Bariatric Surgery

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Line of Business: Medicare

Medical Coverage Policy

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Disclaimer The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medical/Pharmacy Coverage Policies

N/A

Related Documents

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

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<tr>
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Description

Bariatric surgery, also known as weight loss surgery, is performed on the gastrointestinal (GI) tract of an obese individual to alter the digestive process and induce weight loss. Bariatric surgical techniques may be 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.

Currently, the two most commonly performed bariatric procedures include:
• **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/m²).

• **Sleeve gastrectomy (open or laparoscopic)** 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.

Examples of other bariatric procedures and techniques include, but may not be limited to, the following:

• **Aspiration therapy device insertion** (eg, AspireAssist) 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. This device 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. It 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. It 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.

• **Laparoscopic 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)** is being explored for a variety of surgeries, including bariatric procedures. NOTES procedures are incisionless and performed with an endoscope passed through the mouth. Examples of NOTES techniques for bariatric purposes include, but may not be limited to, the following:

  o **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 US Food & Drug Administration (FDA) approved but is undergoing studies for the management of conditions such as diabetes and obesity.

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

  o **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 are kept 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:

    ▪ Allurion Gastric Balloon
    ▪ Obalon Balloon System
    ▪ Orbera Intragastric Balloon System
    ▪ ReShape Integrated Dual Balloon System
    ▪ Spatz3 Adjustable Gastric Balloon

  o **Restorative obesity surgery, endoluminal (ROSE) procedure** is suggested for the treatment of weight regain following gastric bypass surgery due to a gradual expansion of the gastric pouch. The stomach is accessed orally via an endoscope and reduced in size using an endoscopic closure device.

  o **Tissue approximation and endoscopic closure devices** are being developed for use in conjunction with various endoscopic procedures, including NOTES. Endoscopic closure devices proposed for use in conjunction with NOTES include, but may not be limited to, the **OverStitch Endoscopic Suturing System** and **Over-The-Scope Clip (OTSC) System Set**.

  o **Transoral outlet reduction (TORe)** is an endoscopic method of correcting a dilated gastrojejunostomy outlet after **Roux-en-Y** in an individual experiencing weight regain due to a relaxed gastric outlet. The enlarged gastric outlet reduces the sense of fullness and allows greater amounts of food ingestion.
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. It 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)** ([eg, Maestro Rechargeable System](https://www.maestrorechargeablesystem.com)), 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).

- **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**

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

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:*

**Initial Bariatric Procedures**
- Biliopancreatic diversion (BPD) with or without duodenal switch (DS); **OR**
- Laparoscopic adjustable gastric banding (LAGB) (eg, [Lap-Band](https)); **OR**
- Laparoscopic sleeve gastrectomy; **OR**
- Roux-en-Y gastric bypass (RYGB) (short or long limb)
The surgical treatments listed above will be considered reasonable and medically necessary when all the following requirements\(^{39-42}\) are met:

- **BMI** greater than or equal to 35 kg/m\(^2\) 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 [or 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 whereby a BMI of 35 is required; OR
  - Type II diabetes;

AND all 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**\* of 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:

  o Anastomotic leak or stricture; OR
  
  o Band erosion; OR
  
  o Band migration (slippage) with documentation that it was unable to be corrected with a manipulation
    or an adjustment; OR
  
  o Bowel obstruction or perforation; OR
  
  o Candy cane syndrome (Roux syndrome) when an individual is symptomatic (eg, abdominal pain,
    emesis, nausea) and diagnosis has been confirmed by endoscopy or upper gastrointestinal contrast
    studies; OR
  
  o Fistula; OR
  
  o GI bleeding; OR
  
  o Postoperative gastroesophageal reflux disease (GERD) refractory to maximum medical treatment
    including both over-the-counter and prescribed anti-reflux medications; OR
  
  o Staple line dehiscence; OR
  
  o Stomal stenosis
The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. 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 treatments for severe obesity will not be considered medically reasonable and necessary:

- Aspiration therapy (eg, AspireAssist); OR
- Laparoscopic gastric plication; OR
- Natural orifice transluminal endoscopic surgery (NOTES) techniques for bariatric surgery including, but may not be limited to, the following:
  - Endoscopic gastrointestinal bypass device (EGIBD) (also known as a duodenal jejunal bypass or gastrointestinal liner [eg, EndoBarrier]); OR
  - Endoscopic sleeve gastroplasty (ESG) (eg, Apollo ESG); OR
  - Intragastric balloon (eg, Allurion, Obalon, Orbera, ReShape, Spatz3); OR
  - Restorative obesity surgery, endoluminal (ROSE); OR
  - Transoral outlet reduction (TORe); OR
  - TransPyloric Shuttle (TPS) device; OR
  - Use of any endoscopic closure device (eg, OverStitch Endoscopic Suturing System, Over-The-Scope Clip [OTSC] System Set) in conjunction with NOTES; OR
- Vagus/vagal nerve blocking (VBLOC) (eg, Maestro), also referred to as gastric pacing or vagal nerve stimulation; OR
- 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 remains an absence of randomized, blinded clinical studies
examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**Summary of Evidence**

**AspireAssist**
According to low-quality evidence from 2 systematic reviews, adding AspireAssist therapy to lifestyle modification could potentially improve 1 year weight loss in individuals with obesity and weight loss is maintained at up to 4 years. These studies also show that AspireAssist is as effective as minimally invasive endoscopic suturing at up to 1 year follow-up. Whether AspireAssist therapy contributes to abnormal eating behaviors cannot be determined because 1 single-arm extension of a randomized controlled trial (RCT) reported too few events. Additional RCTs would be useful to confirm results, particularly in the long term; additional studies are also needed to compare AspireAssist with other minimally invasive options, such as intragastric balloons, and to assess AspireAssist as a bridge therapy to facilitate bariatric surgery. A small, nonrandomized ongoing study will report on some outcomes of interest, but larger studies are needed.

**Laparoscopic gastric plication**
The quantity (4 studies, less than 300 individuals) and quality (prospective or retrospective case series) of the data available at this time are insufficient to draw any definitive conclusions regarding the safety and efficacy of this procedure. The American Society of Metabolic and Bariatric Surgeons (ASMBS) stated that they will continue to monitor the data on this procedure as it emerges and will issue a formal evidence-based position statement at the appropriate time.

**Natural orifice transluminal endoscopic surgery (NOTES) techniques for bariatric surgery**

**Endoscopic Closure Devices**
A review of full-text systematic reviews suggests minimal support for ESG with the OverStitch device. This level of support reflects 2 systematic reviews addressed ESG generally, although most of the included published literature is on ESG with the OverStitch device. Both reviews found ESG is associated with less weight loss than LSG but also fewer adverse events.

**Endoscopic gastrointestinal bypass device (EGIBD)**
The ASMBS is awaiting review of US trial data to determine the efficacy and safety of the EndoBarrier. To date there is no FDA approval.

**Endoscopic sleeve gastroplasty (ESG)**
There was a moderate-sized body of peer-reviewed published literature assessing the ESG procedure. Twelve abstracts of studies were retrieved including prospective comparative studies, prospective uncontrolled studies, a retrospective uncontrolled study, a learning curve analysis, and a literature review. The limited amount of data provided in the published abstracts suggested that the ESG procedure was effective at inducing weight loss with an acceptable safety profile. It should be noted that the abstracts were missing some of the standard parameters that are recommended by the ASMBS for reporting of outcomes following bariatric surgery.

**Intragastric balloon (IGB)**
The available low-quality evidence suggests that IGBs have mixed results with regard to 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. These devices are consistently associated with high rates of gastrointestinal adverse events that are of mild-to-moderate severity, and infrequently associated with more serious events. Minimal evidence suggests that IGBs may support improved dietary restraint. All of the studies lacked long-term follow-up; the durability of the effects of IGBs on maintaining weight loss and any safety concerns after their removal is unclear. Despite many years of research and clinical use, particularly outside of the United States, no strong benefits favoring the use of IGBs over lifestyle interventions (such as restricted diet and exercise alone) have been established. In addition, the use of IGBs carries risks for adverse effects, some potentially severe. 74

Restorative obesity surgery, endoluminal (ROSE)
Endoluminal bariatric techniques are a promising area of research with the potential to have an impact on this growing health issue. Currently, a number of endoluminal innovations and novel devices and technologies are in various stages of development or application to the elective treatment of obesity, including revisional interventions. The theoretical goals of these therapies include decreasing the invasiveness, risk, and barriers to acceptance of effective treatment of obesity; however, these outcomes cannot be assumed and must be proven. Therefore, the use of novel technologies should 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. 34

Transoral outlet reduction (TORe)
Findings from 1 randomized controlled trial (RCT), 4 nonrandomized comparative studies and 1 pretest-posttest study—all but 1 of which are of poor or very poor quality—indicated that transoral outlet reduction (TORe) with the OverStitch device is technically feasible and usually associated with up to a 2% to 9% weight reduction in individuals who require surgical revision due to weight regain or inadequate weight loss after RYGB. One comparative study found that the addition of TORe with OverStitch did not improve weight reduction compared with an endoscopic alternative alone. Another study reported significantly greater weight loss for TORe performed with the OverStitch compared with an alternative endoscopic suturing device at 6 and 12 months of follow-up. The remaining comparative data evaluated variations in OverStitch TORe procedures or adjunctive treatment. Overall adverse event rates ranged from 2% to 32% among patients treated with OverStitch TORe, with most adverse events being mild to moderate. Follow-up was limited to 1 year in the majority of studies (1 study had 5 years of follow-up), and few studies reported the impact on comorbidity resolution. 66

TransPyloric Shuttle (TPS)
Evidence from a single randomized controlled trial (RCT) reported in the FDA Summary of Safety and Effectiveness Data (SSED) document suggests TPS added to lifestyle counseling may improve weight loss in individuals with a BMI of 35 - 40 kg/m² up to 12 months 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. 61

Vagus/vagal nerve blocking (VBLOC)
Currently, the quantity of the data available (6 published studies [5–10]; approximately 600 implanted
devices) and the length of follow-up indicate adequate safety and efficacy in the short term. More prospective studies with longer follow-up are required to establish the clinically significant efficacy and individual’s tolerance of this device.\textsuperscript{20}

**Vertical banded gastroplasty (VBG)**

There is 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. According to the ASMBS this procedure is becoming obsolete.\textsuperscript{79,91}

The following bariatric surgery modifications will not be considered medically reasonable and necessary:

- Mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB); 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])

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**Summary of Evidence**

**Mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB)**

Current 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. The evidence does not suggest differences in mortality. Current 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).\textsuperscript{72}

**Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)**

There is an overall very-low-quality body of evidence suggesting that SADI-S is effective at promoting weight loss in patients with morbid or extreme obesity. The overall very-low-quality rating for this body of evidence is due to individual study limitations and limited quantity of evidence. Although the studies provided consistent evidence in favor of SADI-S, they were each of poor to very poor quality and limited by small sample sizes, retrospective design, and other methodological flaws. Four of the 5 studies were conducted in the same bariatric center and utilized the same population is a significant limitation to the body of evidence. Substantial uncertainty remains regarding the durability of the treatment effect, the comparative efficacy of SADS compared with other bariatric surgical methods, selection criteria, and safety. Overall quality was based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of the data to general practice.\textsuperscript{71}
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 surgical procedures related to obesity are considered cosmetic and are performed to improve or change appearance or self-esteem. Cosmetic procedures are not a Medicare benefit and are not covered:

- Liposuction (eg, suction assisted lipectomy, ultrasonic assisted liposuction); OR
- Surgical procedures for the removal of excess skin and/or fat in conjunction with weight loss or weight loss surgery

**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.

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<td>Gastrectomy, partial, distal; with Roux-en-Y reconstruction</td>
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<td>Unlisted laparoscopy procedure, stomach</td>
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### References


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<tbody>
<tr>
<td>C9784</td>
<td>Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components</td>
<td></td>
</tr>
<tr>
<td>C9785</td>
<td>Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components</td>
<td></td>
</tr>
</tbody>
</table>


Appendix

N/A
Change Summary

- 01/24/2023 New Policy.