



## Bariatric Surgery Clinical Coverage Criteria

### Description

Bariatric surgery procedures are performed to treat comorbid conditions associated with morbid obesity. Two types of surgical procedures are employed. Malabsorptive procedures divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur. Restrictive procedures restrict the size of the stomach and decrease intake. Surgery can combine both types of procedures.

### Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus
- MassHealth ACO
- NaviCare HMO SNP
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care

Bariatric surgery requires prior authorization. Prior authorization requests for bariatric surgery must be submitted by the surgeon performing the procedure and accompanied by medical record documentation that supports medical necessity for the procedure.

### Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care members.

#### Bariatric Surgery in Adults

Effective March 1, 2024, Fallon Health will use the InterQual® Criteria in effect on the date of service when making medical necessity determinations for the following bariatric surgery procedures for Community Care members ages 18 years of age or older:

- CP:Procedures, Bariatric or Metabolic Surgery, Adjustment of Gastric Band Diameter
- CP:Procedures, Bariatric or Metabolic Surgery, Biliopancreatic Diversion with Duodenal Switch
- CP:Procedures, Bariatric or Metabolic Surgery, Laparoscopic Adjustable Gastric Band
- CP:Procedures, Bariatric or Metabolic Surgery, Laparoscopic Adjustable Gastric Band (Repair, Revision)
- CP:Procedures, Bariatric or Metabolic Surgery, Laparoscopic Adjustable Gastric Band Removal
- CP:Procedures, Bariatric or Metabolic Surgery, One Anastomosis Gastric Bypass (OAGB)
- CP:Procedures, Bariatric or Metabolic Surgery, Revisional Procedure
- CP:Procedures, Bariatric or Metabolic Surgery, Roux-en-Y Gastric Bypass (RYGB)
- CP:Procedures, Bariatric or Metabolic Surgery, Sleeve Gastrectomy

InterQual® Criteria do not address procedures which are not yet standard of care (e.g., gastric balloon, transoral gastroplasty, long limb gastric bypass), or procedures that are not effective or outdated (e.g., jejunoileal bypass, horizontal gastric stapling, vertical band gastroplasty). See **Exclusions** section below.

#### Hiatal Hernia Repair at the Time of Bariatric Surgery

Effective March 1, 2025, Fallon Health will use the InterQual® Criteria in effect on the date of service when making medical necessity determinations for repair of a preoperatively diagnosed hiatal hernia at the time of bariatric surgery for Community Care members ages 18 years of age or older:

- CP:Procedures, Antireflux Surgery or Hiatal Hernia Repair, Hiatal Hernia Repair

### **Bariatric Surgery in Adolescents**

Effective March 1, 2024, Fallon Health will use the InterQual® criteria in effect on the date of service when reviewing requests for the following bariatric and metabolic surgery procedures for Community Care members age ≥ 13 and < 18 years:

- CP:Procedures, Bariatric or Metabolic Surgery (Adolescent), Laparoscopic Adjustable Gastric Band (Repair or Revision)
- CP:Procedures, Bariatric or Metabolic Surgery (Adolescent), Laparoscopic Adjustable Gastric Band Removal
- CP:Procedures, Bariatric or Metabolic Surgery (Adolescent), Revisional Procedure
- CP:Procedures, Bariatric or Metabolic Surgery (Adolescent), Roux-en-Y Gastric Bypass (RYGB)
- CP:Procedures, Bariatric or Metabolic Surgery (Adolescent), Sleeve Gastrectomy

### **Bariatric Surgery in Preadolescent Children**

Bariatric surgery for preadolescent children (< 13 years of age) is considered experimental/investigational due to lack of data on outcomes.

Fallon Health makes InterQual® criteria available through the Transparency Tool on our website, effective January 1, 2024.

## **Medicare Variation**

Medicare statutes and regulations do not have coverage criteria for bariatric surgery. Medicare has an NCD Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1). It is Version Number 5. The Effective Date of this Version is 09/24/2013. NCD 100.1 lists the Nationally Covered and Nationally Non-Covered Indications for bariatric surgery.

The following bariatric surgery procedures are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity:

- Open and laparoscopic Roux-en-Y gastric bypass (RYGBP),
- Open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS)
- Gastric Reduction Duodenal Switch (BPD/GRDS), and
- Laparoscopic adjustable gastric banding (LAGB).

Treatments for obesity alone remain non-covered.

The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:

- Open adjustable gastric banding;
- Open sleeve gastrectomy;
- Laparoscopic sleeve gastrectomy (prior to June 27, 2012);
- Open and laparoscopic vertical banded gastroplasty;
- Intestinal bypass surgery; and,
- Gastric balloon for treatment of obesity.

Per NCD 100.1, the Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy for the treatment of co-morbid conditions related to obesity for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area does not have an LCD for bariatric surgery (Medicare Coverage Database search 1/21/2026). National Government Services, Inc. has a Medical Policy Article for Laparoscopic Sleeve Gastrectomy (A52447). Since this is not an LCD, the criteria in this Medical Policy

Article cannot be used to make medical necessity determinations for the Plan's Medicare Advantage members.

Consistent with NCD 100.1, Fallon Health covers laparoscopic sleeve gastrectomy (CPT 43775) for Medicare Advantage members when all of the following conditions (a-c) are satisfied:

- a. The member has a body-mass index (BMI)  $\geq$  35 kg/m<sup>2</sup>,
- b. The member has at least one co-morbidity related to obesity, and,
- c. The member has been previously unsuccessful with medical treatment for obesity.

Per NCD 100.1, the determination of coverage for bariatric surgery procedures that are not specifically identified in NCD 100.1 as Nationally Covered or Nationally Non-Covered, for Medicare beneficiaries who have a body-mass index  $\geq$  35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local MACs. In these circumstances, Fallon Health will determine coverage on an individual case-by-case basis for Medicare Advantage members in accordance with the definition of medically necessary.

[Link: NCD Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity \(100.1\)](#)

## MassHealth Variation

MassHealth has Guidelines for Medical Necessity Determination for Bariatric Surgery. Fallon Health determines medical necessity for bariatric surgery for MassHealth members in accordance with MassHealth Guidelines for Medical Necessity Determination for Bariatric Surgery.

[Link: MassHealth Guidelines for Medical Necessity Determination for Bariatric Surgery](#)

MassHealth does not provide coverage for bariatric surgery (primary or revision) when the procedures have not been sufficiently studied to determine their effectiveness and safety for the medical indication. MassHealth also does not consider bariatric surgery to be medically necessary under certain other circumstances.

Examples of when the surgery may not be considered medically necessary include, but are not limited to, the following:

- (1) Bariatric procedures with limited evidence of efficacy, such as “Band over sleeve” or Laparoscopic adjustable silicone gastric banding (LASGB) revision of prior sleeve gastrectomy; and
- (2) Bariatric surgery not meeting the medical-necessity criteria in the MassHealth Guidelines for Medical Necessity Determination for Bariatric Surgery.

## Exclusions

- Bariatric surgery for preadolescent children (< 13 years of age).
- Bariatric surgery procedures which are not yet standard of care (e.g., gastric (intra-gastric) balloon, transoral gastroplasty, long limb gastric bypass), or procedures that are not effective or outdated (e.g., jejunioileal bypass, horizontal gastric stapling, vertical banded gastroplasty).
- Endoscopic procedures (e.g., insertion of the StomaphyX device) as a primary bariatric procedure or as a revision procedure.
- Gastric electric stimulation for the treatment of obesity.
- Band over bypass, band over sleeve or laparoscopic adjustable silicone gastric banding (LASGB) revision of prior sleeve gastrectomy.
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in individuals who do not meet criteria for surgical repair.
- Endoscopic sleeve gastrectomy (CPT 43889) is considered experimental and investigational due to limited published evidence with which to evaluate the sustained benefit of ESG in weight reduction compared to conservative measures and accepted bariatric procedures.

## Summary of Evidence

### Hiatal hernia repair at the time of bariatric surgery

The major clinical significance of a Type I hernia is its association with reflux disease. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Guidelines strongly recommends not repairing type I hiatal hernia in the absence of reflux disease and symptoms; this recommendation remains valid to this day, as sustained by several authors (Sfara and Dumitrascu, 2019). The SAGES Guidelines strongly recommend that all symptomatic paraesophageal hiatal hernias should be repaired (++++, strong), particularly those with acute obstructive symptoms or which have undergone volvulus. Routine elective repair of completely asymptomatic paraesophageal hernias may not always be indicated. Consideration for surgery should include the patient's age and comorbidities (moderate quality evidence, weak recommendation). The SAGES Guidelines also recommend repairing all detected hiatal hernias during Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands (Kohn et al., 2013). This recommendation is largely based on references in the literature of increased complications (gastroesophageal reflux symptoms) after placement of an adjustable gastric band in patients with a hiatal hernia. Laparoscopic adjustable gastric band placement was once the most popular bariatric procedure in the United States, but use of this procedure has decreased sharply due to the inadequate weight loss, weight regain, and high long-term complication rate. According to American Society of Metabolic and Surgery (ASMBS), about 35.4% of all bariatric procedures were lap band in 2011. Utilization has decreased steadily, and in 2021, less than 1% (0.43%) of bariatric procedures in the United States were lap band.

Some insurers have stopped reimbursing concurrent hiatal hernia repair with bariatric surgery. Lewis et al. (2022) examined the outcomes of adults who underwent laparoscopic sleeve gastrectomy (SG) or Roux-en-Y gastric bypass (RYGB) with or without concurrent hiatal hernia repair (HHR) between January 2010 and June 2017 using a large nationwide insurance claims database (Optum Clinformatics Data Mart). Patients who underwent concurrent SG and HHR were more likely to have additional abdominal operations (adjusted hazard ratio [aHR], 2.1; 95% CI, 1.5–3.1,  $p < 0.001$ ) and endoscopies (aHR, 1.5; 95% CI, 1.2–1.8,  $p < 0.001$ ) but not bariatric revisions/conversions (aHR, 1.7; 95% CI, .6–4.6,  $p = 0.33$ ) by 1 year after surgery, a pattern maintained at 3 years of follow-up. Among RYGB patients, concurrent HHR was associated only with an increased risk of endoscopy (aHR, 1.4; 95% CI, 1.1–1.8,  $p = 0.01$ ) at 1 year of follow-up, persisting at 3 years. The authors conclude that concurrent SG and HHR was associated with increased risk of some subsequent operative and nonoperative interventions, a pattern that was not consistently observed for RYGB. Although risk of subsequent operative intervention did not differ for RYGB patients by concurrent HHR status, this does not suggest that hiatal hernia patients should be triaged to RYGB because the overall risk of operative reintervention remains higher for RYGB. Limitations of this study include the observational, nonrandomized design, which precludes causal inference. Because this study used claims data, there is potential for unmeasured confounding by provider and patient characteristics. There is a need for additional studies to better understand the risks and benefits associated with concurrent HHR, and how they may differ between SG and RYGB.

### **Abdominal wall hernia repair**

While the timing of bariatric surgery relative to hernia repair remains controversial, evidence suggests that patients with large, chronic abdominal wall hernia may benefit from significant weight loss initially as staged procedure to definitive hernia repair. Thus, in patients with severe obesity and an abdominal wall hernia requiring elective repair, bariatric surgery should be considered first to induce significant weight loss and consequently reduce the rate of complications associated with hernia repair and increase durability of the repair (Eisenberg et al., 2022).

### **Endoscopic sleeve gastropasty**

Endoscopic sleeve gastropasty (ESG) has emerged as a promising minimally invasive approach to weight loss. The procedure involves using an endoscopic suturing device to create plications in the stomach to reduce stomach volume. The plications form a sleeve, which reduces stomach capacity and slows gastric emptying.

Patients having previous Roux-en-Y gastric bypass bariatric surgery may experience dilation of the gastrojejunostomy outlet and the gastric pouch, followed by weight gain. This can be addressed by

reducing the diameter of the gastric outlet by suturing. This procedure is often referred to as Transoral Outlet Reduction (TO Re).

The Apollo ESG, Apollo ESG SX, Apollo Revise, and Apollo Revise SX Systems (Apollo Endosurgery, Inc.) were granted U.S. Food and Drug Administration (FDA) approval under [DEN210045](#) on July 12, 2022 (Product Code QTD). The APOLLO ESG and APOLLO REVISE Systems are designed to accomplish ESG and TORe, respectively, using a dual channel scope. The APOLLO ESG SX and APOLLO REVISE SX Systems are designed to accomplish ESG and TORe, respectively, using a single channel endoscope. A version of the Apollo ESG System that uses newer materials was cleared on September 18, 2023 (K232544). Boston Scientific acquired Apollo Endosurgery, Inc. in November 2022.

The APOLLO ESG and Apollo ESG SX Systems are intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastropasty in adult patients with obesity with BMI 30-50 kg/m<sup>2</sup> who have not been able to lose weight, or maintain weight loss, through more conservative measures.

The APOLLO REVISE and REVISE SX Systems are intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI 30 - 50 kg/m<sup>2</sup> by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

The APOLLO ESG, ESG SX, REVISE and REVISE SX Systems are identical in design to the OverStitch Systems previously cleared for marketing (K081853, K171886, K181141 , K191439, and K210266) for a different intended use.

#### Randomized controlled trials

FDA approval of the Apollo ESG and Apollo ESG SX Systems was based on results from the pivotal Multicenter Endoscopic Sleeve Gastrectomy (ESG) Trial (MERIT Trial) (ClinicalTrials.gov, NCT03406975). Results of the MERIT Trial are published by Abu Dayyeh et al., 2022. The MERIT Trial evaluated the effectiveness and safety of ESG as an adjunct to life-style intervention for weight loss compared to lifestyle intervention alone in participants 21-65 years of age with BMI  $\geq 30$  and  $\leq 40$  kg/m<sup>2</sup> who had failed to achieve and maintain weight loss with a non-surgical program. Patients with insulin-dependent diabetes (either Type 1 or Type 2) or a significant likelihood of requiring insulin treatment in the following 12 months or a HgbA1C  $\geq 9$  were excluded.

MERIT was a prospective, randomized, multicenter study and subjects were followed for two years. Patients were randomized in a 1:1.5 ratio of treatment (ESG with lifestyle modifications) to control (lifestyle modifications alone), with potential retightening or crossover to ESG, respectively, at 52 weeks. Lifestyle modifications included a low-calorie diet and physical activity. Participants in the treatment group were followed up for 104 weeks. Patients in the Control group were allowed to crossover to ESG if they had not responded to lifestyle modification (defined as not having achieved  $\geq 25\%$  Excess Weight Loss (EWL)) and had completed their follow-up visits.

The primary effectiveness endpoint was the percentage of subjects who were responders to treatment at 52 weeks follow-up, where response was defined as achieving  $\geq 10\%$  Total Body Weight Loss (TBWL). Secondary endpoints included % EWL and change in BMI from baseline. Along with % TBWL, these data were collected at each visit and used to evaluate the effectiveness of treatment and control, retightening of an ESG, and crossing over from lifestyle modification to ESG, over time.

259 subjects provided informed consent and 209 subjects were randomized: 85 Treatment and 124 Control. This represents the ITT population. Eight subjects in the treatment group did not receive treatment, because they did not meet eligibility criteria; they were removed from the study. Twelve subjects in the control group did not complete any study visits and were removed from the study. Two additional Control subjects were determined to be ineligible prior to starting the study. As a result, 77 treatment and 110 control subjects received the assigned treatment. Three treatment subjects withdrew consent prior to the 52 week visit and six were lost to follow-up. In the control group, 13 withdrew consent

and eight were lost to follow-up prior to completing the 52 week visit. As a result, there were 68 treatment and 89 control subjects with effectiveness data at 52 weeks.

Responder rates at 52 weeks, as defined by achieving  $\geq 10\%$  TBWL, in the completers population (modified ITT) were 44/68 (64.7%) and 4/89 (4.5%) in treatment and control groups, respectively ( $p < 0.001$ ). Additional analyses were performed to report responder rates at 52 weeks (10% TBWL) by various subgroups.

Subjects in the treatment group began to lose weight as early as the one week visit. Weight loss steadily progressed through 24 weeks ( $14.70 \pm 5.62\%$  TBWL) then plateaued, with minimal weight regain at 52 weeks ( $13.86 \pm 8.06\%$  TBWL). Comparatively, subjects in the control group experienced very little weight loss through 52 weeks ( $0.76 \pm 4.97\%$  TBWL). The mean % TBWL in the treatment group at 52 weeks was  $-13.86 \pm 8.0585$  (n=68), and the mean % TBWL in the control group at 52 weeks was  $-0.76 \pm 4.971$  (n=89). At 104 weeks, the % TBWL in the treatment group was  $-12.20 \pm 8.5461$  (n=59).

The modified ITT populations also observed the same type of changes in % EWL and changes in BMI. At the 52 week visit, treatment and control subjects reported a loss of  $49.81 \pm 31.40$  and  $2.98 \pm 17.97\%$  EWL, respectively. Similarly, BMI in treatment and control subjects reduced by  $4.76 \pm 2.57$  and  $0.26 \pm 1.77$  kg/m<sup>2</sup>, respectively, at 52 weeks.

At the conclusion of the first year of treatment, 89 control subjects were evaluated for crossover ESG procedure. As early as the 1 week visit, subjects that crossed over to ESG lost more weight than they had with lifestyle modification. Weight loss steadily progressed through 24 weeks then plateaued, with minimal weight regain at 52 weeks. This was the same pattern demonstrated by subjects randomized to ESG. After 52 weeks of lifestyle modification alone, these cross-over subjects lost  $0.18 \pm 4.47\%$  TBWL. Then, 52 weeks after crossing over to ESG, these same subjects had lost  $12.95 \pm 8.64\%$  TBWL. The cross-over population also demonstrated the same type of changes in % EWL and changes in BMI.

At the conclusion of the first year of treatment, 68 treatment subjects were available to continue another year of follow-up. Of these subjects, 18 underwent an EGD for potential retightening. Fourteen subjects were retightened, 9 of these subjects were eligible per the protocol requirements and 5 subjects were not eligible per protocol (protocol deviations). Four were not retightened because they had intact plications. The treatment group with extended follow-up had 59 subjects complete the additional 52-week visit (104 weeks total). At 52 weeks prior to the retightening procedure, mean weight loss was  $3.84 \pm 4.31\%$  TBWL in 9 subjects that had not experienced at least 25% EWL, and  $10.94 \pm 3.02\%$  TBWL in 5 subjects that had lost more than 25% EWL. This is compared to  $15.8 \pm 7.5\%$  TBWL in the 54 treatment subjects still under study at 52 weeks that were not retightened. At 104 weeks, 52 weeks after retightening, the mean weight loss from baseline (index ESG procedure) was  $7.10 \pm 5.1\%$  TBWL in the  $< 25\%$  EWL group (9 subjects) and  $11.6 \pm 7.6\%$  TBWL in the  $> 25\%$  EWL group (5 subjects). Similarly, % EWL and change in BMI were greater for the subjects with  $> 25\%$  EWL prior to the retightening procedure.

The safety population includes subjects from both the initial ESG group (77 subjects) and cross-over ESG group (73 subjects) for a total of 150 subjects. Of these 150 subjects, 146 and 131 subjects had complete safety data through 24 and 52 weeks since the ESG, respectively. The primary safety endpoint was the percentage of subjects having device and procedure related adverse events with Clavien-Dindo Grade III or higher at 52 weeks following ESG treatment. All adverse events were recorded. The three adverse events rated Clavien-Dindo Grade III or higher were recorded. All three cases resolved with medical intervention.

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

The FDA concluded that clinical data support that the device can be used to facilitate the endoscopic sleeve gastroplasty (ESG) procedure. Factors that increase uncertainty in determining probable benefits for the APOLLO ESG and APOLLO ESG SX Systems include:

- The MERIT Trial analysis was done on a modified intent-to-treat (mITT) subset of enrolled subjects. Under ITT, study participants are analyzed as members of the treatment group to which they were randomized regardless of their adherence to, or whether they received, the intended treatment. Reported outcomes from the MERIT Trial are potentially biased at the level of adherence in the study.
- The withdrawal rate was 20% (17/85) for the Treatment group and 28% (35/124) for the Control group of randomized patients in the MERIT Trial. The large amount of missing data made the effectiveness analyses more dependent on the statistical models used.
- Primary outcome measurement of weight was done remotely for some patients during the MERIT Trial. SARS-CoV-2 and the associated lock-down of communities and elective medical care had an impact on this study. One of the biggest impacts is missing data from completed remote or telemedicine visits.
- The lifestyle modification program provided to treatment and control subjects was a low intensity program. A low-intensity lifestyle modification program is not anticipated to result in significant weight loss. Considering that this patient population is refractory to weight loss via diet and exercise, there is limited value to the control arm intervention. The treatment effect of the APOLLO ESG and APOLLO ESG SX Systems is unknown relative to a robust lifestyle modification program.

#### Non-randomized studies

A small number of non-randomized studies describe experiences of patients undergoing endoscopic sleeve gastrectomy (Alqahtani et al., 2022, Cheskin et al., 2020, Novikov et al., 2018, Lopez-Nava et al., 2021, Spry et al., 2023).

Alqahtani et al. (2022) conducted a propensity score-matched study enrolling 6,036 patients with obesity in which 3,018 patients received ESG using Apollo ESG and 3,018 patients received laparoscopic sleeve gastrectomy (LSG). Average age and body mass index (BMI) were  $34 \pm 10$  years and  $33 \pm 3$  kg/m<sup>2</sup>, respectively, and 89% were women. Other baseline patient characteristics reported include diabetes mellitus: 3.7% (112/3,018) vs 11.6% (350/3,018), dyslipidemia 2.1% (62/3,018) vs 5.4% (163/3,018), and hypertension: 3.3% (101/3,018) vs 3.9% (118/3,018) for ESG vs LSG, respectively. Primary outcome was weight loss at 6, 12, 24, and 36 months. A noninferiority margin of 10% total weight loss (%TWL) was used. Secondary outcomes were safety and comorbidity resolution. Total body weight loss (TBWL)  $\pm$ SD at 1, 2, and 3 years after Apollo ESG was 19.2% ( $\pm$  7.7), 16.2% ( $\pm$  9.7), 14.0% ( $\pm$ 12.1) respectively. Total body weight loss (TBWL)  $\pm$ SD at 1, 2, and 3 years after LSG was 28.9% ( $\pm$  8.2), 22.2% ( $\pm$  8.2), 18.8% ( $\pm$ 7.5) respectively. Although the % TBWL at all timepoints was numerically lower in the ESG grp compared w/ the LSG grp, ESG was statistically noninferior to LSG (using a 10% TBWL margin for noninferiority) at all time points. The % excess body weight (EBW)  $\pm$ SD for ESG and LSG at 1 year were 77.1% ( $\pm$  24.6); 95.1% ( $\pm$  20.5), respectively, at 2 years were 75.2% ( $\pm$  47.9); 93.6% ( $\pm$  31.3), and at 3 years were 59.7% ( $\pm$  57.1); 74.3% ( $\pm$  35.2). Statistical significance of those differences was not reported. Noninferiority was based on % TBWL, whereas the between group differences were greater for EWL and may have resulted in ESG being inferior to LSG. Remission rates for diabetes, dyslipidemia, and hypertension after ESG were 64%, 66%, and 51%, respectively. Rates of dyslipidemia and hypertension remission were similar between ESG and LSG, but statistical significance was not reported; rate of diabetes remission was lower after ESG, but statistical significance was not reported. Eighty ESG patients (2.7%) underwent revision to LSG for insufficient weight loss or weight regain, and 28 had resuturing after primary ESG (.9%). Exact patient attrition rates are unclear.

Cheskin et al. (2020) conducted a retrospective case-matched study, comparing weight loss in patients undergoing Apollo ESG with that of matched patients undergoing high-intensity diet and lifestyle therapy (HIDLT). Patients were matched by age, sex, and body mass index (BMI). One hundred five patients (30 men) who underwent ESG + low-intensity diet and lifestyle therapy (LIDLTL) between 2016 and 2018 were compared with 281 patients (92 men) who underwent HIDLT at the Johns Hopkins Medical Institutions from 2013 to 2014. Weight was evaluated 1, 3, 6, and 12 months after beginning HIDLT or post-ESG to determine the mean percent total body weight loss (%TBWL). Mean age across both cohorts was  $48.0 \pm$

12.1, and baseline BMI was  $40.0 \pm 7.7$  kg/m<sup>2</sup>. At 3 months, the mean %TBWL in the ESG cohort was 14.0% compared with 11.3% in the HIDLT cohort ( $P < 0.011$ ), and at 12 months the mean %TBWL in the ESG cohort was 20.6% versus 14.3% in the HIDLT cohort ( $P < 0.001$ ). Patients treated with ESG lost statistically significantly more total body weight compared with patients in the HIDLT grp, but the difference is of unclear clinical significance. In both as-treated and ITT analyses, statistically significantly more pts in the ESG group achieved  $\geq 10\%$  TBWL compared w/ the HIDLT group. Approximately 5% of pts in the ESG group experienced a moderate to severe AE, compared with none in the HIDLT grp. A limitation of this study is high attrition starting at 3 months and very high attrition at 6 months and later, although last observed weight was carried forward in sensitivity analyses for some outcomes to partially avoid missing data; weight loss results could be biased if weight gain occurred or further weight was lost.

#### Clinical Practice Guidelines

The American Society for Gastrointestinal Endoscopy along with the European Society of Gastrointestinal Endoscopy (ASGE-ESGE) published a guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity (2024). They include the following:

“In adults with overweight or obesity, the ASGE–ESGE suggests the use of endoscopic bariatric and metabolic therapies plus lifestyle modification (LM) over LM alone for patients with a body mass index (BMI) of  $\geq 30$  kg/m<sup>2</sup> or BMI of 27.0 to 29.9 kg/m<sup>2</sup> with at least 1 obesity-related comorbidity. (Conditional recommendation, very low certainty) (p. 868).”

### **Analysis of Evidence (Rationale for Determination)**

The evidence regarding endoscopic sleeve gastroplasty (ESG) is limited. Large, long-term data remain lacking with which to evaluate the sustained benefit of ESG in weight reduction compared to conservative measures and accepted bariatric procedures.

### **Coding**

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

#### **Periodic adjustment of gastric restrictive device after the global period**

Claims for an adjustment of a gastric restrictive device after the global period (90 days after surgery) may be reimbursable in the office setting. An adjustment of the gastric band (CPT code 43999) and an evaluation and management service (E & M) service are not payable on the same day of service. An E & M and the adjustment of a gastric band (CPT code 43999) will only be allowed on the same day if there was a significantly separate service provided. The CPT modifier 25 should be appended to the E & M code to indicate the E & M service was a significantly separate service.

Periodic adjustment of gastric restrictive device after the global period is only reimbursable in the office setting.

HCPCS code S2083 (Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline) is non-payable by Fallon Health. Claims for MassHealth ACO and Community Care members will deny vendor liable. The Medicare Physician Fee Schedule Status Indicator for HCPCS code S2083 is I (Not valid for Medicare purposes). Consistent with Medicare, Fallon Health will not reimburse HCPCS code S2083 for Medicare Advantage and NaviCare members.

#### **CPT 43842**

CPT code 43842 is for vertical banded gastroplasty and is non-covered for Medicare Advantage plan members per NCD 100.1 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity.

CPT 43842 is nonpayable by MassHealth (MassHealth Transmittal Letter PHY-171 eff 11/25/2024; MassHealth Transmittal Letter AOH-59 eff 12/05/2024). Therefore, CPT 43842 is nonpayable for MassHealth ACO members.

**CPT 43843**

CPT code 43843 is for a gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical banded gastroplasty.

CPT 43843 is nonpayable by MassHealth (MassHealth Transmittal Letter PHY-171 eff 11/25/2024). Therefore, CPT 43843 is nonpayable for MassHealth ACO members.

**CPT codes 43886, 43887 and 43888**

CPT codes 43886, 43887 and 43888 are for open port revision, removal, and removal and replacement, respectively. These open port procedures are associated with the non-covered open gastric restrictive procedures: adjustable gastric banding and vertical banded gastroplasty and per the National Coverage Determination (NCD) 100.1.

<b>Code</b>	<b>Description</b>
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (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 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	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; 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
43889	Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed
43999	Unlisted procedure, stomach

## Hiatal hernia repair at the time of bariatric surgery

Code	Description
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh
43283	Laparoscopy, surgical, esophageal lengthening procedure (eg, Collis gastroplasty or wedge gastroplasty) [when performed with repair of paraesophageal hernia]

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## Policy history

Origination date:	07/01/2014
Review/Approval(s):	Technology Assessment Committee: 06/25/2014 (new modified policy to include InterQual and Fallon Health Criteria) 07/22/2015 (annual review no changes) 10/28/2015 (modifications to additional criteria) 10/26/2016 (annual review), 2/28/2018 (annual review), 02/27/2019 (annual review); 05/27/2019 (changed title: formerly Weight Loss Surgery; adopted Fallon Health criteria); 02/08/2022 (Added clarifying language related to Medicare Advantage, NaviCare, PACE and MassHealth under policy section); 12/12/2023 (annual review; adopting InterQual Criteria for Community Care members effective for dates of service on or after March 1, 2024), 01/28/2025 (annual review; updated to include criteria for hiatal hernia repair at the time of bariatric surgery; adopting InterQual Criteria for hiatal hernia repair at the time of bariatric surgery for Community Care members effective for dates of service on or after March 1, 2025; updated References and Coding), 01/27/2026 (annual review; no changes to coverage criteria; added

Exclusion for endoscopic sleeve gastroplasty; updated Summary of Evidence to include Endoscopic Sleeve Gastroplasty). Utilization Management Committee: 02/18/2025 (annual review and approval), 01/17/2026 (annual review; approved with no changes to coverage criteria and addition of Exclusion for endoscopic sleeve gastroplasty), 04/01/2026 (Coding table for Hiatal hernia repair at the time of bariatric surgery updated).

## Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.