Bariatric Surgery

MEDICAL POLICY NUMBER: 41

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

- Bariatric Surgery: Guideline Note 8

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- Member benefits, which address coverage or non-coverage of specific bariatric surgery services, may vary. Member benefit contract language takes precedent over medical policy.
- **Current and/or recent smokers** (i.e. within the past year) (see Policy Guidelines for definition of smoker) must have ceased smoking for at least 6 weeks prior to bariatric surgery. To ensure compliance, laboratory testing will be required at Medical Director discretion.

Initial Bariatric Surgery for Adults

I. The following bariatric surgical procedures may be considered **medically necessary** for the treatment of morbid obesity in adults:

- Roux-en-Y gastric bypass with an alimentary limb of 150 cm or less; **or**
- sleeve gastrectomy

(Note: biliopancreatic bypass with duodenal switch is addressed in criterion II. below.)

when **all** of the following (A.-E.) criteria are met:

A. Member is 18 years of age or older; **and**
B. **One** of the following (1. **or** 2.) criteria is met:

1. Body mass index (BMI) at the start of the bariatric surgery program is ≥ 40 kg/m^2**; **or**
2. BMI at the start of the bariatric surgery program is between 35.0-39.9 kg/m^2** and the member has **any** of the following (a.-e.) comorbid conditions:
   a. Type II diabetes mellitus; **or**
   b. Hypertension which has not responded to optimal medical management; **or**
   c. Life-threatening cardio-pulmonary disease (severe obstructive sleep apnea [defined as an AHI or RDI ≥ 30], obesity hypoventilation syndrome) which has not responded to optimal medical management; **or**
   d. Non-alcoholic steatohepatitis (NASH); or
   e. Gastroesophageal reflux disease (GERD) which has not responded to optimal medical management.
   (Note: The presence of gastroesophageal reflux (GERD) or other condition does not negate the requirement for pre-surgical evaluation); **and**

C. Member has had a behavioral health or psychological evaluation and clearance to rule out any behavioral health disorders that may hinder compliance with medical/surgical recommendations (e.g. substance use disorders, major depression, schizophrenia); **and**

D. Medical records document **all** of the following (1.-4.) pre-operative requirements for bariatric surgery have been completed **within 6 months prior to surgery**:
   1. The member has undergone a bariatric surgery evaluation, which includes documentation of nutritional counseling and compliance with dietary and exercise recommendations made at the initial surgery visit and follow-up visits; **and**
   2. The member has undergone a pre-operative medical consultation by the bariatric surgeon or another physician caring for the member (e.g. primary care provider) and is determined to be a suitable bariatric surgery candidate; **and**
   3. The member has received a thorough explanation of the risks, benefits, and the expected post-operative outcomes of bariatric surgery; **and**
   4. The member's treatment plan includes post-operative dietary evaluations, nutrition and exercise counseling, and supportive resources available as needed; **and**

E. The bariatric surgery is performed at a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited center (see Policy Guidelines below for more information). (Note: Specific member benefits may vary and take precedence over medical policy. Please see member benefits for additional information regarding centers of excellence.)

Note: If race is known, lower BMI thresholds (usually reduced by 2.5 kg/m2) are used for people from South Asian, Chinese, other Asian, Middle Eastern, Black African, African-Caribbean, Native Hawaiian, Pacific Islanders, or American Indians/Alaska Natives family backgrounds. If race is not known, standard BMI parameters will be applied.[1]

II. Biliopancreatic bypass with duodenal switch may be considered **medically necessary** when **all** of the following (A.-B.) criteria are met:

   A. Body mass index (BMI) ≥ 50 kg/m^2; **and**
   B. Criteria I.B.-I.D. above are met.

III. Bariatric surgery is considered **not medically necessary** when criterion I. or II. above is not met, including but not limited to, the following:

A. Members with a BMI of 30-34.9 kg/m^2, regardless of comorbidities; **or**
B. For the treatment of non-alcoholic fatty liver disease (NAFLD) or non-alcoholic steatohepatitis (NASH) that does not meet criterion I. above; **or**
C. For the treatment of gastroesophageal reflux disease (GERD) that does not meet criterion I. above.

Initial Bariatric Surgery for Adolescents

IV. Bariatric surgical procedures may be considered **medically necessary** for the treatment of morbid obesity in adolescents when all of the following criteria are met (A.-F.):

A. Member is younger than 18 years of age; **and**
B. **One** of the following (1. **or** 2.) criteria is met:
    1. Body mass index (BMI) at the start of the bariatric surgery program is ≥ 40 kg/m^2 or equal to 140% of the 95% for age and sex; **or**
    2. BMI at the start of the bariatric surgery program is between 35.0-39.9 kg/m^2 or equal to 120% of the 95th percentile for age and sex and the member has **any** of the following (a.-f.) comorbid conditions:
        a. Type II diabetes mellitus; **or**
        b. Hypertension which has not responded to optimal medical management; **or**
        c. Non-alcoholic steatohepatitis (NASH); **or**
        d. Orthopedic disease (e.g. Blount's disease, slipped capital femoral epiphysis); **or**
        e. Life-threatening cardio-pulmonary disease (severe obstructive sleep apnea [defined as an AHI or RDI ≥ 30], obesity hypoventilation syndrome) which has not responded to optimal medical management; **or**
        f. Gastroesophageal reflux disease (GERD) which has not responded to optimal medical management
        (Note: The presence of gastroesophageal reflux (GERD) or other condition does not negate the requirement for pre-surgical evaluation); **and**
C. Member demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment, **and**
D. Member's family is supportive but not coercing the member into having a procedure, **and**
E. Member has had a behavioral health or psychological evaluation and clearance to rule out any behavioral health disorders that may hinder compliance with medical/surgical recommendations (e.g. substance use disorders, major depression, schizophrenia); **and**
F. Medical records document **all** of the following (1.-4.) pre-operative requirements for bariatric surgery have been completed **within 6 months prior to surgery**:
    1. The member has undergone a bariatric surgery evaluation, which includes documentation of nutritional counseling and compliance with dietary and exercise recommendations made at the initial surgery visit and follow-up visits; **and**
    2. The member has undergone a pre-operative medical consultation by the bariatric surgeon or another physician caring for the member (e.g. primary care provider) and is determined to be a suitable bariatric surgery candidate; **and**
    3. The member has received a thorough explanation of the risks, benefits, and the expected post-operative outcomes of bariatric surgery; **and**

4. The member's treatment plan includes post-operative dietary evaluations, nutrition and exercise counseling, and supportive resources available as needed; **and**

G. The bariatric surgery is performed at a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited center (see Policy Guidelines below for more information). Note: Specific member benefits may vary and take precedence over medical policy. Please see member benefits for additional information regarding centers of excellence.

Non-Covered Bariatric Surgery

V. The following bariatric surgery procedures are considered **not medically necessary** for all indications:

A. Adjustable gastric banding (i.e., Lap-Band® system)
B. Biliopancreatic bypass without duodenal switch (i.e., the Scopinaro procedure)
C. Vertical banded gastroplasty
D. Vagus nerve blocking (e.g., Maestro)
E. Intragastric balloon (IGB)
F. Single-anastomosis duodenal switch (SADI-S)
G. Transpyloric shuttle (TPS)
H. Gastric electrical stimulation
I. Duodenal-jejunal bypass liner (e.g., EndoBarrier™ Gastrointestinal Liner)
J. Transoral gastroplasty (e.g., TOGA® system)
K. Mini-gastric bypass
L. Parietal cell separating gastrojejunostomy when used to treat gastroesophageal reflux disease (GERD) in the setting of morbid obesity
M. Endoscopic procedures as the primary bariatric procedure (e.g., endoscopic gastric sleeve)
N. Transcatheter bariatric embolotherapy

Repeat Bariatric Surgery Due to Inadequate Weight Loss

VI. A repeat bariatric surgery, following an initial, primary bariatric procedure, may be considered **medically necessary** due to inadequate weight loss when **all** of the following (A.-D.) criteria are met:

A. There is documentation of full compliance with the previously prescribed postoperative dietary and exercise program; **and**
B. There is technical failure of the original bariatric surgical procedure (e.g., pouch dilatation) documented by imaging or an endoscope; **and**
C. The member has failed to achieve adequate weight loss, which is defined as failure within two (2) years to lose at least 50% of excess body weight due to technical failure; **and**
D. The proposed repeat bariatric procedure is considered medically necessary.

Note: Repeat bariatric surgeries are limited to once per lifetime. A third, bariatric procedure following an initial, primary procedure and a secondary, repeat procedure is not covered.

Revision or Conversion Bariatric Surgery Due to Complications NOT Related to an Adjustable Gastric Band

VII. Surgical repair, reversal (i.e., take down), or conversion to a different, medically necessary bariatric surgery may be considered **medically necessary** as treatment of **any one or more** of the following documented major complication related to the primary bariatric procedure (A.-N.):
    A. Barrett's Esophagus
    B. Bleeding
    C. Fistula
    D. Internal (e.g., hiatal) hernia or ventral hernia
    E. Gastric prolapse
    F. Infection
    G. Leak/perforation
    H. Metabolic derangement
    I. Obstruction
    J. Stricture
    K. Stomal Stenosis
    L. Ulcer
    M. Excess weight loss to ≤ 80% or less of ideal body weight
    N. Gastroesophageal reflux disease (GERD) when **all** of the following criteria are met (1.-3.):
        1. There is documentation of full compliance with the previously prescribed postoperative dietary and exercise program; **and**
        2. If member has respiratory symptoms, documents must indicate member has refrained from smoking for three (3) months; **and**
        3. GERD symptoms are refractory to anti-reflux medication.

Revision or Conversion of Bariatric Surgery Related to the Adjustable Band

VIII. Surgical repair of an adjustable gastric band or surgical conversion of an adjustable gastric band to a sleeve gastrectomy or bypass may be considered **medically necessary** as a treatment of **either** of the following (A.-B.):

    A. Member has documented major complication related to band placement, which cannot be corrected with manipulation or adjustment (i.e., deflation) and **any** of the following are met (1.-4.):
        1. Any **one or more** of the major complications listed in criterion VII.; **or**
        2. Band or balloon rupture; **or**
        3. Image documentation of erosion, perforation, or slippage; **or**
        4. Port malfunction; **or**
        5. Vomiting when **both** of the following (a.-b.) criteria are met:
            a. There is documentation of full compliance with the previously prescribed postoperative dietary and exercise program; **and**
            b. Vomiting is persistent despite band manipulation or adjustment, which includes band deflation.
        6. Esophageal or stomach dilation when **both** of the following (a.-b.) criteria are met:

a. There is documentation of full compliance with the previously prescribed postoperative dietary and exercise program; **and**
b. Esophageal or stomach dilation or esophageal dysmotility is persistent despite band manipulation or adjustment, which includes band deflation.

Removal of an Adjustable Gastric Band

IX. Surgical removal of an adjustable gastric band may be considered **medically necessary** if either of the following have been met (A.-B.):

A. The device has been thoroughly evaluated and found to be no longer functional; **or**
B. When criterion VIII. has been met.

Non-covered Repeat Procedures

X. Repeat bariatric surgery or surgical repair, revision, or conversion is considered **not medically necessary** when any of the above criteria (VI.-IX.) are not met, including, but not limited to, any of the following:

A. Dissatisfaction with a previous bariatric procedure
B. Early satiety
C. Weight gain after weight loss of 50% or more of excess body weight in the absence of any complications or symptoms as described above in criteria VII.-IX.

XI. Transoral outlet reduction (TORe) following bariatric surgery is considered **not medically necessary** following bariatric surgery to treat dilated gastrojejunostomy (GJ) outlet.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Gastric Electrical Stimulation, MP107

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

The following information must be submitted to determine if medical necessity criteria are met:

- Medical records document the following components of the bariatric evaluation:
  - Body mass index (BMI).

- Nutritional counseling.
- A behavioral health evaluation.

- If BMI is between 35-39.9 kg/m^2, clinical documentation that hypertension, obstructive sleep apnea, or gastroesophageal reflux disease has not responded to optimum medical management and/or type II diabetes mellitus.
- Documentation of a preoperative medical consultation which indicates all of the following:
  - The member has been determined to be a suitable bariatric surgery candidate; and
  - The member has received a thorough explanation of the risks, benefits, and the expected post-operative outcomes of bariatric surgery; and
  - The member treatment plan includes post-operative dietary evaluations, nutrition and exercise counseling, and supportive resources available as needed.

Note: The presence of gastroesophageal reflux (GERD) or other conditions does not negate the requirement for pre-surgical evaluation.

Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)

The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) is administered through the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS). This program "works to advance safe, high-quality care for bariatric surgical patients through the accreditation of bariatric surgical centers. A bariatric surgical center achieves accreditation following a rigorous review process during which it proves that it can maintain certain physical resources, human resources, and standards of practice. All accredited centers report their outcomes to the MBSAQIP database."[2]

The MBSAQIP Standards Manual provides detailed information on the accreditation requirements.[3] In general, to become an accredited comprehensive inpatient center the facility must demonstrate the following:

- Center has demonstrated compliance with all MBSAQIP Core Standards and successfully completed a site visit. The MBSAQIP Core Standards include:
  - Case Volume, Patient Selection, and Approved Procedures by Designation Level
  - Commitment to Quality Care
  - Appropriate Equipment and Instruments
  - Critical Care Support
  - Continuum of Care
  - Data Collection (and reporting to MBSAQIP)
  - Continuous Quality Improvement
- Center performs a minimum of 50 approved bariatric stapling procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Data Registry Platform.

The following link provides a search function for identifying MBSAQIP certified centers: https://www.facs.org/search/bariatric-surgery-centers

Body Mass Index (BMI)[4]

Metric BMI Formula: BMI= weight (kg) ÷ height^2 (m^2)
Imperial BMI Formula: BMI= weight (lb) ÷ height^2 (in^2) x 703

- Obesity is defined as a BMI of 30.0 kg/m^2 or higher.
- Obesity is frequently divided into categories:
  - Class I: BMI of 30 kg/m^2 to < 35 kg/m^2
  - Class II: BMI of 35 kg/m^2 to < 40 kg/m^2
  - Class III: BMI of 40 kg/m^2 or higher.
    - A BMI of 40-49.9 kg/m^2 is considered morbidly obese.
    - A BMI of 50 kg/m^2 or more is considered superobesity or super morbid obesity.

Obesity

Approximately 78.6 million adults and 12.7 million children in the United States are obese.[5] The causes of obesity are complex and may result from behavioral, genetic, and societal factors. Obesity is associated with an increased risk for several conditions, including hypertension, dyslipidemia, type II diabetes mellitus, coronary heart disease, stroke, gall bladder disease, osteoarthritis, sleep apnea and breathing problems, certain cancers, and behavioral health disorders.

"The mainstay of treatment for obesity is a reduced-calorie diet along with increased activity and exercise. Patients may undergo an intensive lifestyle intervention that combines dietary modification, exercise, and behavioral counseling."[4] Additionally, severely obese patients or obese patient with a comorbid condition may also receive medication. Severely obese patients may also undergo bariatric surgery to promote significant weight loss. The main types of bariatric surgery are Roux-en-Y gastric bypass, adjustable gastric banding, sleeve gastrectomy, and biliopancreatic bypass with duodenal switch.

Bariatric Surgery Procedure	Description
Roux-en-Y gastric bypass[6]	• Combines restriction and malabsorption by creating both a small gastric pouch and a bypass that prevents the patient from absorbing all they have eaten.
Sleeve gastrectomy[6]	• Divides the stomach vertically to reduce its size about 25%. • Leaves the pyloric valve at the bottom of the stomach intact so the stomach function and digestion are unaltered
Biliopancreatic bypass (BPB) with duodenal switch[6]	• Primarily a malabsorptive procedure • Involves removal of part of the stomach to limit oral intake and induce weight loss. • The pylorus is left intact (compared to BPB without a duodenal switch)

	• A gastric pouch is created and part of the small intestine is also bypassed • Used only in patients with 'superobesity' (BMI > 50 kg/m^2) due to high rates of complications.
Laparoscopic adjustable gastric banding (e.g., Lap-Band® system)[6]	• Least invasive of purely restrictive bariatric surgery procedures • Limits food intake by placing an adjustable constricting ring completely around the top end of the stomach. • Reversible
Biliopancreatic bypass (BPB) without duodenal switch (i.e., Scopinaro procedure)[6]	• A different part of the stomach (from BPB with a duodenal switch), including the pylorus, is removed. • The remaining part of the stomach is connected to the lower portion of the small intestine.
Vertical banded gastroplasty[7]	• Restrictive gastric operation that decreases food intake. • The upper stomach near the esophagus is stapled vertically to create a small pouch along the inner curve of the stomach. This causes the feeling of fullness sooner.
Rechargeable vagal blocking system (e.g., Maestro)[8]	• A pacemaker-type device that is designed to intermittently deliver electrical pulses to the vagus nerve in order to transiently block vagal nerve signals between the stomach and brain, thereby reducing appetite and, consequently, weight.
Intragastric balloon (IGB)[5]	• Balloons are inserted into the stomach via an endoscope and inflated with air or filled with saline. • The balloons occupy space in the stomach creating a sense of fullness with the goal of decreasing the amount of food ingested.
Single-anastomosis duodenal switch[9]	• The majority of the stomach is permanently removed. • The small intestine is transected at one point and roughly half of the upper small intestine is bypassed.
BARONova transpyloric shuttle	• An endoscopically implanted device intended to temporarily reduce stomach volume, increase feelings of fullness, and delay gastric emptying.
Gastric electrical stimulation (GES)[10]	• The exact mechanism of GES remains largely unknown. • GES is thought to impair physiological gastric electrical activity, inducing gastric distension, gastric accommodation reduction, and stomach peristalsis inhibition, leading to delayed gastric emptying and increased satiety.

Endoscopic duodenal-jejunal bypass liner[11]	• An implanted thin, flexible tube that creates a physical barrier between ingested food and the duodenum/proximal jejunum. • This prevents the interaction of food enzymes and hormones in the proximal intestine.
Transoral gastroplasty (e.g., TOGA® system)[12]	• Stomach is stapled endoscopically to create a small pouch. • When food enters the stomach it enters this small pouch allowing the feeling of fullness faster
Mini-gastric bypass[13]	• Restrictive and malabsorptive • Stomach is divided with a laparoscopic stapler • Most of the stomach is detached from the esophagus • 2 to 7 feet of intestines are bypassed

Repeat or Revision of Bariatric Surgery

According to UpToDate®, "The number of bariatric surgical operations performed in the United States has been relatively stable for the last five years. It is estimated that 179,000 weight-loss surgeries were performed in 2013. Of those, 42 percent were sleeve gastrectomy, 34 percent were gastric bypass, 14 percent were gastric band, and 1 percent were biliopancreatic diversion with duodenal switch. The remaining 6 percent were revisional procedures."[14]

Hayes outlined three main categories of revisional procedures as well as the most common types of revisional procedures:[15]

- "Conversion: A change from 1 type of procedure to a different type.
- Corrective: A procedure that attempts to remedy complications or incomplete treatment effects of a previous bariatric operation.
- Reversal: A procedure that restores the original anatomy.

The type of revisional bariatric surgery (RBS) procedure performed is determined by factors such as type of primary bariatric procedure (PBS), patient's anatomy and medical history, indications for RBS, and surgeon's experience.

Common Types of Revisional Bariatric Surgery

Key: AGB, adjustable gastric banding; BPD-DS, biliopancreatic diversion with duodenal switch; GERD, gastroesophageal reflux disease; PBS, primary bariatric surgery; RBS, revisional bariatric surgery; RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; VBG, vertical banded gastroplasty; WL, weight loss

PBS	Indications for RBS	RBS Options

Loop gastric bypass	Weight regain; marginal ulcerations; stricture of gastrojejunal stoma; poor gastric pouch emptying; bile reflux	Conversion to RYGB
RYGB	Weight regain; WL failure and/or recurrence of obesity-related comorbidities	AGB placement Conversion of proximal RYGB to distal RYGB (by increasing length of Roux or biliopancreatic limb) Conversion to BPD-DS
VBG	Weight regain secondary to maladaptive eating; weight regain due to staple line breakdown w/o severe GERD and esophagitis	VBG band removal w/out gastrogastrostomy Conversion to RYGB Revision of VBG
AGB	Inadequate WL due to technical problems w/ band, esophageal motility issues, GERD, or psychological band intolerance	AGB removal AGB replacement Conversion to SG Conversion to RYGB Conversion to BPD-DS
BPD-DS	Complications (e.g., micronutrient and macronutrient deficiency w/ malnutrition), weight regain, WL failure	Revision of SG Modification of common channel

This report focuses on studies of conversion and corrective RBS procedures without consideration of stand-alone reversal operations."[15]

In 2017, UpToDate® published a review of late complications of bariatric surgery which detailed a variety of complications related to specific procedures:[14]

"Complications following surgical treatment of severe obesity vary based upon the procedure performed and can be as high as 40 percent. Due to the high surgical volume, improving the safety of these operations has become a high priority, leading to the development of strict criteria for center accreditation, guidelines for safe and effective bariatric surgery, and careful monitoring of surgical outcomes."

Complications of Specific Bariatric Procedures

Roux-en-Y Gastric Bypass (RYGB)

Complications related to RYGB may include, gastric remnant distension, stomal stenosis, marginal ulcers, cholelithiasis, ventral incisional hernia, internal hernias, short bowel syndrome, dumping syndrome, metabolic and nutritional derangements, nephrolithiasis and renal failure, postoperative hypoglycemia, change in bowel habits, and failure to lose weight and weight regain.[14]

Gastric Banding (GB)

Early complications of gastric banding may include acute stomal obstruction, band infection, gastric perforation, hemorrhage, bronchopneumonia, and delayed gastric emptying and pulmonary embolism. Late complications of this procedure include band erosion, band slippage or prolapse, port or tubing malfunction, leakage at the port site tubing or band, pouch or esophageal dilatation and esophagitis.[14] According to UpToDate®, "(a)lmost 50 percent of patients will need surgical revision or removal of the band. Failed bands (due either to complications or inadequate weight loss) can generally be converted to other bariatric procedures such as RYGB or a duodenal switch."[14]

Sleeve Gastrectomy (SG)

Complications related to sleeve gastrectomy may include bleeding, stenosis, gastric leaks and reflux.[14]

Vertical Banded Gastroplasty (VGB)
Complications related to vertical banded gastroplasty may include staple line disruption, obstruction, erosion of mesh band, reflux, and vomiting.[14]

Smoker: Includes smoking cigarettes, cigars, and pipe smoking of tobacco.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of bariatric surgery as a treatment of morbid obesity in adults and adolescents. Below is a summary of the available evidence identified through February 2025. **Medically Necessary Bariatric Surgery Procedures for the Treatment of Morbid Obesity**

In 2014, Colquitt et al. conducted a Cochrane systematic review to assess the effects of bariatric surgery for obesity in adults, including the control of comorbidities.[6] Independent reviewers identified relevant evidence, extracted data, and assessed quality. Outcomes of interest included mean BMI, weight loss, and resolution of comorbidities. The authors identified 22 randomized controlled trials (RCT) encompassing 1,798 patients. These studies evaluated Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), adjustable gastric banding (AGB), and biliopancreatic bypass with duodenal switch (BDDS).

Key Results

- Of the 7 studies comparing surgery with non-surgical interventions, the results indicated people who had surgery achieved greater weight loss, improvement in comorbidities, and improvement in quality of life at one to two years compared to people who had non-surgical interventions. Serious adverse events (SAEs) ranged from 0% to 37% in the surgery groups and 0% to 25% in the no surgery groups.
- Three studies found that RYGB achieved greater weight loss up to 5 years after surgery compared to AGB. The mean difference (MD) was -5.2 kg/m² (95% confidence interval (CI) -6.4to -4.0; P < 0.00001; 265 participants; 3 trials; moderate quality evidence). RYGB resulted in greater hospitalization duration and late major complications; however, AGB required high rates of reoperation for removal of the band.
- A total of 7 studies compared RYGB with SG, and found no major difference for weight loss. The mean difference was -0.2 kg/m² (95% CI -1.8 to 1.3); 353 participants; 6 trials; low quality evidence). No statistically significant differences were found for quality of life. "Effects on comorbidities, complications and additional surgical procedures were neutral, except gastro-oesophageal reflux disease improved following LRYGB (one RCT)."[5]
- The results of studies comparing BDDS to RYGB indicated greater weight loss in the BDDS group in super morbidly obese patients at 2 to 4 years follow-up. "End-of-study mean BMI loss was greater following BDDS: MD -7.3 kg/m² (95% CI -9.3 to -5.4); P < 0.00001; 107participants; 2 trials; moderate quality evidence)."[5] Quality of life was similar between groups. Additionally, one study showed that 82-100% of participants with diabetes had an HbA1C level of less than 5% at 3 years after surgery. One death occurred and more reoperations were reported in the BDDS group.
- One RCT found that BMI was reduced by 10 units more in the SG group compared to AGB at 3 years follow-up. Reoperations occurred in 10% of SG patients and 20% of AGB patients.

This Cochrane systematic review was of very good quality and had several strengths, including:

1. the systematic gathering of evidence, assessment of quality, and extraction of data by several independent reviewers following a pre-defined protocol
2. contacting authors of selected studies for additional information or data
3. assessment of heterogeneity, reporting bias, and publication bias
4. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

Limitations of this systematic review were the inclusion of studies with lower quality evidence and the inability to conduct meta-analyses due to inter-study heterogeneity. The authors offered the following conclusions:

- Outcomes were similar between Roux-en-Y gastric bypass and sleeve gastrectomy, and both of these procedures had better outcomes than adjustable gastric banding.
- For people with very high BMI, biliopancreatic diversion with duodenal switch resulted in greater weight loss than Roux-en-Y gastric bypass.
- Overall, surgery results in greater improvement in weight loss outcomes and obesity-associated comorbidities compared to non-surgical interventions, regardless of the type of bariatric surgery used.

- In 2018, Clapp and colleagues conducted a systematic review and meta-analysis assessing long-term outcomes of the sleeve gastrectomy.[16] Independent investigators systematically searched the

literature through April 2017, identified eligible studies, assessed study quality, extracted data and pooled results with a random effects model. In total, 9 cohort studies evaluating outcomes among 2,280 patients were included for review. At 7-year follow-up, only 652 patients remained, as authors included studies had follow-up periods ranging from 2 to 11 years. Authors calculated weight recidivism rate among these patients to be 27.8% (I^2 = .60%; 95% CI: 22.8%-32.7%). Investigators estimated the overall revision rate to be 19.9% (I^2 = 93.8%; 95% CI: 11.3%-28.5%), with approximately 13.1% due to weight regain (5 studies) and 2.9% due to gastroesophageal reflux disease (5 studies). Limitations include the lack of a standard definition of "recidivism," incomplete search terms, and lack of information in studies regarding the resolution of patients' comorbidities. Investigators called for additional studies to better establish the long-term outcomes of sleeve gastrectomy.

Bariatric Surgery in Children and Adolescents

- In 2022, Hayes conducted an evidence review to evaluate bariatric surgeries for treatment of obesity in adolescents.[17] Searching the literature through April 2018, the review identified 15 studies (1 randomized controlled trial, 3 nonrandomized prospective comparative cohort studies, 6 retrospective comparative cohort studies, 3 comparative analyses of registry data, and 2 noncomparative cohort studies) encompassing 50 to 890 adolescent patients with severe obesity. Follow-up varied from 1 to 8 years, and outcome measures included excess weight loss (EWL), BMI, changes in comorbidities, quality of life, and complications.

  The available evidence "supports the use of bariatric surgery for the treatment of some adolescents with severe obesity to induce weight loss, reduce BMI, and improve obesity-related outcomes."[17] However, bariatric surgery in adolescents is associated with risk of complications and nutritional deficiencies. Additionally, the overall quality of evidence was determined to be low due to individual study quality and a lack of comparative data for different types of bariatric procedures.

  The Hayes review stated, "(t)he evidence for bariatric surgery in adolescents with severe obesity is limited by the lack of large, well-designed clinical trials that provide data on long-term efficacy and safety of these surgeries."[17] Therefore, the following Hayes ratings were given:

  - C (potential but unproven benefit): For use of vertical sleeve gastrectomy (VSG) in adolescents with severe obesity who have failed to respond to nonsurgical weight loss interventions.
  - C (potential but unproven benefit): For use of Roux-en-Y gastric bypass (RYGB) in adolescents with severe obesity who have failed to respond to nonsurgical weight loss interventions.
  - D1 (insufficient evidence): For use of adjustable gastric band (AGB) in adolescents with severe obesity who have failed to respond to nonsurgical weight loss interventions.

- In 2019, Ruiz-Costa conducted a systematic review to evaluate the long-term outcomes of metabolic and bariatric surgery in adolescents with severe obesity with a follow-up of at least 5 years.[18] Searching the literature through July 2018, investigators identified eligible studies, assessed study quality and extracted data. In total, 10 studies with follow-up of at least 5 years were included for review. Surgeries performed included gastric bypass, gastric band, and sleeve gastrectomy. Mean

BMI at follow-up was 32.4kg/m2, down from 47 at baseline. Most studies reported weight regain within 1 to 12 years of follow-up. Remission rate of co-morbidities was 75% for dyslipidemia, 78% for musculoskeletal problems, 85% for hypertension, and 85% for type 2 diabetes. Complications were inadequately reported, yet high prevalence of iron deficiency and anemia were found. On the basis of low- to moderate-quality evidence, authors concluded that metabolic and bariatric surgery result in substantial reduction in BMI but low evidence that related co-morbidities resolve. Authors called for additional, adequately powered studies with long-term follow-up were needed to further validate results reported to date.

- In 2017, Shoar and colleagues conducted a systematic review to evaluate the long-term outcomes of bariatric surgery in morbidly obese adolescents.[19] Independent reviewers systematically identified the longest available studies, extracted data, and analyzed quality and bias. The outcomes of interest include weight loss and comorbidity resolution. A total of 14 studies reporting the results of bariatric surgery after 3 years in 950 morbidly obese adolescents were included.
  The most commonly performed procedures were Roux-en-Y gastric bypass (RYGBP)(n=453) and adjustable gastric banding (n=265). Of the 950 patients at study initiation, only 677 were available at the latest follow-up. "On average, patients lost 13.3 kg/m^2 of their BMI. Among comorbidities, only diabetes mellitus resolved or improved dramatically."[19] A total of 108 patients were readmitted to the hospital, and 91 of these led to reoperation. The majority of these reoperations were primarily due to removal, exchange, or conversion of a band. Three deaths were reported. There was no long-term data available on nutritional deficiency or growth status of adolescents who underwent bariatric surgery.

  Strengths of this study include the systematic review of evidence following a predefined protocol by several independent reviewers and the inclusion of a large number of encompassing a large sample size. However, methodological limitations are present in the poor quality of the selected studies and significant inter-study heterogeneity. Ultimately, the authors concluded "(a)lthough bariatric surgery is a safe and effective procedure in the treatment of adolescent morbid obesity, long-term data is scarce regarding its nutritional and developmental complication in this growing population of patients."[19]

- In 2017, Pedroso et al. conducted a systematic review and meta-analysis to evaluate weight loss after bariatric surgery in obese adolescents.[20] Independent reviewers identified relevant literature, extracted data and assessed quality of studies assessing weight loss after gastric band, gastric sleeve, and gastric bypass in obese adolescents. Outcomes of interest included absolute change in body mass index (BMI, kg/m^2) and percent excess weight loss at 6-, 12-, 24-, and 36-months post-operative. A total of 24 studies evaluating gastric band, gastric sleeve, and gastric bypass in 1,928 patients (gastric band: 1010, gastric sleeve: 139, gastric bypass: 779) were identified.

  The average pre-operative BMI was 45.5 for gastric band, 48.8 for gastric sleeve, and 53.3 for gastric bypass. "The short-term weight loss, measured as mean (95%CI) absolute change in BMI (kg/m^2) at 6 months, was -5.4 (-3.0, -7.8) after gastric band, -11.5 (-8.8, -14.2) after gastric sleeve, and -18.8 (-10.9, -26.6) after gastric bypass."[20] Weight loss at 36 months (measured as the mean change in BMI) was -10.3 after gastric band, -13.0 after gastric sleeve, and -15.0 after gastric bypass. The authors did not report any analyses of reoperation or complication rates.

Strengths of this systematic review include the identification of relevant evidence by independent authors following a predefined protocol and the inclusion of a large number of studies encompassing a large patient population. However, methodological limitations are present in the poor quality of included studies and the short follow-up periods of these studies. Additionally, the authors did not report any data on reoperation or complication rates. The authors concluded, "(b)ariatric surgery in obese adolescent patients is effective in achieving short-term and sustained weight loss at 36 months; however, long-term data remains necessary to better understand its long-term efficacy."[20]

- In 2024, the Washington State Health Care Authority conducted a health technology assessment to evaluate bariatric surgery.[21] This tech assessment included a systematic evaluation of the published, peer-reviewed medical literature. On the basis of a systematic review of evidence, authors wrote that metabolic and bariatric surgeries continue to be a safe and effective intervention to reduce weight and resolve obesity-related comorbidities like hypertension and T2DM in adults with overweight or obesity. There remains limited published evidence for the use of MBS in children, adolescents, and individuals over the age of 50, but the available evidence does support the use of these interventions in adolescents. Serious adverse events and deaths are relatively rare in both adults and adolescents. Metabolic and bariatric surgeries are generally cost-effective compared with nonsurgical interventions. Many professional societies have recently updated their clinical practice guidelines by expanding eligibility criteria (e.g., lowering BMI thresholds and comorbidity status) as well as recognizing that there are differences in BMI for different races and ethnicities (e.g., obesity is defined as a BMI ≥ 27 kg/m2 in some Asian populations). Guidance related to revisional surgeries remains scant. Public and private payer policies vary, but generally cover individuals with BMI ≥ 35 to < 40 kg/m2 (with a comorbidity) or individuals with a BMI ≥ 40 kg/m2 regardless of comorbidity status. On the basis of this evidence, authors made the following recommendations for medical necessity criteria:

    - **Adults**

        o Adults with body mass index (BMI) ≥35 (non-Asian descent) OR BMI ≥32.5 (Asian descent), OR

        o Adults with type 2 diabetes mellitus (T2DM) AND BMI ≥30 (non-Asian descent) OR BMI ≥27.5 (Asian descent) AND

        o Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation

    - **Adolescents**

        o Adolescents (13+) with bone maturity AND BMI ≥40 OR BMI ≥35 with one obesity related complication AND

        o Procedure is sleeve gastrectomy or Roux-en-Y gastric bypass AND

        o Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation

- Approved procedures include:
    - o Adjustable gastric banding
    - o Sleeve gastrectomy
    - o Endoscopic sleeve gastroplasty
    - o Roux-en-Y gastric bypass
    - o Biliopancreatic diversion with or without duodenal switch
    - o Single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S)
    - o One-anastomosis gastric bypass (OAGB)

Non-Covered Bariatric Surgery Procedures

Adjustable Gastric Banding (i.e., Lap-Band® system)

In 2017, Vinzens et al. evaluated the long-term outcomes of laparoscopic adjustable gastric banding.[22] A total of 405 patients from a Swiss bariatric surgery center were followed up with for up to 18 years. A total of 216 patients (63%) required revisional surgery, and 27 patients (8%) refused revisional surgery after band removal. Of the 100 patients (29%) that still had a band in place, the failure rate was 25% according to the Bariatric Analysis and Reporting Outcome System (BAROS). Additionally, the authors argue that LAGB is not completely reversible as 23% of patients who had the band removed still experienced symptoms. The authors concluded that, "(m)ore than 10 years after LAGB, 71% of patients lost their bands and only 15% of the 343 followed patients with the band in place have a good to excellent result, according to BAROS."[22]

In 2018, Khoraki et al. evaluated the long-term outcomes of laparoscopic adjustable gastric banding (LAGB).[23] A total of 208 patients who underwent LAGB between 2005 and 2012 were enrolled and followed-up with for up to 10 years. LAGB failure occurred in 118 (57%) of patients and 48 patients (23%) required a reoperation. The authors concluded that "LAGB was associated with poor short and long-term weight loss outcomes and a high failure rate. With the increased safety profile and greater efficacy of other surgical techniques, LAGB utilization should be discouraged."[23]

Biliopancreatic Bypass (i.e., the Scopinaro procedure)

The Scopinaro procedure has been largely abandoned due to life-threatening complications, nutritional deficiencies, and malnourishment.[24-27] This procedure has been replaced with a modified procedure known as biliopancreatic bypass with a duodenal switch (BPDDS), which has shown increased weight loss, decreased revision rates, fewer side effects, and improved nutrient absorption at 10 year follow-up compared to the Scopinaro procedure.[28] Therefore, biliopancreatic bypass without a duodenal switch (i.e., the Scopinaro procedure) is considered not medically necessary.

Vertical Banded Gastroplasty

Vertical banded gastroplasty (i.e., stomach stapling) has also been largely abandoned due to insufficient weight loss, increased complications, and high reoperations rates.[6] Additionally, a 2014 systematic review by Hsieh et al. evaluated the 10-year outcomes of vertical banded gastroplasty and concluded there was a "lack of strong evidence to support favorable long-term outcomes following vertical transected gastric bypass for obesity."[29] Therefore, this procedure is considered not medically necessary.

Rechargeable Vagal Blocking System (e.g., Maestro)

In 2018, Hayes conducted an evidence review to evaluate the Maestro Rechargeable System (EnteroMedics, Inc.) for vagal blocking and obesity control.[8] The review concluded the following rating:

- **D2 (insufficient evidence)** – For use of the Maestro device for weight loss in obese adults. This Rating reflects a sparse and low-quality body of evidence that is insufficient to determine the relative safety and efficacy of the technology.

Intragastric Balloon (IGB)

In 2022, Hayes conducted an evidence review to evaluate intragastric balloons for the treatment of obesity.[5] The review concluded the following ratings:

- **D2 (insufficient evidence)** – For use of intragastric balloons (IGBs), as an adjunct to lifestyle interventions (i.e., diet and exercise), for treatment of obesity in patients unable to lose sufficient weight by conservative means.
- **D2 (insufficient evidence)** — For use of gas-filled IGBs versus saline-filled IGBs, as an adjunct to lifestyle interventions (i.e., diet and exercise), for treatment of obesity in patients unable to lose sufficient weight by conservative means.
- **D2 (insufficient evidence)** — For use of IGBs versus hyaluronic acid (HA) injections for treatment of obesity in patients unable to lose sufficient weight by conservative means.

Single-Anastomosis Duodenal Switch (SAD-S)

In 2024, Hayes conducted a review of single anastomosis duodenal switch for weight loss.[9] The review concluded insufficient published evidence to evaluate SAD-S for weight loss. Additionally, the available evidence presented conflicting findings regarding SAD-S for weight loss.

Gastric Electrical Stimulation (GES)

See the PHP Medical Policy: Gastric Electrical Stimulation for the evidence review evaluating GES for obesity.

Endoscopic Duodenal-Jejunal Bypass Liner (e.g., EndoBarrier™ Gastrointestinal Liner), TransPyloric Shuttle (TPS), Transoral Gastroplasty (e.g., TOGA® System)

The endoscopic duodenal-jejunal bypass liner (EndoBarrier™), TransPyloric Shuttle, and Transoral Gastroplasty (TOGA® System) have not received FDA approval; therefore, these bariatric surgery procedures are considered investigational.

Mini-Gastric Bypass

Systematic Reviews

- In 2023, Hayes conducted a review of reviews evaluating the efficacy of mini gastric bypass-one anastomosis gastric bypass (MGB) as an alternative to either Roux-en-Y gastric bypass (RYGB) or laparoscopic sleeve gastrectomy (LSG) for the treatment of morbid obesity in adults.[30] For comparison with RYGB, Hayes evaluated a systematic review (n=3101) and 2 subsequently published RCTs (n= 253 and 400). For comparison with LSG, one systematic review (n= 2221) and 2 subsequently published RCTs (n=201 and 400) were included for review. One RCT compared MGB-OAGB with both RYGB and LSG. Outcomes of interest included weight loss, comorbidity resolution and complications. Follow-up was assessed at 5-years.

  Compared to RYGB, MGB patients reportedly experienced less weight loss, although results were mixed. In studies evaluated by the systematic review (n=3101), approximately 8% to 9% mean greater excess weight loss with MGB at 1 year, 2 years, and 5 years of follow-up. A subsequently published RCT reported an approximately 20% greater mean percentage of excess BMI loss with MGB than with RYGB at 1 year, 2 years, and 5 years of follow-up. A second RCT reported similar weight loss outcomes between MGB and RYGB patients. Studies suggested that MGB patients experienced a higher incidence of malnutrition with MGB but lower incidence of internal hernia and bowel obstruction relative to RYGB patients. There were no reported differences in mortality between the two groups. Compared to LSG, MGB patients reportedly experienced greater weight loss at one-year follow-up across the 3 included studies. Fewer studies address longer follow-up durations (2 years or longer), and studies published to date have not suggested sustained benefits at longer follow-up.

  Hayes assessed the overall quality of evidence for MGB as "low." Limitations included the small number of comparative studies available for review, lack of studies with long-term follow-up, preponderance of nonrandomized studies included in the two systematic reviews and inconsistent findings across both comparator groups. Investigators ultimately awarded "C" ratings (potential but unproven benefit) for the use of MGB as an alternative to RYGB and LSG. Investigators called for additional studies with long-term follow-up to establish patient selection criteria and the validity of results published to date.

- Since Hayes conducted its literature search on January 1, 2017, three systematic reviews were published evaluative outcomes for patients undergoing MGB.[31-33] Each study reported that MGB patients experienced a high percentage of excess weight loss at follow-up (e.g. 77% at 60 months in a non-comparative study).[33] One study found no improvement in weight loss compared to LSG patients at 2-year follow-up, but significantly greater weight loss at 5-year follow-up.[31] Rates of resolution of Type 2 diabetes and obstructive sleep apnea were also higher compared to LSG patients.[31]

Randomized Controlled Trials

One randomized controlled trial (Lee at al., 2005) not included in the Hayes review above evaluated the effectiveness of laparoscopic mini-gastric bypass (LMGBP) versus traditional Roux-en-Y gastric bypass

(RYGBP).[34] This RCT evaluated 80 patients undergoing LMGBP (n=40) or RYGBP (n=40). Although this study showed the LMGBP procedure to be as effective as RYGBP, the follow-up period was too short (2 years) and the sample size too small to adequately evaluate the long-term efficacy of LMGBP compared to RYGBP. Since this RCT, no additional RCTs have been published.

Nonrandomized Studies

Additional nonrandomized studies assessing mini-gastric bypass were identified.[35-40] The poor methodological quality of these studies (e.g., lack of randomized design, lack of control group, small sample size, short follow-up period) does not permit meaningful conclusions regarding the safety and efficacy of mini-gastric bypass for the treatment of obesity. Additional high-quality studies are required to adequately evaluate this bariatric surgery procedure.

Parietal Cell Separating Gastrojejunostomy or Roux-en-Y Gastrojejunostomy

There is insufficient published evidence to determine the medical necessity of parietal cell separating gastrojejunostomy for the treatment of obesity and/or gastroesophageal reflux disease. Studies of good methodological quality (e.g., long-term randomized controlled trials) comparing this treatment to other gold standard therapies are required.

Endoscopic Procedures as the Primary Bariatric Procedure

There is insufficient published evidence to adequately evaluate the efficacy and safety of endoscopic bariatric surgery procedures. Studies of good methodological quality comparing endoscopic procedures to gold standard therapies (e.g., Roux-en-Y gastric bypass) are required to establish the medical necessity of these procedures.

Transcatheter Bariatric Embolotherapy

In 2020, Reddy and colleagues conducted a single-blind, sham procedure randomized trial assessing the efficacy of transcatheter bariatric embolotherapy (TBE) of the left artery.[41] In total, 44 individuals were randomized 1:1 to either sham or TBE targeting the left gastric artery using an occlusion balloon microcatheter to administer 300- to 500-µm embolic beads. All patients entered a lifestyle counseling program. Patients and physicians performing follow-up were blind to the allocated therapy. Endoscopy was performed at baseline and 1-week post-procedure. The primary endpoint was 6-month total body weight loss (TBWL). At 6 months, in both the intention-to-treat and per-protocol populations, the TBWL was greater with TBE (7.4 kg/6.4% and 9.4 kg/8.3% loss, respectively) than sham (3.0 kg/2.8% and 1.9 kg/1.8%, respectively; p = 0.034/0.052 and p = 0.0002/0.0011, respectively). The TBWL was maintained with TBE at 12 months (intention-to-treat 7.8 kg/6.5% loss, per-protocol 9.3 kg/9.3% loss; p = 0.0011/0.0008, p = 0.0005/0.0005, respectively). Investigators concluded that transcatheter bariatric embolotherapy of the left gastric artery is well-tolerated and promotes clinically significant weight loss over a sham procedure. Authors also noted that large, multi-center studies are required to assess results' generalizability. Other limitations included the lack of a control group, small sample size and lack of long-term follow-up.

Repeat or Revision of Bariatric Surgery

In 2018, Hayes published a systematic review of evidence evaluating the safety and efficacy of revisional bariatric surgery (RBS) due to complication or a lack of weight reduction after primary bariatric surgery.[15] The review included 22 peer-reviewed, mostly retrospective comparative studies and 1 randomized controlled trial comparing RBS to sham procedure. Revisional procedures included in the review varied and 16 studies compared revision versus primary bariatric procedures. Only 2 included studies evaluated outcomes of revisional procedures following primary bariatric surgery. The Hayes report concluded there was potential but unproven benefit for RBS to treat weight loss failure following primary bariatric surgery in patients with severe obesity (defined as body mass index [BMI] ≥ 35 kilograms per square meter [kg/m²] or a lower BMI with ≥ 1 severe weight-associated comorbidity) who are eligible to undergo additional weight loss surgery. (**Grade C** evidence based on low-quality studies regarding the efficacy of RBS as well as an increased risk of complications associated with RBS.) The Hayes report indicated there was insufficient evidence (**D2 rating**) for RBS to treat relapse of complications. Results from three included studies did not provide evidence to determine whether one type of revisional procedure resulted in better outcomes over another.

Conversion of Sleeve Gastrectomy to Roux-en-Y Gastric Bypass

A number of small retrospective studies found that conversion to Roux-en-Y gastric bypass surgery was effective in resolving refractory GERD from sleeve gastrectomy. These studies had a number of limitations, including small sample sizes, retrospective study design, and lack of comparator groups.

- In 2017, Parmar and colleagues published results of a retrospective study evaluating the efficacy of converting from sleeve gastrectomy to Roux-en-Y gastric bypass (RYGB) in patients with gastro-esophageal reflux disease (GERD).[42] The study included 22 conversions with a mean follow up of 16 months. Conversion was effective for improving symptoms of GERD in 100% of patients, and 80% were able to stop their antiacid medications.
- In 2018, Landreneau and colleagues published results of a retrospective study evaluating patients with previous sleeve gastrectomy conversion to RYBG.[43] Seventeen patients underwent conversion due to medically refractory GERD, 75% of which had complete resolution over a 12 month follow up.
- In 2020, Caradina and colleagues published results of a retrospective study reporting on conversion of sleeve gastrectomy to RYGB due to GERD.[44] Eighty patients were reviewed, 71.3% of which experienced resolved GERD symptoms post-surgery.

Bariatric Surgery in Patients with Type 1 Diabetes

Several recent systematic reviews have evaluated the safety and efficacy of bariatric surgery in adult obese patients with Type 1 Diabetes.[45-47] While reports indicated that bariatric surgery leads to significant weight loss in severely obese patients with T1D and significant improvements in insulin requirements and glycemic status, all investigators called for larger, long-term studies to verify findings.

Effects of Smoking on Bariatric Surgery

Several recent systematic reviews have evaluated the effect of smoking on postoperative morbidity and weight loss in adults following bariatric surgery.[48-51] Low-quality evidence indicated that smoking within 1 year prior to bariatric surgery is an independent risk factor for increased 30-day mortality and major postoperative complications, particularly wound and pulmonary complications. Smoking was significantly associated with long-term complications including marginal ulceration and bone fracture.

Smoking was reported to have little to no effect on weight loss following bariatric surgery, with studies reporting at most a 3% increased percentage excess weight loss. Rates of smoking recidivism were high with studies reporting that up to 17% of patients continue to smoke postoperatively. Additional prospective studies with long-term follow-up were judged necessary to better determine the effects of smoking on bariatric surgery.

CLINICAL PRACTICE GUIDELINES

Initial Bariatric Surgery

American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)

In 2022, ASMBS and IFSO published clinical guidelines on indications for metabolic and bariatric surgery. They offer the following recommendations based on clinical evidence and expert opinion:[52]

- MBS is recommended for individuals with BMI ≥35 kg/m ^{2}, regardless of presence, absence, or severity of co-morbidities.
- MBS is recommended in patients with T2D and BMI ≥30 kg/m ^{2}.
- MBS should be considered in individuals with BMI of 30–34.9 kg/m ^{2} who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.
- Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m ^{2}. Access to MBS should not be denied solely based on traditional BMI risk zones.
- There is no upper patient-age limit to MBS. Older individuals who could benefit from MBS should be considered for surgery after careful assessment of co-morbidities and frailty.
- Children and adolescents with BMI >120% of the 95th percentile and a major co-morbidity, or a BMI >140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center.

American Heart Association/American College of Cardiology/The Obesity Society (AHA/ACC/TOS)

The 2013 AHA/ACC/TOS evidence-based guideline for the management of overweight and obesity in adults gave the following recommendations regarding the selection of patients for bariatric surgical treatment for obesity:

"Advise adults with a BMI ≥40 kg/m^2 or BMI ≥35 kg/m^2 with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. NHLBI Grade: A (Strong); ACC/AHA COR: IIa; ACC/AHA LOE: A
For individuals with a BMI <35 kg/m^2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade: N (No Recommendation)
Advise patients that choice of a specific bariatric surgical procedure may be affected by patient factors, including age, severity of obesity/BMI, obesity-related comorbid conditions, other operative risk factors,

risk of short- and long-term complications, behavioral and psychosocial factors, and patient tolerance for risk, as well as provider factors (surgeon and facility). NHLBI Grade: E (Expert Opinion); ACC/AHA COR: IIb; ACC/AHA LOE: C"[53]

Department of Veterans Affairs/Department of Defense (VA/DoD)

The 2020, Version 3.0 VA/DoD evidence-based clinical practice guideline for the screening and management of overweight and obesity gave the following recommendations regarding bariatric surgery:

- "We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, to patients with a body mass index of ≥30 kg/m2 and type 2 diabetes mellitus. (Weak for | Reviewed, New-added)
- We suggest offering the option of metabolic/bariatric surgery, in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s) in adult patients with a body mass index ≥40 kg/m2 or those with body mass index ≥35 kg/m2 with obesity-associated condition(s). (Weak for | Reviewed, New-replaced)
- There is insufficient evidence to recommend for or against metabolic/bariatric surgery to patients over age 65. (Neither for nor against | Reviewed, Amended)
- There is insufficient evidence to recommend for or against percutaneous gastrostomy devices for weight loss in patients with obesity. (Neither for nor against | Reviewed, New-added)"[54]

Health Evidence Review Commission (HERC)

The 2016 HERC coverage guidance on metabolic and bariatric surgery recommend the following:

"Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, and sleeve gastrectomy) is recommended for:

- Adult obese patients (BMI ≥ 35) with
    - Type 2 diabetes (strong recommendation) OR
    - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea (weak recommendation)
- Adult obese patients (BMI ≥ 40) (strong recommendation)

Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (weak recommendation).

Metabolic and bariatric surgery is not recommended for coverage in:

- Patients with BMI <35, or 35-40 without the defined comorbid conditions above (weak recommendation)
- Children and adolescents (weak recommendation)"[55]

National Institute for Health and Care Excellence (NICE)

The 2023 evidence-based NICE guideline for the identification, assessment, and management of obesity gave the following recommendations for bariatric surgery:
Bariatric surgery is a treatment option for people with obesity if all of the following criteria are fulfilled:

> ~ They "have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 39.9 kg/m^2 with a significant health condition that could be improved if they lost weight **and**
>
> ~ Consider referral for people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background using a lower BMI threshold (reduced by 2.5 kg/m2) than in recommendation 1.10.1 to account for the fact that these groups are prone to central adiposity and their cardiometabolic risk occurs at a lower BMI."[1]

<u>Bariatric Surgery in Type II Diabetes Patients with BMI 30-34.9 kg/m^2</u>

International Diabetes Organization

The 2016 joint statement by the International Diabetes Organizations evaluating metabolic surgery for type 2 diabetes (T2D) stated the following:

"Metabolic surgery should also be *considered* to be an option to treat T2D in patients with class I obesity (BMI 30.0-34.9 kg/m^2) and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin)."[56]
However, the authors also state that the evidence indicates the benefits of bariatric surgery for T2D wanes over time and further randomized controlled trials are needed in patients with a BMI <35.

American Diabetes Association (ADA)

The 2020 ADA "standards of medical care in diabetes" for obesity management in the treatment of type 2 diabetes, recommended the following:

"Metabolic surgery should be recommended as an option to treat type 2 diabetes in appropriate surgical candidates with BMI ≥ 40 kg/m2 (BMI ≥ 37.5 kg/m2 in Asian Americans), and in adults with BMI 35.0–39.9 kg/m2 (32.5–37.4 kg/m2 in Asian Americans) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with reasonable nonsurgical methods.

Metabolic surgery should be considered as an option for adults with type 2 diabetes and BMI 30.0–34.9 kg/m2 (27.5–32.4 kg/m2 in Asian Americans) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with reasonable nonsurgical methods."[57]

American Association of Clinical Endocrinologists (AACE)

The 2016 AACE evidence-based clinical practice guideline for medical care of patients with obesity stated,

" Patients with a BMI of ≥ 35kg/m^2 and 1 or more severe obesity-related complications, including T2DM, hypertension, obstructive sleep apnea, obesity hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or non-alcoholic , nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired QOL may also be considered for a bariatric surgery procedure.

Patients with BMI of 30 to 34.9 kg/m2 with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit…

…Independent of BMI criteria, there is insufficient evidence to recommend a bariatric surgical procedure specifically for glycemic control, lipid lowering, or CVD risk reduction alone."[58]

Bariatric Surgery for the Treatment of Non-Alcoholic Steatohepatitis

American Association for the Study of Liver Diseases (AASLD)

The 2018 AASLD practice guidance for the diagnosis and management of nonalcoholic fatty liver disease, stated foregut bariatric surgery can be considered in otherwise eligible obese individuals with NAFLD or NASH, but it is premature to consider foregut bariatric surgery as an established option to specifically treat NASH.[59]

Bariatric Surgery for the Treatment of Gastroesophageal Reflux Disease

American College of Gastroenterology (ACG)

The 2022 ACG guidelines for the diagnosis and management of gastroesophageal reflux disease (GERD) gives a "conditional recommendation" based on a moderate level of evidence that obese patients contemplating surgical therapy for GERD should be considered for bariatric surgery.[60,61] The ACG gives a "conditional recommendation" when there is uncertainty that the desirable effects of an intervention clearly outweigh the undesirable effects.

Bariatric Surgery in Adolescents

American Academy of Pediatrics (AAP)

In 2019, the AAP released a policy statement made on the basis of a non-systematic review of evidence, addressing bariatric surgery for adolescents aged 13 to 18 years with severe obesity.[62] The AAP identified the following indications for adolescent metabolic and bariatric surgery:

- Youth with Class 2 obesity, BMI ≥ 35 or 120% of the 95th percentile for age and sex, whichever is lower, with clinically significant disease (including obstructive sleep apnea (AHI >5); type 2 diabetes mellitus; idiopathic intracranial hypertension; nonalcoholic steatohepatitis; slipped capital femoral epiphysis; Blount disease; gastroesophageal reflux disease; and hypertension.)

- Youth with Class 3 obesity BMI ≥ 40, or 140% of the 95% percentile for age and sex, whichever is lower. While commonly present, comorbid conditions are not required.

The guideline noted that generally accepted contraindications include a medically correctable cause of obesity, intreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes.

American Society for Metabolic and Bariatric Surgery (ASMBS)

In 2018, the ASMBS published evidence-based guidelines addressing pediatric metabolic and bariatric surgery.[63] Investigators recommended that adolescents with class II obesity and a co-morbidity (e.g. type 2 diabetes, obstructive sleep apnea, nonalcoholic steatohepatitis), or with class III obesity should be considered for bariatric surgery. The guidelines also stated that adolescents with cognitive disabilities, a history of behavioral health disorders or eating disorders that are treated, immature bone growth, or low Tanner stage should not be denied treatment.

Endocrine Society

In 2017, the Endocrine Society clinical practice guideline based on a non-systematic review of evidence regarding the assessment, treatment and prevention of pediatric obesity.[64] On the basis of evidence assessed as “very low quality” and “low quality,” authors listed the following indications for adolescent bariatric surgery:

- The patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height, the patient has a BMI of >40 kg/m2 or has a BMI of >35 kg/m2 and significant, extreme comorbidities

- Extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy

- Psychological evaluation confirms the stability and competence of the family unit [psychological distress due to impaired quality of live (QOL) from obesity may be present, but the patient does not have an underlying untreated behavioral health illness]

- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits

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

Health Evidence Review Commission (HERC)

In 2016, the Oregon Health Evidence Review Commission published a coverage guidance addressing metabolic and bariatric surgery.[55] On the basis of findings from three "fair or good quality" systematic reviews, investigators recommended against metabolic and bariatric surgery for children and adolescents. Despite noting that bariatric surgery is associated with significant improvements in BMI and co-morbidities, authors called for additional, large studies with long-term follow-up to validate findings reported to date.

National Institute for Health and Care Excellence (NICE)

In 2023, NICE published a guidance on obesity stating that while surgical intervention is generally not recommended for children and young people, bariatric surgery may be considered in young people in exceptional circumstances and if they have achieved or almost achieved physiological maturity.[1] Moreover, only a multidisciplinary team with pediatric expertise should perform the surgery.

Institute for Clinical Systems Improvement (ICSI)

In 2013, the ISCI published a guideline on prevention and management of obesity for children and adolescents. Authors issued the following selection criteria for adolescent bariatric surgery:[65]

- BMI > 40 kilograms per square meter (kg/m^2) or BMI > 35 kg/m^2 and significant, severe comorbidities (e.g., type 2 diabetes mellitus, obstructive sleep apnea, pseudotumor cerebri)
- Tanner 4 or 5 pubertal development achieved or bone age ≥ 13 years in girls or ≥ 15 years in boys
- At least 6 months organized attempts at weight management without success
- Capacity to make decision and exhibit commitment to comprehensive medical and psychological evaluations before and following surgery
- A complete evaluation of the home environment by trained personnel is necessary to ensure a supportive family environment

American Society for Metabolic and Bariatric Surgery (ASMBS)

In 2018, the ASMBS pediatric committee published a best practice guideline and issued the following selection criteria for adolescents to be considered for a bariatric procedure:

"Indications for adolescent MBS include:

- BMI ≥35 kg/m2 or 120% of the 95th percentile with clinically significant co-morbid conditions such as obstructive sleep apnea (AHI 45), T2D, IIH, NASH, Blount's disease, SCFE, GERD, or hypertension; or BMI ≥40 kg/m2 or 140% of the 95th percentile (whichever is lower).

- A multidisciplinary team must also consider whether the patient and family have the ability and motivation to adhere to recommended treatments pre- and postoperatively, including consistent use of micronutrient supplements.

Contraindications for adolescent MBS include

- A medically correctable cause of obesity
- An ongoing substance abuse problem (within the preceding yr)
- A medical, behavioral health, psychosocial, or cognitive condition that prevents adherence to postoperative dietary and medication regimens.
- Current or planned pregnancy within 12 to 18 mo of the procedure"[63]

Repeat or Revision of Bariatric Surgery

American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic & Bariatric Surgery

In 2019, the American Association of Clinical Endocrinologists, Obesity Society, and American Society for Metabolic & Bariatric Surgery updated a co-sponsored guideline regarding perioperative support of bariatric surgery patients.[66] The group made the following recommendations regarding repeat or revision bariatric surgeries:

- "Patients who previously underwent a RYGB with a nonpartitioned stomach who develop a gastrogastric fistula or herniation with symptoms of weight regain, marginal ulcer, stricture or gastroesophageal reflux, may benefit from a revisional procedure (Grade C; BEL 3).

- Persistent vomiting, regurgitation, and UGI (upper gastrointestinal) obstruction after LAGB should be treated with immediate removal of fluid from the adjustable band (Grade D). Persistent symptoms of gastroesophageal reflux, regurgitation, chronic cough, or recurrent aspiration pneumonia after LAGB raise concern for the band being too tight or the development of an abnormally large gastric pouch above the band or esophageal dilation. These symptoms should prompt immediate referral to a bariatric surgeon (Grade D).

- Definitive repair of asymptomatic abdominal wall hernias can be deferred until weight loss has stabilized and nutritional status has improved, to allow for adequate healing (12 to 18 months after bariatric surgery) (Grade D). Symptomatic hernias that occur after bariatric surgery require prompt surgical evaluation (Grade C; BEL 3). Patients with sudden onset, severe cramping periumbilical pain or recurrent episodes of severe abdominal pain any time after weight loss surgery should be evaluated with an abdominal and pelvic CT scan to exclude the potentially life-threatening complication of a closed loop bowel obstruction (Grade D). Exploratory laparotomy or laparoscopy is indicated in patients who are suspected of having an internal hernia because this complication can be missed with UGI x-ray studies and CT scans (Grade C; BEL 3)."

These recommendations are based on limited evidence or consensus opinion.

Effects of Smoking on Bariatric Surgery

American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery (AACE, TOS, ASMBS)

In 2013, the AACE, TOS and ASMBS issued a joint clinical practice guideline addressing the perioperative nutritional, metabolic and nonsurgical support of the bariatric surgery patient. [67] Investigators issue a grade "A" recommendation that patients who smoke cigarettes should stop, preferably at least 6 weeks before bariatric surgery.

Behavioral Health/Psychological Evaluation

American Society for Metabolic and Bariatric Surgery

In 2016 (updated in 2019), the American Society for Metabolic and Bariatric Surgery issued clinical practice guidelines with recommendations for the presurgical psychosocial evaluation of bariatric surgery patients. Investigators recommended that bariatric behavioral health clinicians with specialized knowledge and experience be involved in the evaluation and care of patients both before and after surgery, noting that "psychosocial factors and adherence to the recommended postoperative dietary and lifestyle regimen have significant potential to affect postoperative outcomes." Such evaluations could "identify factors that may pose challenges to optimal surgical outcome and providing recommendations to the patient and bariatric team on how to address these issues."[68]

EVIDENCE SUMMARY

Roux-en-Y gastric bypass is the gold standard bariatric surgery procedure and is well-established in peer-reviewed medical literature and clinical practice. The evidence supports the use of sleeve gastrectomy and indicates it is as effective as Roux-en-Y. In super obese patients (> 50 kg/m^2), biliopancreatic bypass with a duodenal switch has also been shown to be effective. Several evidence-based clinical practice guidelines recommend the use of bariatric surgery in adults with a BMI greater than 40 kg/m^2 or 35 kg/m^2 with obesity-related comorbidities. These guidelines do not recommend which bariatric surgery procedure should be used.

Limited but consistent evidence also suggests that bariatric surgery is a safe and effective treatment for obesity in adolescents. At short- to intermediate term follow-up, bariatric surgery patients experienced significant weight loss and improvements in certain obesity-associated comorbidities (e.g. type 2 diabetes, dyslipidemia and hypertension) when compared to non-surgical interventions. Additionally, guidelines from 5 clinical practice organizations endorse bariatric surgery for adolescents. Due to barriers to conducting RCTs in this population, evidence quality is unlikely to improve in coming years.

A number of bariatric surgery procedures have not been proven safe and/or effective in the long-term and are not covered. Examples of these non-covered procedures include: adjustable gastric banding (i.e., Lap-Band system); biliopancreatic bypass without a duodenal switch (i.e., the Scopinaro procedure); and vertical banded gastroplasty (i.e., stomach stapling). There are several other bariatric surgery procedures and technologies that have been proposed as a treatment of morbid obesity, including vagal nerve stimulation, intragastric balloons, mini-gastric bypass, transcatheter bariatric

embolotherapy. These procedures are not covered because they too lack evidence proving their superiority over established treatments.

Additional measures are required to improve bariatric surgery patients' outcomes. These include: nutritional counseling, smoking cessation (if the patient is a smoker), and a behavioral health or psychological evaluation prior to the operation. In a joint guideline, the American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery (AACE, TOS, ASMBS) issued a grade "A" recommendation that patients who smoke cigarettes should stop, preferably at least 6 weeks before bariatric surgery. The American Society for Metabolic and Bariatric Surgery also recommended that behavioral health clinicians with specialized knowledge and experience be involved in the evaluation and care of patients both before and after surgery.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

Only the codes listed on this policy may be used for reporting bariatric procedures. Codes 43631-43634 are specific to gastrectomy and should not be used to report bariatric procedures.

Code 43843 should not be used when there is a procedure-specific bariatric surgery code.

CODES*		
CPT	0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
Roux-en-Y Gastric Bypass		

	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
	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
Sleeve Gastrectomy		
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
Biliopancreatic Bypass with Duodenal Switch		
	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)
Removal/Revision of Bariatric Surgery		
	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)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	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
	43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
	43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
	43659	Unlisted laparoscopy procedure, stomach

	43999	Unlisted procedure, stomach
HCPCS	C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
	C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Added medical necessity criteria for device removal
6/2023	Added new criteria for adolescent bariatric surgery and removed Tanner score requirement. Changed denial criteria language from investigational to not medically necessary.
7/2023	Two new HCPCS codes added per quarterly code release.
1/2024	Code set update for 1/1/2024, new codes added.
4/2024	Annual review. Updated criteria regarding BMI ranges for members of Asian ancestry and medical necessity of adjustable gastric band removal.
4/2025	Annual review. Updated criterion VII.B.