

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:

- ☑ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- ☑ NaviCare HMO SNP
- ☑ NaviCare SCO
- ☑ 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

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care (e.g., gastric balloon, transoral gastroplasty, long limb gastric bypass), or procedures that are not effective or outdated (e.g., jejunoileal bypass, horizontal gastric stapling, vertical band gastroplasty).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:

- 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 for bariatric surgery. NCD 100.1 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (Version Number 5; Effective 09/24/2013) 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. 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/m2,
- 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 any bariatric surgery procedures that are not specifically identified in NCD 100.1 as Covered or Non-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, is left to the local MACs (Medicare Coverage Database search 01/21/2025). Coverage criteria are not fully established by Medicare for bariatric surgery procedures that are not specifically identified in NCD 100.1 as covered or non-covered for Medicare Advantage members 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. 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.

<u>Link</u>: 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:

- 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 (intragastric) balloon, transoral gastroplasty, long limb gastric bypass), or procedures that are not effective or outdated (e.g., jejunoileal 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.

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 paraoesophageal 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).

Analysis of Evidence (Rationale for Determination)

N/A

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 for other than vertical banded gastroplasty is used for open adjustable gastric banding and open sleeve gastrectomy. Open adjustable gastric banding and open sleeve gastrectomy are non-covered for Medicare Advantage plan members per NCD 100.1 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity.

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 43845

CPT code 43845 is for biliopancreatic diversion with duodenal switch. CPT 43845 is payable by MassHealth (MassHealth Transmittal Letter PHY-171 eff 11/25/2024), and therefore, CPT 43845 is payable 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 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity, open port revision, removal, and removal and replacement procedures are noncovered for Medicare Advantage plan members.

CPT codes 43886, 43887 and 43888 are payable by MassHealth (MH Transmittal Letter PHY-171 (eff 11/25/2024), and therefore are payable for MassHealth ACO members.

Code	Description
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
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]
43325	Esophagogastric fundoplasty, with fundic patch (Thal-Nissen procedure)
43327	Esophagogastric fundoplasty partial or complete; laparotomy
43328	Esophagogastric fundoplasty partial or complete; laparotomy
43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis
43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis
43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis
43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis

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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).

Utilization Management Committee: 02/18/2025 (annual review and approval).

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 follow's 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.