group). Although weight loss in the AT group

was greater at 52 weeks than the LT group (18.6% ± 2.3% of body weight vs 5.9% ± 5.0%) the study was limited by the very small sample size, and unblinded design. The study was partially funded by the manufacturer. The authors all disclosed having previously performed contracted research for the manufacturer of the device and one author also disclosed having consulted on a pivotal trial for the company.

In 2013, Fuller published a small RCT (n=66) which evaluated intragastric balloons (IGB) compared to behavioral modification as a treatment of obesity.<sup>[89]</sup> Subjects were either randomized to IGB and 12 months behavior modification (BH) and or 12 months BH alone. At six months the IGB treatment group demonstrated superior weight loss compared to the BH group (-14.2 vs. -4.8; P < 0.0001). However, at 12 months the difference in weight loss between groups, although still statistically significant, diminished (-9.2 vs. -5.2; P = 0.007). There were numerous adverse events related to IGB placement which typically resolved in two weeks. Limitations of this study include a relatively small population size and short-term follow-up with which to evaluate the lasting effects of weight reduction with IGB. In addition, RCTs which evaluate IGB to other standard surgical treatments of obesity are needed.

Additional, small RCTs assessing IGB were identified<sup>[90-92]</sup>; however, large, long-term data remain lacking with which to evaluate the safety and sustained benefit of IGB in weight reduction compared to conservative measures and accepted bariatric procedures.

## **NONRANDOMIZED STUDIES**

A small number of non-randomized studies, primarily case series, describe experiences of patients undergoing different endoluminal procedures, such as endoscopic gastroplasty and endoscopically placed sleeves, gastric balloons or tissue anchors.<sup>[83,93-110]</sup> As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

## **LAPAROSCOPIC GASTRIC PPLICATION**

Similar to the data for endoscopic bariatric procedures, the data for laparoscopic gastric plication (also known as laparoscopic gastric imbrication) is limited to case series and case reports and few, small RCT's.

## **RANDOMIZED CONTROLLED TRIALS**

Sullivan (2017) published results from the ESSENTIAL trial, a randomized sham-controlled trial evaluating the efficacy and safety of endoscopic gastric plication.<sup>[111]</sup> Patients (N=332) were randomized 2:1 to the active or sham procedure. All patients were provided low-intensity lifestyle therapy. The primary end point was total body weight loss (TBWL) at 12-month follow-up. The mean difference in TBWL for patients receiving the procedure compared with patients receiving the sham procedure was 3.6% (95% CI, 2.1% to 5.1%). Significant differences between the active and sham groups were also reported in a change in weight from baseline, percent excess weight loss, BMI, and improvement in diabetes. No significant differences were detected in improvements in hyperlipidemia or hypertension between the treatment groups.

Talebpour (2017) randomized patients to laparoscopic gastric plication (n=35) or laparoscopic SG (n=35).<sup>[112]</sup> Patients were followed for 2 years. Both procedures were equally effective based on weight reduction outcomes. Adverse events (eg, nausea, hair loss, vitamin D deficiency, iron deficiency) were similar between groups. One death due to pulmonary thromboembolism occurred in the gastric plication group.

## NONRANDOMIZED STUDIES

Additional studies describe patient outcomes after different laparoscopic plication procedures.<sup>[113-117]</sup> As noted at the beginning of the evidence section, conclusions cannot be reached as this evidence is considered unreliable.

## REVISION BARIATRIC SURGICAL PROCEDURES

There are a number of reasons why patients who are treated with accepted forms of bariatric surgery may not lose weight or may regain weight that is initially lost. These reasons include issues of adherence (compliance), as well as technical (structural) issues. A number of studies<sup>[118-120]</sup> have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of co-morbidities with somewhat higher complication rates than for primary surgery. However, criteria for classifying what constitutes a failed, primary bariatric procedure, has not been clearly established.<sup>[121]</sup>

In 2016, Dang reported results from a systematic review and meta-analysis comparing revisional single-step versus two-step bariatric surgery from laparoscopic adjustable gastric banding (LAGB) to Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG).<sup>[122]</sup> Single-step procedures involved revisional surgery wherein the LAGB was removed and replaced by RYGB or SG in the same operation; two-step procedures allowed a delay before the second bariatric procedure was performed. Although the authors found comparable rates of complications, morbidity and mortality between the one- and two-step procedures, the study was not designed to evaluate differences in patient outcomes between the second bariatric procedure (i.e., RYGB vs SG).

In 2014, Sudan reported safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database.<sup>[123]</sup> The Bariatric Outcomes Longitudinal Database is a large multi-institutional bariatric surgery-specific database to which data was submitted from June 2007 through March 2012 by 1,029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric surgery. Reoperations were further divided into corrective operations (when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy.) There were a total of 449,473 bariatric operations in the database of which 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3 %) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective operations and 8,750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N=204,705, 49.1 %), adjustable gastric banding (N=153,142, 36.5 %), sleeve gastrectomy (N=42,178, 10 %), and BPD±DS (N=4,260, 1 %), with the rest classified as miscellaneous. Adjustable gastric banding was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to Roux-en-Y gastric bypass). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 vs 1.8±4.9, P<0.001) and for conversions (2.86±4.58 vs 1.8±4.9, P<0.001). The mean % excess weight loss at one year was 43.5 % after primary operation, 39.3 % after conversions, and 35.9 % after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions compared with primary operations (0.31% vs 0.17%, P<0.001), but not for corrections compared with primary operations (0.24% vs 0.17%, P=NS). One-year serious adverse event rates were higher for

conversions compared with primary operations (3.61% vs 1.87%,  $P < 0.001$ ), but not for corrections compared with primary operations (1.9% vs 1.87%,  $P = \text{NS}$ ). The authors conclude that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

As part of the American Society for Metabolic and Bariatric Surgery Revision Task Force, Brethauer conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews.<sup>[124]</sup> The review was primarily descriptive, but the authors made the following conclusions:

“The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise.”

## **REVISION OR REMOVAL OF ADJUSTABLE GASTRIC BAND**

Evidence regarding the indications for band removal or revision procedure is primarily limited to small cohort<sup>[125]</sup> and case series studies; however, reoperation or removal rates are estimated to range from 4.1%- 53%, depending on the time of reported follow-up.<sup>[126-129]</sup> Several of the largest cohort studies have reported the following complications which resulted in reoperation or band removal:

Arapis reported the following complications in 87 patients who underwent reoperation:<sup>[130]</sup> chronic dilatation of the proximal gastric pouch (27 patients - 14.5%), acute dilatation (21 patients - 11.3%), intragastric migration of the prosthesis (6 patients - 3.2%), reflux esophagitis (6 patients - 3.2%), infection of the gastric band (1 patient - 0.5%), and Barrett's esophagus (1 patient - 0.5%).

Perathoner reported on 108 patients who underwent laparoscopic conversion of gastric banding to gastric bypass due to the following complications: band migration, inadequate weight loss, pouch dilation, band leakage, band intolerance, band infection and esophageal dilation.<sup>[131]</sup>

Other reported complications included: band erosion,<sup>[128,132,133]</sup> gastric obstruction,<sup>[11]</sup> and gastric slippage.<sup>[128,133]</sup>

Avriel reported major respiratory complications and chronic disease development in 30 patients who underwent LAGB.<sup>[134]</sup> Reported complications included aspiration pneumonia (19 patients) including pulmonary abscess (4 patients) and empyema (2 patients), exacerbation of asthma (3 patients), hemoptysis (1 patient), interstitial lung disease (5 patients) and bronchiectasis (3 patients). However, the impact of LAGB upon the development of these conditions is unclear given that 83% of the patients smoked or had a smoking history (mean pack years 34).

Studies which evaluated band conversion to a second bariatric surgery primarily indicated that bypass was the preferred revision surgery due to better long-term outcomes compared to sleeve gastrectomy.<sup>[135-138]</sup> In one large retrospective study published in 2014, bypass was



compared to sleeve gastrectomy after band removal and conversion.<sup>[139]</sup> National Surgical Quality Improvement Project data from 2005-2011 were analyzed and included 495 patients who converted from LAGB to bypass and 130 patients who converted to sleeve gastrectomy. Conversion to bypass was not associated with higher morbidity or mortality compared to primary RYGB; however, conversion to sleeve gastrectomy was independently associated with a higher rate of major complications and mortality compared to primary sleeve gastrectomy (OR 8.02, 95 % CI 1.08-59.34,  $p = 0.04$ ).

## SECTION SUMMARY

For surgical revision of bariatric surgery after failed treatment, evidence from nonrandomized studies suggests that revisions are associated with improvements in weight similar to those seen in primary surgery. However, evidence from large long-term studies is required to determine the appropriate clinical indications for band removal or reoperation.

## BARIATRIC SURGERY IN PATIENTS WITH DIABETES WITH BMI < 35KG/M<sup>2</sup>

### SYSTEMATIC REVIEWS

In 2015 Muller-Stich published a systematic review comparing surgical versus medical treatment of type II diabetes in patients with a BMI less than 35 kg/m<sup>2</sup>.<sup>[140]</sup> The analysis included data from five RCTs and six observational studies for a total of 702 patients. The follow-up of included studies ranged from 12-36 months. Authors concluded that surgery was associated with higher diabetes remission rate (OR: 14.1, 95% CI: 6.7–29.9,  $P < 0.001$ ), higher rate of glycemic control (OR: 8.0, 95% CI: 4.2–15.2,  $P < 0.001$ ) and lower HbA1c level (MD: -1.4%, 95% CI -1.9% to -0.9%,  $P < 0.001$ ) compared to medical treatment. However, results are limited by inclusion of studies in which the BMI of some patients was greater than 35 kg/m<sup>2</sup> and short-term follow-up, limiting conclusion regarding the long-term benefits of bariatric surgery upon glycemic control.

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/m<sup>2</sup>.<sup>[141]</sup> 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/m<sup>2</sup>. 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/m<sup>2</sup>. 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 report 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 pointed 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.”

## **RANDOMIZED CONTROLLED TRIALS**

Since the publication of the AHRQ report, two RCTs have been reported on bariatric surgery compared to medical therapy in diabetic patients with a BMI between 30-40 kg/m<sup>2</sup>.

Ikramuddin 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%.<sup>[142]</sup> Patients were followed for 12 months with the primary endpoint being a composite of HgA1C 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/m<sup>2</sup>, thus restricting conclusions regarding the benefits of bariatric surgery compared to medical management in diabetic patients with a BMI < 35 kg/m<sup>2</sup>.

In 2014, Prikh published a small (n=57), short-term (6-month follow-up) RCT which compared intensive medical weight management to bariatric surgery in patients with a BMI of 30-35 kg/m<sup>2</sup> and type 2 diabetes.<sup>[143]</sup> Significant improvements in primary outcome measures of homeostatic model of insulin resistance and higher diabetes remission rates were observed in the surgical group compared to the MWM group. Additional small RCTs have been identified;<sup>[144]</sup> however, larger, long-term RCTs are needed to confirm these findings.

In 2015, Mingrone published results of a small (n=60) RCT comparing long-term outcomes of either medical treatment or surgery by Roux-en-Y gastric bypass or biliopancreatic diversion in patients with type II diabetes.<sup>[145]</sup> A total of 53 patients were included in the 5-year follow-up assessment. Primary outcome measures included the rate of diabetes remission at 2 years which was defined as glycated HbA1c concentration of 6.5% or less ( $\leq 47.5$  mmol/mol) and a fasting glucose concentration of 5.6 mmol/L or less without active pharmacological treatment for 1 year. At 5-year follow-up 19 (50%) of the 38 surgical patients (7 of 19 [37%] in the gastric bypass group and 12 of 19 in the [63%] bilipancreatic diversion group) maintained diabetes remission at 5 years, compared with none of the 15 medically treated patients (p=0.0007). Fifteen incidents of hyperglycemic relapse occurred in 34 surgical of the patients who achieved 2-year remission, suggesting continued monitoring of glycemic control may be necessary. Authors also reported that both surgical procedures were associated with significantly lower plasma lipids, cardiovascular risk, and medication use and no late complications or deaths.

## **CLINICAL PRACTICE GUIDELINES**

### **American College of Cardiology, American Heart Association, and the Obesity Society**

In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published guidelines on the management of obesity and overweight in adults.<sup>[146]</sup> The guidelines were based upon a high-quality systematic review of the evidence which included transparent methods for grading the strength of the evidence and subsequent

recommendations. The guidelines make the following recommendations related to bariatric surgery:

“For adults with a BMI >40kg/m<sup>2</sup> or BMI >35 kg/m<sup>2</sup> with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment (with or without pharmacotherapy) with sufficient weight loss to achieve targeted health outcome goals, advise that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation.” (Grade A: Indicating a strong recommendation, indicating there is a high certainty based on the evidence that the net benefit is substantial).

“For individuals with a BMI <35 kg/m<sup>2</sup>, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures.” (No recommendation given, indicating there is insufficient evidence or evidence is unclear or conflicting)

### **American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery**

In 2013, joint guidelines were published by the American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (AACE/ASM/Obesity Society) regarding the perioperative nutritional, metabolic and nonsurgical support of the bariatric surgery patient.<sup>[147]</sup> Recommendations regarding which patients should be offered bariatric surgery indicated the following:

“Patients with BMI of 30–34.9kg/m<sup>2</sup> 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**

In 2014, the Institute for Clinical Systems Improvement (ICSI) published revised guidelines regarding the diagnosis and management of type 2 diabetes mellitus in adults and indicated:<sup>[148]</sup>

A clinician may recommend a patient diagnosed with T2DM and a BMI >35 kg/m<sup>2</sup> consider bariatric surgery if diabetes or comorbidities are difficult to control with lifestyle and pharmacologic therapy. [Quality of Evidence: Moderate, Strength of Recommendation: Weak]

### **SECTION SUMMARY**

Evidence regarding the efficacy of bariatric surgery as a treatment for diabetes in patients with a BMI < 35 kg/m<sup>2</sup> primarily consists of small cases series with short-term follow-up as noted in the 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/m<sup>2</sup>) and non-obese (BMI 30-34.9 kg/m<sup>2</sup>) 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/m<sup>2</sup>.

## ADOLESCENT AND PEDIATRIC BARIATRIC SURGERY

### SYSTEMATIC REVIEWS

The 2007 Washington State Health Technology Assessment evaluated the published, peer reviewed scientific literature describing bariatric surgery in the pediatric population.<sup>[149]</sup> 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.

In 2013, Black published a systematic review and meta-analysis of 23 studies (22 nonrandomized) that included 637 young patients (age 6-18 years) who underwent bariatric surgery.<sup>[150]</sup> Although significant weight loss was reported at the 1-year follow-up, limitations of the evidence were similar to those reported in the Washington State Health Technology Assessment. Included studies were limited by small sample size with a median number of 24 patients per study (range: 10-108) and short term follow-up (range: 6-12 months). Authors reported that complications were inconsistently reported and indicated that, “long-term, prospectively designed studies, with clear reporting of complications and comorbidity resolution, alongside measures of [health-related quality of life], are needed to firmly establish the harms and benefits of bariatric surgery in children and adolescents.”

In 2015, the Washington State Health Technology Assessment compared various bariatric procedures and also re-examined the role of bariatric surgery in children and adolescents upon obesity related comorbidities.<sup>[151]</sup> The group concluded that there was, “a lack of both short- and long-term data demonstrating effectiveness for any bariatric surgery procedure in both children and adolescents.” Only two studies were identified which were deemed to be of sufficient quality and only one of those was a RCT. In addition, no comparative studies were identified which evaluated any bariatric procedure exclusively in children (under 13 years).

Additional reviews were identified; however, conclusions were limited due to a lack of long-term follow-up.<sup>[152-156]</sup>

## **RANDOMIZED CONTROLLED TRIALS**

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.<sup>[157]</sup> 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 STUDIES**

### **Studies with short follow-up time**

A small number of nonrandomized comparative studies reported significant weight loss and resolution of some of the comorbidities in pediatric patients undergoing bariatric surgery.<sup>[158-160]</sup> However, the studies were small and had a very short follow up time.

In 2014, Inge reported results from Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study, a prospective, multicenter observational study of bariatric surgery in patients aged 19 or under.<sup>[161]</sup> The study enrolled 242 participants, with mean age 17.1 and median

BMI 50.5 (IQR 45.2-58.2) at the time of operation. All patients had at least 1 obesity-related comorbidity, most commonly dyslipidemia (74%), followed by sleep apnea (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%). Roux-en-Y gastric bypass, adjustable gastric banding, and vertical sleeve gastrectomy were performed in 66.5%, 5.8%, and 27.7%, respectively. Within 30 days of surgery, 20 major complications occurred in 19 patients (7.9%), most of which were perioperative complications. The cohort will be followed to assess longer-term outcomes.

### **Studies with mid-term follow-up time**

Two observational studies with mid-term follow-up times ( $\leq 10$  and  $\leq 8$  years) reported experiences of pediatric patients undergoing LAGB (sample size 41 and 107 respectively).<sup>[162,163]</sup> 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**

The 2005 American College of Physicians (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.<sup>[164]</sup> 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.

### **American Academy of Pediatrics**

In 2007, the American Academy of Pediatrics (AAP) published, “Recommendations for Treatment of Child and Adolescent Overweight and Obesity,” which stated that although there is increased use of bariatric surgery in adults:<sup>[165]</sup>

“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**

In 2013, the American Heart Association (AHA) published a statement regarding severe obesity in children and adolescents which concluded:<sup>[166]</sup>

“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  $\beta$ -cell function.”

### **Society of American Gastrointestinal and Endoscopic Surgeons**

The 2008 the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) evidence-based guidelines state:<sup>[167]</sup>

“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 2017, the Endocrine Society published an updated clinical practice regarding the assessment, treatment, and prevention of pediatric obesity.<sup>[168]</sup> The guideline was developed according to the GRADE system. The following statements were given a rating of “we suggest”, i.e., weak recommendations, and were based on “very low quality” to “low quality” evidence. Given the evidence quality, and the suggestion as opposed to a *recommendation*, the following statements are ultimately, expert opinion.

For pre-adolescent children, pregnant or breast-feeding adolescents (and those planning on becoming pregnant within two years of surgery), and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has unresolved substance abuse, eating disorder or untreated psychiatric disorder, the Society suggests against bariatric surgery.

The Endocrine Society suggests that bariatric surgery be considered for adolescents only under the following conditions:

- The patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height, the patient has a BMI of  $>40$  kg/m<sup>2</sup> or has a BMI of  $>35$  kg/m<sup>2</sup> and significant, extreme comorbidities
- extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy
- psychological evaluation confirms the stability and competence of the family unit [psychological distress due to impaired quality of live (QOL) from obesity may be present, but the patient does not have an underlying untreated psychiatric illness]
- the patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits

- there is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.

### **Institute for Clinical Systems Improvement**

In 2013, ICSI published updated guidelines regarding the prevention and management of obesity for children and adolescents.<sup>[169]</sup> 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**

In 2011, National Heart, Lung and Blood Institute (NHLBI) published guidelines regarding cardiovascular health and risk reduction in overweight and obese children and adolescents which indicated bariatric surgery may be considered:<sup>[170]</sup>

“For adolescents with BMI far above 35 kg/m<sup>2</sup> 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).”

### **SECTION SUMMARY**

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**

This section focuses on evidence related to gastroesophageal reflux disease (GERD) as it relates to bariatric procedures as a treatment for obesity. See Cross References section, above, for policies focused on treatment of GERD.

### **SYSTEMATIC REVIEWS**

In 2016, Osland compared the efficacy of Roux-En-Y gastric bypass versus vertical sleeve gastrectomy in randomized controlled trials.<sup>[35]</sup> Six RCTs performed between 2005 and 2015 were included (N = 695; 347 for SG and 348 for RYGB). The authors summarized recent publications, citing worsened GERD symptoms following sleeve gastrectomy in patients with preoperative symptoms, and new symptoms in 9% of patients with no previous symptoms. Preexisting GERD in those who undergo sleeve gastrectomy is noted as being the cause of frequent revisional surgeries, and high rates of surgical complications. In addition those with



preexisting GERD were found to have failure to achieve weight loss, and failure to resolve weight related comorbidities such as diabetes, obstructive sleep apnea, and hypertension.

In 2016, Oor reported results from a systematic review and meta-analysis of studies reporting prevalence of GERD symptoms, the use of anti-reflux medication, and/or outcome of esophageal function tests before and after laparoscopic sleeve gastrectomy (LSG) in patients with a BMI of more than 35.<sup>[171]</sup> Pooled data from seven studies using validated symptom questionnaires for new-onset of GERD symptoms resulted in a 20% incidence following LSG (follow-up time ranging from one- to 60-months). There was heterogeneity amongst these studies ( $I^2=68\%$ ). For difference in prevalence of GERD before and after LSG, the pooled risk difference was found to be 4.3%; with heterogeneity present ( $I^2=89\%$ ). Of the 24 studies reviewed, the authors found new-onset GERD symptom incidence to range from zero to 34.9%. The authors therefore concluded that LSG could induce serious GERD symptoms in patients with no preoperative GERD complaints. The heterogeneity found in analyses may be due to a lack of a standardized approach to LSG, as well as the variability in follow-up length. The authors also noted that range in prevalence of GERD symptoms may be in part due to the variability in reported preoperative BMI, as the LSG will be a more technically challenging procedure in those with a BMI of 60 kg/m<sup>2</sup> versus those with a BMI of 40 kg/m<sup>2</sup>.

Li and colleagues (2016) conducted a systematic review and meta-analysis comparing Roux-en-Y gastric bypass (LRYGB) with LSG for treating morbid obesity.<sup>[172]</sup> Randomized controlled trials and nonrandomized studies were included. Amongst five studies that reported GERD resolution post-operation (147 in the LRYGB group and 93 in the LSG group), symptoms resolved significantly more after LRYGB as compared to LSG (OR = 8.99, 95% CI 4.77-16.95). Heterogeneity was not detected between these groups ( $I^2 = 48\%$   $P=0.12$ ).

## **NONRANDOMIZED STUDIES**

Several nonrandomized studies have retrospectively reviewed weight reduction and GERD symptoms following Roux-en-Y gastric bypass surgery for treatment of morbid obesity.<sup>[173-178]</sup> Authors have reported reduction in self-reported GERD symptoms, prescribed medications, and weight loss. As demonstrated in small case series, in combination with takedown of fundoplication, Roux-en-Y gastric bypass for morbid obesity has been effective in weight reduction as well as self-reported GERD symptom improvement.<sup>[176,177]</sup> Evidence regarding high incidence of GERD following laparoscopic adjustable gastric banding and laparoscopic sleeve gastrectomy makes Roux-en-Y gastric bypass the ideal procedure in the presence of already existing reflux symptoms.<sup>[34,179-183]</sup>

## **CLINICAL PRACTICE GUIDELINES**

### **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)**

The SAGES clinical practice guidelines for the surgical treatment of GERD (2010) state the following:<sup>[184]</sup>

Due to concerns for higher failure rates after fundoplication in the morbidly obese patient (BMI >35 kg/m<sup>2</sup>) and the inability of fundoplication to address the underlying problem (obesity) and its associated comorbidities, gastric bypass should be the procedure of choice when treating GERD in this patient group (Grade B). The benefits in patients with BMI > 30 is less clear and needs further study.

## **SECTION SUMMARY**

Systematic review of GERD symptoms following laparoscopic sleeve gastrectomy (LSG) as a treatment for morbid obesity is limited by heterogeneity in the technical approach to the procedure, therefore presenting statistical challenges to analyzing pooled results. In comparing LSG with Roux-en-Y gastric bypass (RYGB) directly, GERD symptoms resolve significantly more post-RYGB as compared to LSG. In the presence of GERD, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) clinical practice guidelines state that gastric bypass is the procedure of choice in patients who are morbidly obese. In those who are not morbidly obese, evidence does not indicate that bariatric surgery is an appropriate treatment for GERD, and SAGES states this is an area in need of further study.

## 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.

<b>RYGBP</b> <sup>[2,185,186]</sup>	<b>LL-RYGBP</b> <sup>[2]</sup>	<b>BPD/BPD-DS</b> <sup>[2,10,185]</sup>	<b>SG</b> <sup>[10,185,187-190]</sup>	<b>LAGB</b> <sup>[50,185]</sup>	<b>MGB</b> <sup>[63]</sup>	<b>Endoluminal Procedures</b>
<ul style="list-style-type: none"> <li>• Cholecystitis</li> <li>• Depression</li> <li>• Dilated stomach pouch</li> <li>• Dumping syndrome<sup>†</sup></li> <li>• Gastritis</li> <li>• Leaks or obstructions at the anastomotic site</li> <li>• Marginal ulcer</li> <li>• Reoperations<sup>†††</sup></li> <li>• Staple line failure</li> <li>• Vitamin/mineral deficiencies (iron, folate, B<sub>12</sub>)</li> <li>• Kidney stones</li> </ul>	<ul style="list-style-type: none"> <li>• All RYGBP risks</li> <li>• Additional unknown risks associated with the greater bypass of the small intestine and consequent increase in malabsorption<sup>††</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Dilated stomach pouch</li> <li>• Gastric obstruction</li> <li>• GERD</li> <li>• Leaks or stenoses at anastomotic sites</li> <li>• Malnutrition and/or vitamin deficiencies</li> <li>• Nausea/vomiting</li> <li>• Wound dehiscence</li> </ul>	<ul style="list-style-type: none"> <li>• Abscesses</li> <li>• Frequent vomiting</li> <li>• Gastric fistulas</li> <li>• GERD</li> <li>• Leaking from the stomach pouch</li> <li>• Reoperations<sup>†</sup> ††</li> </ul>	<ul style="list-style-type: none"> <li>• Band slippage</li> <li>• Dilated stomach pouch</li> <li>• Erosion of the device through gastric wall</li> <li>• GERD</li> <li>• Malnutrition and vitamin deficiencies</li> <li>• Nausea and vomiting</li> </ul>	<ul style="list-style-type: none"> <li>• Bile reflux</li> <li>• Gastrojejunostomy leak</li> <li>• Marginal ulcer</li> <li>• Reoperations<sup>†††</sup></li> <li>• Vitamin/mineral deficiency</li> </ul>	<p>The safety concerns are specific to the endoluminal procedure performed:</p> <p><u>Transoral circular stapler (SurgASSIST®)</u>:<sup>[191]</sup></p> <ul style="list-style-type: none"> <li>• Bowel obstruction</li> <li>• Intra-abdominal adhesions</li> </ul> <p><u>Dduodenal-jejunal bypass sleeve (DJBS)</u>:<sup>[96]</sup></p> <ul style="list-style-type: none"> <li>• Abdominal pain</li> <li>• Implant site inflammation</li> <li>• Nausea and vomiting</li> </ul> <p><u>TOGa system endoscopic stapling</u>:<sup>[97]</sup></p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Pain</li> <li>• Transient dysphagia</li> </ul>

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

<sup>††</sup>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;

<sup>†††</sup>Due to insufficient weight loss or technical issues;

## SUMMARY

### **ROUX-EN-Y GASTRIC BYPASS, ADJUSTABLE GASTRIC BANDING, AND SLEEVE GASTRECTOMY**

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 minimal complications. Sleeve gastrectomy as a stand-alone procedure gained acceptance in clinical practice. Sleeve gastrectomy offers an alternative to adjustable gastric banding with potentially greater weight loss and fewer complications. Therefore, Roux-en-Y gastric bypass, adjustable gastric banding, and sleeve gastrectomy may be considered medically necessary in the treatment of morbid obesity when policy criteria are met.

There is not enough research to show that any of the following procedures improves health outcomes. Therefore, 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.

There is not enough research to show that any of the following procedures improves health outcomes. Therefore, the use of distal, partial (not including sleeve gastrectomy) or complete gastrectomy with or without gastroduodenostomy, gastrojejunostomy, or Roux-en-Y reconstruction, are considered investigational as a treatment of obesity.

### **MINI-GASTRIC BYPASS, DISTAL GASTRIC BYPASS, BILIOPANCREATIC BYPASS, BILIOPANCREATIC BYPASS WITH DUODENAL SWITCH, AND LAPAROSCOPIC DUODENAL SWITCH WITH SINGLE ANASTOMOSIS**

There is not enough research for these procedures on health outcomes. Therefore, mini-gastric bypass, distal gastric bypass, biliopancreatic bypass, biliopancreatic bypass with duodenal switch, and laparoscopic duodenal switch with single anastomosis are considered investigational for the treatment of morbid obesity, gastroesophageal reflux disease or any other condition.

### **HIATAL HERNIA REPAIR**

There is not enough research regarding the use of hiatal hernia repair as an independent treatment of obesity. In addition, no evidence-based clinical practice guidelines were identified which addressed the use of hiatal hernia repair as a treatment of obesity. Therefore, hiatal hernia repair is considered investigational as an independent treatment of obesity.

### **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**

There is not enough evidence to establish the safety and efficacy of any endoscopic bariatric

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procedure. Therefore, endoscopic bariatric procedures are considered investigational for all indications.

### **LAPAROSCOPIC GASTRIC PPLICATION**

There is not enough evidence to establish the safety and efficacy of any laparoscopic gastric plication bariatric procedure. Therefore, laparoscopic gastric plication procedures are considered investigational for all indications.

### **REVISION BARIATRIC SURGICAL PROCEDURES**

Research regarding reoperation of a primary bariatric surgery is limited to noncomparative studies without long-term outcome data. In addition, current research shows that the complication and mortality rate is slightly higher in cases of reoperation. However, reoperation appears to be beneficial for patients with serious complications related to the primary bariatric surgery and may be considered medically necessary when criteria are met.

Research regarding the revision or removal of an adjustable gastric band is limited to noncomparative studies with short-term follow-up. These studies suggest band removal or revision is associated with improvement in band related complications. In addition, studies indicate gastric bypass is the preferred secondary procedure in cases of adjustable band conversion as bypass is associated with fewer complications and lower mortality rates compared to sleeve gastrectomy. Therefore, adjustable gastric band removal and/or conversion to gastric bypass may be considered medically necessary when criteria are met.

The research is insufficient to determine the safety or efficacy of all other bariatric surgery reoperations or revisions; therefore, reoperations or revisions are considered not medically necessary when criteria are not met.

### **TWO-STAGED BARIATRIC PROCEDURES**

There is not enough research to establish the safety and efficacy of any two-stage bariatric procedure. Therefore, two-stage bariatric procedures are considered investigational for all indications.

### **ADOLESCENT AND PEDIATRIC BARIATRIC SURGERY**

Research for the safety and effectiveness of bariatric surgery as a treatment for obesity in patients younger than 18 years of age is of limited quality. Studies mostly report short-term outcomes, and though there are few studies with longer follow-up, researchers and clinical practice guidelines state there is still a need for additional high-quality studies. Such trials would 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/M<sup>2</sup>**

Research for the safety and effectiveness of bariatric procedures as a treatment for diabetes in patients with a BMI < 35 kg/m<sup>2</sup> is limited by small study sizes and short-term follow-up. High-quality studies that include long-term follow-up are needed in order to evaluate the impact of bariatric surgery on health outcomes in this population. In addition, the majority of

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evidence-based clinical practice guidelines do not recommend bariatric surgery in diabetic patients with a BMI < 35 kg/m<sup>2</sup>. Therefore, bariatric procedures in diabetic patients with a BMI < 35 kg/m<sup>2</sup> are considered not medically necessary.

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## CODES

**NOTE:** Code 43843 should not be reported if there is a more specific bariatric surgery code within code range listed below.

Codes	Number	Description
CPT	43631	Gastrectomy, partial, distal; with gastroduodenostomy
	43632	;with gastrojejunostomy
	43633	;with roux-en-Y reconstruction
	43634	;with formation of intestinal pouch
	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
	43659	Unlisted laparoscopy procedure, stomach
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (gastric band and subcutaneous port components)

<b>Codes</b>	<b>Number</b>	<b>Description</b>
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical banded gastroplasty
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
	43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
	43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
	43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
	43865	;with vagotomy
	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

**Date of Origin:** January 1996