Bariatric Surgery

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

Type	Title	Document ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories

Internet-Only Manuals (IOMs)	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 16 General Exclusions from Coverage; Section 120 Cosmetic Surgery	§120 Cosmetic Surgery		
NCD	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity	100.1		
LCA	Billing and Coding: Bariatric Surgery for Treatment of Co-Morbidities Conditions Related to Morbid Obesity	A54923	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE IN, MI
LCA	Laparoscopic Sleeve Gastrectomy (LSG) – Medical Policy Article	A52447	J6 - National Government Services, Inc. (Part A/B MAC) JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCA	Billing and Coding: Bariatric Surgery Coverage	A53026	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Bariatric Surgery Coverage	A53028	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Bariatric Surgical Management of Morbid Obesity	L35022 A56422	JH - Novitas Solutions, Inc. (Part A/B MAC) JH, JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, DC, MD, NJ, PA
LCD LCA	Laparoscopic Sleeve Gastrectomy for Severe Obesity	L34576 A56852	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN

LCA	Billing and Coding: Periodic Adjustment of Gastric Restrictive Device after the Global Period	A53444	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD LCA	Surgical Management of Morbid Obesity	L33411 A57145	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, US VI

Description

Obesity may be treated with bariatric surgery (weight loss surgery) performed on the gastrointestinal (GI) tract to alter the digestive process and induce weight loss. Bariatric surgical techniques are classified as restrictive, malabsorptive or a combination of both. Restrictive procedures reduce the stomach size, thus decreasing the amount of food the stomach can hold. Malabsorptive procedures limit the amount of nutrients and calories that the body can absorb. Most procedures are performed using a laparoscopic or open approach; however, endoscopic approaches are also being investigated.

The two most commonly performed bariatric procedures include:

- **Laparoscopic sleeve gastrectomy (LSG)** involves the removal of the greater curvature of the stomach and approximately 80 percent of the stomach volume. While pyloric sphincter and stomach functions are preserved, the remaining stomach resembles a slender curved tube. Sleeve gastrectomy was originally the first step of a more extensive two step bariatric surgery (eg, biliopancreatic diversion with duodenal switch), but may also be performed as a single stage primary procedure for a potential bariatric surgery candidate.

- **Roux-en-Y gastric bypass (RYGB) (open or laparoscopic)** is a malabsorptive surgery and is generally known as gastric bypass. In this procedure, a small stomach pouch is created to restrict food intake. The rest of the stomach is bypassed via a Y-shaped segment of the small intestine, which reduces the number of calories and nutrients the body absorbs. Long-limb RYGB is similar to standard RYGB, except that the limb through which food passes is longer and is typically performed to treat a super obese individual (defined as a body mass index [BMI] greater than or equal to 50 kg/m^2).[82]

Other bariatric procedures and techniques include, but may not be limited to:

- **Aspiration therapy device insertion** involves the endoscopic surgical placement of a drainage tube in the stomach that connects to an externally accessible port that sits flush against abdominal skin. Approximately 20 to 30 minutes after eating each daily meal, the individual attaches external components which open the port valve. The stomach contents are drained, irrigated with water and drained again. The only US Food & Drug Administration (FDA)-approved device (AspireAssist) was voluntarily withdrawn from the market in 2022.

- **Biliopancreatic diversion (BPD)** consists of a partial gastrectomy (resection of the stomach) and gastroileostomy (surgical connection of the stomach to the ileum, the last section of small intestine). It allows for relatively normal meal size, since the most proximal areas of the small intestine are bypassed, and substantial malabsorption occurs. BPD is less frequently used than other types of procedures because of the elevated risk for nutritional deficiencies.

- **Biliopancreatic diversion (BPD) with duodenal switch (DS)**, while like the above procedure, this technique leaves a larger portion of the stomach intact, including the pyloric valve that regulates the release of stomach contents into the small intestine. The procedure also keeps a small portion of the duodenum in the digestive pathway.

- **Laparoscopic adjustable gastric banding (LAGB)** (eg, Lap-Band) involves the placement of a hollow band around the upper end of the stomach, creating a small pouch and a narrow passage into the larger remainder of the stomach. The band is inflated with a saline solution, which can be increased or decreased over time to alter the size of the passage.

- **Laparoscopic gastric plication** is the creation of a smaller stomach pouch by folding and sewing the stomach. It may also be performed in conjunction with gastric banding, which purportedly increases early weight loss and decreases the need for band adjustments.

- **Mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB)** divides the stomach similar to a traditional gastric bypass, but instead of creating a Roux-en-Y connection, the jejunum is attached directly to the stomach.

- **Natural orifice transluminal endoscopic surgery (NOTES)** procedures are incisionless and performed with an endoscope passed through the mouth. NOTES techniques for bariatric purposes include, but may not be limited to, the following:

    - **Endoscopic gastrointestinal bypass device (EGIBD)**, also known as a **duodenal jejunal bypass** or **gastrointestinal liner**, is a removable barrier that extends from the upper segment of the GI tract (gastroesophageal junction or duodenum) to the jejunum. By lining the upper portion of the small intestine, it causes nutrient absorption to occur further along the GI tract, which purportedly affects hormone levels. The EndoBarrier is an example of an EGIBD, which is not yet FDA approved but is undergoing studies for the management of conditions such as diabetes and obesity.

    - **Endoscopic sleeve gastroplasty (ESG)** is an incisionless procedure in which the stomach is restricted with staples or sutures by using endoscopic surgical tools (eg, Apollo ESG, Apollo ESG SX) guided through the mouth and esophagus.

    - **Intragastric balloon (IGB) insertion** involves temporary endoscopic placement or deglutition (swallowing) of a silicone balloon or dual balloon system filled with air or saline solution into the

stomach. The presence of the balloon conveys a sense of fullness and restricts the stomach volume, thereby purportedly decreasing food intake. Intragastric balloons differ in their insertion method, volume, duration in the stomach, adjustability and means of removal. These balloons remain in place for 4 to 6 months and then removed endoscopically or excreted naturally, depending on the type. Examples of intragastric balloons include, but may not be limited to:

  - Allurion Gastric Balloon
  - Obalon Balloon System
  - Orbera Intragastric Balloon System
  - Spatz3 Adjustable Gastric Balloon

- **Restorative obesity surgery endoluminal (ROSE) procedure** is suggested for the treatment of weight regain following gastric bypass surgery. The pouch and stoma are reduced in size using an endoscopic closure device.

- **Transoral outlet reduction (TORe)** is an endoscopic method of correcting a dilated gastro-jejunostomy outlet after Roux-en-Y in an individual experiencing weight regain due to a relaxed gastric outlet. An endoscopic suturing device (eg, Apollo Revise, Apollo Revise SX) is used to reduce the diameter of the gastric outlet.

- **TransPyloric Shuttle (TPS)** is another kind of space occupying device intended to treat obesity by slowing gastric emptying. It consists of a large spherical bulb connected to a smaller cylindrical bulb by a flexible tether that is placed endoscopically into the stomach. The TPS self-positions across the pylorus to create an intermittent obstruction to gastric outflow that purportedly delays gastric emptying. The device is temporary and intended for endoscopic removal after 12 months.

- **Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S),** also referred to as a **single anastomosis duodenal switch (SADS)** or **stomach intestinal pylorus sparing surgery (SIPS)**, is an operation based on the biliopancreatic diversion with duodenal switch (BPD-DS), however the pylorus is able to be preserved. The reconstruction occurs in one loop, which purportedly reduces operating time and requires no mesenteric opening.

- **Vagus/vagal nerve block, vagal blocking for obesity control (VBLOC),** also referred to as gastric pacing or vagal nerve stimulation, involves laparoscopic placement of two leads (electrodes) in contact with vagal nerve trunks and a subcutaneously implanted neuromodulation device which is externally programmed to intermittently send electrical impulses via the implanted electrodes. The electrical impulses are purported to block vagus nerve signals in the abdominal region, inhibiting gastric motility and increasing satiety (feeling full). The only FDA-approved device (Maestro Rechargeable System) was voluntarily withdrawn from the market.[109]

- **Vertical banded gastroplasty (VBG) (open or laparoscopic)** involves removal of stomach tissue with the subsequent use of a band and staples to create a small stomach pouch. VBG has been largely replaced by other procedures deemed to be more successful regarding sustained weight loss and is

therefore rarely performed.

Bariatric Surgery Revision/Conversion
Revision of a bariatric surgery procedure and/or conversion from one type of bariatric surgery procedure to another type may be necessary due to insufficient weight loss despite postoperative compliance to dietary or behavior modifications, specific complications from the primary procedure, nutritional problems or other reasons. The revision performed and subsequent coverage depends on several factors, including the initial bariatric surgery performed and the type of complication that has occurred.

Coverage Determination

iCare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

While NCD 100.1 – Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity addresses some **bariatric surgical procedures** as nationally covered, it does not provide criteria specific to when each procedure is considered medically reasonable and necessary. Although some jurisdictions have LCD guidance regarding **laparoscopic sleeve gastrectomy**, most do not. If a determination cannot be made based on the CMS guidance above (NCD 100.1, L35022, L34576, L33411) because such criteria is not fully established, iCare may consider the following to interpret or supplement such criteria in order to determine medical necessity consistently:

Initial Bariatric Procedures
- Biliopancreatic diversion (BPD) with or without duodenal switch (DS); **OR**
- Laparoscopic adjustable gastric banding (LAGB); **OR**
- Laparoscopic sleeve gastrectomy; **OR**
- Roux-en-Y gastric bypass (RYGB) (short or long limb)

The **surgical treatments listed above** will be considered medically reasonable and necessary when the following requirements[42,43,44,46] are met:

- BMI greater than or equal to 35 kg/m^2 (greater than or equal to 32.5 kg/m^2 for individuals with Asian ancestry[9,31,89,90,91,92,101]) with at least one of the following associated comorbidities:
    - Cardiovascular disease (eg, uncontrolled hypertension and/or uncontrolled hyperlipidemia); **OR**
    - Evidence of fatty liver disease (eg, nonalcoholic fatty liver disease [NAFLD], nonalcoholic steatohepatitis [NASH]); **OR**

- Gastroesophageal reflux disease (GERD) refractory to a 2 month trial of appropriate treatment and medications; **OR**
- Idiopathic intracranial hypertension (pseudotumor cerebri); **OR**
- Joint disease (eg, osteoarthritis); **OR**
- Life threatening cardiopulmonary conditions (eg, severe obstructive sleep apnea [apnea-hypopnea index greater than 30], obesity hypoventilation syndrome [Pickwickian syndrome] or obesity related cardiomyopathy); **OR**
- Obstructive sleep apnea (OSA) requiring continuous positive airway pressure (CPAP); **OR**
- Potential organ transplant candidacy at a United Network for Organ Sharing (UNOS)-certified center where a BMI less than or equal to 35 kg/m^2 is required; **OR**
- Type II diabetes;

AND all of the following:

- Clinical record demonstrating that the individual has failed previous attempts to achieve and maintain weight loss with medically supervised nonsurgical treatment for obesity; **AND**
- Clinical record showing participation in and compliance with a multidisciplinary surgical preparatory regimen which includes the following:
  - Behavior modification regarding dietary intake and physical activity (unless medically contraindicated); **AND**
  - Nutrition education/counseling with a dietician or nutritionist that addresses pre- and postoperative dietary intake expectations; **AND**
- Preoperative evaluation for comorbid medical conditions and medical/surgical history to ensure that underlying medical conditions that could impact or complicate the individual's surgical and postoperative course are adequately controlled before surgery; **AND**
- Preoperative psychological evaluation and clearance by a mental health professional experienced in the evaluation and management of bariatric surgery candidates to exclude individuals who are unable to provide informed consent, unable to comply with a reasonable pre- and postoperative regimen or have a significant risk of postoperative decompensation **(only required if the individual has a history of psychiatric or psychological disorder, is currently under the care of a psychologist/psychiatrist and is on psychotropic medications)**

***Clinical record documentation should include a summary of historical (failed) weight loss attempts as well as details of present exercise program participation (eg, physical activity, workout plan), nutrition program (eg, calorie intake, meal plan, diet followed), BMI and/or weight loss.

Bariatric Surgery Revision/Conversion in Adults

Bariatric surgery revision/conversion will be considered medically reasonable and necessary when the following requirements are met:

- Initial bariatric surgery requirements are met; **OR**
- Major surgical complication resulting from the initial bariatric procedure or its mechanical failure. Examples of such a complication may include, but are not limited to:
  - Anastomotic leak or stricture; **OR**
  - Band erosion; **OR**
  - Band migration (slippage) with documentation that it was unable to be corrected with a manipulation or an adjustment; **OR**
  - Band removal for gastrointestinal symptoms (eg, persistent nausea and/or vomiting, GERD) with or without imaging evidence of obstruction; **OR**
  - Bowel obstruction or perforation; **OR**
  - Candy cane syndrome (Roux syndrome) when an individual is symptomatic (eg, abdominal pain, emesis, nausea) and diagnosis confirmed by endoscopy or upper gastrointestinal contrast studies; **OR**
  - Fistula; **OR**
  - GI bleeding; **OR**
  - Postoperative GERD refractory to maximum medical treatment including both over-the-counter and prescribed anti-reflux medications; **OR**
  - Staple line dehiscence; **OR**
  - Stomal stenosis

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, band erosion or slippage, bleeding, esophagitis and reflux, fistula, gallstones, hiatal hernia, incisional hernia, infection, intestinal obstruction, metabolic changes, perforation, vitamin deficiency[98,99]). Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following **surgical procedures related to obesity** may not be considered a benefit (statutory exclusion):

- Liposuction (suction-assisted lipectomy, ultrasonic-assisted liposuction);
- Removal of excess skin and/or fat in conjunction with weight loss or weight loss surgery

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act).

Note: This exclusion does not apply to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.[45]

Bariatric surgery revision/conversion due to complications related to dietary or behavior modification noncompliance (eg, stretching or pouch dilatation) or subsequent postoperative weight regain will not be considered medically reasonable and necessary.

The following **bariatric procedures** will not be considered medically reasonable and necessary:

- Any device that has not received FDA approval (eg, endoscopic gastrointestinal bypass device [EGIBD], also known as a duodenal jejunal bypass or gastrointestinal liner);

- Any device no longer manufactured and/or no longer marketed in the US, even if removal from the US market was not due to a safety issue:

    - Aspiration therapy
    - Vagus/vagal nerve blocking (VBLOC)

A review of the current medical literature shows that there is **no evidence** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or

acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following **bariatric procedures** will not be considered medically reasonable and necessary:

- Laparoscopic gastric plication; **OR**
- Mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB); **OR**
- Natural orifice transluminal endoscopic surgery (NOTES) techniques for bariatric surgery including, but may not be limited to:
    - Endoscopic sleeve gastroplasty (ESG); **OR**
    - Intragastric balloon; **OR**
    - Restorative obesity surgery endoluminal (ROSE); **OR**
    - Transoral outlet reduction (TORe); **OR**
    - TransPyloric Shuttle (TPS) device; **OR**
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) (also known as single anastomosis duodenal switch [SADS] or stomach intestinal pylorus sparing surgery [SIPS])
- Vertical banded gastroplasty (VBG) (open or laparoscopic)

A review of the current medical literature shows that the **evidence is insufficient** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Summary of Evidence

Laparoscopic gastric plication

An evidence-based clinical resource organization[100] notes uncertainty regarding laparoscopic gastric plication (LGP) becoming a consequential option for obesity and metabolic control. Despite a less invasive approach than laparoscopic sleeve gastrectomy (LSG), LGP results in more complications and worse long-term outcomes (eg, weight loss, diabetes resolution) with no reduction in operating room time or length of hospital stay. The American Society of Metabolic and Bariatric Surgeons (ASMBS)[27] states that the quantity (4 studies involving less than 300 patients) and quality (prospective or

retrospective case series) of data available are insufficient to draw definitive conclusions regarding the safety and efficacy of the procedure. Barichello and colleagues[35] note that LGP remains an experimental procedure unlikely to replace LSG due to failure to accomplish presumed weight loss expectations. LPG was assumed to be less invasive and better tolerated than LSG, but all studies included in the systematic review and meta-analysis reported a higher number of patients with symptoms in the postoperative period than LSG.

Mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB)
In a report comparing MGB-OAGB with RYGB and LSG separately, an independent technology assessment organization[75] rate the overall quality of evidence as low. For comparison with RYGB, a systematic review with a total of 3101 patients and 2 subsequently published RCTs, with 253 and 400 patients, met the inclusion criteria. For comparison with LSG, a systematic review with a total of 2221 patients and 2 subsequently published RCTs, with 201 and 400 patients, met the inclusion criteria. One RCT compared MGB-OAGB with both RYGB and LSG. The evidence suggests that MGB-OAGB may have modest advantages over RYGB in excess weight loss, and a greater incidence of resolution of type 2 diabetes, but with a different adverse event profile and no difference in mortality. The evidence suggests that MGB-OAGB may also have modest advantages over LSG for weight loss and is more likely to induce resolution of type 2 diabetes and hypertension. Although some adverse events do occur more often with MGB-OAGB (malnutrition, marginal ulcer), the data suggest lower incidence of others (bile reflux, revision surgery, and mortality). The American Society for Metabolic and Bariatric Surgery[21] notes that the MGB-OAGB has been studied primarily outside the US and may be an effective revision option if needed after other restrictive procedures. Concerns regarding the procedure include esophageal bile reflux, malnutrition and nutrient deficiencies.

NOTES Techniques *Summary of Evidence*

Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)
A 2018 literature search by an independent technology assessment organization[74] identified 5 studies (n=106-182 patients) meeting inclusion criteria to evaluate SADI-S for weight loss. No randomized controlled trials were identified; evidence primarily consists of retrospective cohort studies. Four studies were from one bariatric center and used the same pool of SADI-S patients in retrospective matched cohort analyses. The overall very-low-quality body of evidence suggests that SADI-S is effective at promoting weight loss in patients with morbid or extreme obesity. Weight loss appears to cease by 15 months and may be durable for up to 2 years post-surgery. SADI-S is more effective at promoting weight loss than both Roux-en-Y gastric bypass (RYGB) and vertical sleeve gastrectomy; however, comparisons with biliopancreatic diversion with duodenal switch (BPD-DS) yield mixed results. Although the studies provide consistent evidence in support of SADI-S, they were each of poor to very poor quality and limited by small sample sizes, retrospective design, and other methodological flaws. Substantial uncertainty remains regarding the durability of the treatment effect, the comparative efficacy of SADI-S compared with other bariatric surgical methods, selection criteria, and safety. In a systematic review and meta-analysis comparing SADI-S or biliopancreatic diversion with duodenal switch (BPD-DS) versus Roux-en-Y gastric bypass (RYGB) as a revisional procedure, Lee and coauthors[87] included 6 retrospective cohort studies involving 377 patients. Compared with RYGB, SADI-S demonstrated a similar safety

profile, and higher percentage of total weight loss; however there is insufficient data on whether these differences translated to differences in final BMI. The authors note that the lack of randomization, small sample size, and lack of baseline equivalence in initial BMI between the groups limit the conclusions that can be made from the analysis and recommend randomized controlled trials or large scale studies. In evaluating single-site data from 750 patients who underwent a primary laparoscopic SADI-S, Surve et al[96] conclude that laparoscopic SADI-S is effective in achieving initial weight loss and treating comorbid conditions. Noting the follow-up rate was 61% at 5 years, the authors recommend further long-term outcome studies with better follow-up rates to confirm efficacy and safety of the procedure, as well as enduring nutritional results. Although the American Society for Metabolic and Bariatric Surgery (ASMBS)[24] endorses SADI-S as an appropriate bariatric surgical procedure, the group notes remaining concerns regarding intestinal adaptation, nutritional issues, optimal limb lengths and long-term weight loss/regain. As such, ASMBS recommends a cautious approach to the adoption of this procedure.

Vertical banded gastroplasty (VBG)

An evidence-based clinical resource[100] notes that VBG has been replaced largely by other procedures and is rarely performed due to lack of sustained/desired weight loss and a high incidence of complications (20 to 56 percent) requiring revision. VBG is categorized as an obsolete procedure. An independent technology assessment organization[82] found moderately strong evidence that, on average, VBG achieves clinically important long-term weight loss. Evidence of improvement in obesity-related comorbidities is positive, but the quantity of evidence is modest. VBG is on the CMS[46] nationally noncovered indications list.

NOTES TECHNIQUES

Endoscopic sleeve gastroplasty (ESG)

An independent technology assessment organization[68] found minimal support in clinical studies or systematic reviews for ESG using the OverStitch device. Evidence from 4 fair- or poor-quality comparative studies indicates that ESG performed using the OverStitch device is associated with clinically significant weight loss but clinically significantly less weight loss than with laparoscopic sleeve gastrectomy (LSG). The same organization found weak support in clinical guidelines regarding ESG. The American Gastroenterological Association (AGA)[13] summarizes findings regarding all endoscopic bariatric therapies (including ESG) as potentially effective adjunctive therapies with variable and temporary weight loss results.

Intragastric balloon (IGB)

An independent technology assessment organization[78] evaluated the available evidence as low-quality, citing a need for additional, larger, randomized controlled and comparative trials that evaluate the long-term safety and efficacy of IGBs and ascertain the optimal role of these devices. Limited evidence suggests that IGBs have mixed results regarding weight loss over the short term when used as an adjunct to diet and exercise. IGBs may improve quality of life but do not appear to have any effect on satiety compared with restricted diet and exercise. Kotzampassi et al [86] report that in a study of 500 patients who underwent six months of treatment with intragastric balloon therapy, only one-half maintained 20 percent excess weight loss at one year after balloon removal, and one-quarter kept this

weight loss at five years. Chan and coauthors [47] found that at 10 years, the IGB group reverts to baseline weight, and the control group experienced weight gain (0.03 vs − 2.32 kg, p = 0.05). The US Food & Drug Administration (FDA)[110] received adverse event reports involving balloon hyperinflation (over 200) and pancreatitis (nearly 30) and issued safety communications to health care providers. The communication included recommendations to consider post-approval study results when discussing risks and benefits with patients, to carefully follow product labeling, to monitor patients closely and to instruct patients about the symptoms of potentially life-threatening complications (balloon deflation, gastro-intestinal obstruction, ulceration, gastric/esophageal perforation) and advise when to seek medical attention. IGBs are on the CMS[46] nationally noncovered indications list.

Restorative obesity surgery endoluminal (ROSE)

In describing ROSE, Abboud[1] and coauthors state the procedure uses full-thickness plications to manage weight regain after RYGB and is a modified variant of the POSE: Primary Obesity Surgery Endoluminal procedure. POSE uses the Incisionless Operating Platform (IOP) to grasp, plicate (fold) and anchor tissue to reduce the size of the gastric pouch and the anastomosis. Horgan[85] et al report on a multicenter registry of 116 patients, 112 of whom (97%) had successful incisionless anchor placement using the IOP to reduce the stoma and pouch size. At 6 months after the procedure (96 patients remaining), an average of 32% of weight regain that had occurred after RYGB had been lost. There is a paucity of published clinical evidence on the ROSE procedure. According to the American Society for Metabolic and Bariatric Surgery (ASMBS)[34] the theoretical goals of endoluminal bariatric procedures, including those for revision, involve decreasing the invasiveness, risk, and barriers to acceptance of effective treatment of obesity; however, these outcomes cannot be assumed and must be proven. ASMBS recommends use of novel technologies be limited to clinical trials done in accordance with the ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention.

Transoral outlet reduction (TORe)

Endoscopic techniques such as TORe for the revision of a dilated gastrojejunal anastomosis have been proposed as a minimally invasive treatment for weight regain after RYGB. More recently TORe has been proposed for dumping syndrome, a cluster of symptoms induced by the rapid transit of undigested food into the small bowel. Failure of sustained weight loss with the onset of dumping syndrome has been associated with gastrojejunal anastomotic dilation. In a retrospective study of 87 patients, 66.7% (n=58) were classified as “dumpers” at baseline. Pontecorvi et al[93] notes that 35 patients reached 24 month follow-up with only 21 (57.2%) showing symptom resolution. Additionally, patients with a resolution of dumping syndrome after TORe had better weight loss results than those with refractory symptoms. Acknowledged limitations of the study include retrospective design, lack of a control group, possible selection bias due to the use of a single center and most importantly, the availability of 2-year data for only 64.4% of study participants. In a systematic review and meta-analysis including 13 studies and 850 patients, Dhindsa and coauthors[49] conclude that TORe shows promising short-term results, but further studies are needed to evaluate long-term success. An independent technology assessment organization[69] found the totality of evidence to be of poor or very poor quality due to lack of comparison groups, small sample sizes and limited follow-up.

TransPyloric Shuttle (TPS)

An independent technology assessment organization[64] found the data pertaining to TPS insufficient, citing evidence from a single randomized controlled trial (RCT) reported in the FDA Summary of Safety and Effectiveness Data (SSED) document. Findings suggest TPS in conjunction with lifestyle counseling may improve weight loss up to 12 months in individuals with a BMI of 35 - 40 kg/m^2 compared with lifestyle counseling alone. Results need confirmation in additional controlled trials with longer follow-up, especially because TPS is a temporary device. Use of TPS should also be compared with minimally invasive procedures, such as use of gastric banding and intragastric balloons. Published evidence on the TPS is limited to a single report on outcomes of an uncontrolled feasibility study involving 20 participants. Marinos et al[88] assigned 20 patients (mean (BMI) of 36.0 kg/m^2) to two groups of 10, scheduled to retain the device for 3 or months. Primary outcomes include the following percentages: excess weight loss (%EWL), excess BMI loss (%EBMIL), weight loss (%WL), and adverse events. Three-month patients had mean %EWL of 25.1%, mean %EBMIL of 33.1%, and mean %WL of 8.9%. Six-month patients had mean %EWL of 41.0%, mean %EBMIL of 50.0%, and mean %WL of 14.5%. Early device removal occurred in 2 patients due to symptomatic gastric ulcerations, which resolved after device removal. The authors conclude that while the device appears promising, the lack of longer treatment duration is a limitation.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon	
43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)	
43631	Gastrectomy, partial, distal; with gastroduodenostomy	
43632	Gastrectomy, partial, distal; with gastrojejunostomy	
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction	
43634	Gastrectomy, partial, distal; 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 (eg, gastric band and subcutaneous port components)	
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only	
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)	
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty	
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty	
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)	
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)	
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without 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	

43999	Unlisted procedure, stomach	
44238	Unlisted laparoscopy procedure, intestine (except rectum)	
44799	Unlisted procedure, small intestine	
64999	Unlisted procedure, nervous system	
CPT® Category III Code(s)	**Description**	**Comments**
0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon	-
HCPCS Code(s)	**Description**	**Comments**
C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components	
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components	

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Appendix

Appendix A
BMI Categories for Adults[36]

BMI Category	BMI Range (kg/m^2)
Underweight	Less than 18.5
Healthy Weight	18.5 to less than 25
Overweight	25 to less than 30
Obesity	30 or greater
Class 1 Obesity	30 to less than 35
Class 2 Obesity	35 to less than 40
Class 3 Obesity (Severe Obesity)	40 or greater
BMI is a calculation of a body person's weight (in kilograms) divided by the square of their height (in meters).	

Change Summary

01/23/2024 New Policy.
08/27/2024 Annual Review, Coverage Change