Clinical Policy: Obesity Management & Bariatric Surgery

Reference Number: QCP.CP.041
Effective Date: 01/01/2020
Date of Last Revision:

CPT Codes: 43644, 43645, 43770-43775, 43842-43843, 43845-43848, 43860, 43865, 43886-43888, S2083,00797

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Public Statement

a) This policy will apply to all services performed on or after the above Revision date which will become the new effective date.

b) For all services referred to in this policy that were performed before the revision date, contact customer service for the rules that would apply.

Please refer to your plan documents for coverage of obesity management programs and bariatric (weight loss) surgery.

Obesity management programs and bariatric (weight loss) surgery require preauthorization.

Effective Date:

Medical Statement

It is the policy of QualChoice that an obesity management program (nutritional counseling for diet & exercise +/- medication) for adults is **medically necessary** when the following criteria are met**:**

Age > 18 years and BMI ≥ 30 kg/m² with no untreated, medically correctable cause of obesity (such as hypothyroidism).

Up to a combined total 8 units of the following codes will be allowed annually (See BI342):

97802 – 97803	Dietary Counseling, (1 unit = 15 mins)
98960 – 98962	Education and Training for patient self-management (1 unit = 30 mins)
99078	Physician Educational Services
S9470	Nutritional counseling, dietician visit

Allowed/covered weight loss medications include:

- Metformin (off label—no PA required)
- Topiramate (off label—no PA required)
- Phentermine for up to 6 weeks—PA required and will need to document there are no contraindications to using

It is the policy of QualChoice that the bariatric surgery procedures LAGB, LSG, laparoscopic RYGB or laparoscopic BPD-DS/BPD-GRDS are **medically necessary** (along with elective cholecystectomy) when the following criteria under **section I, II and III** are met**:**

I. **Medical history**, meets all of the following:
Age > 18 years and (a, b or c):
   A. Documented BMI ≥ 40 kg/m² for at least 3 years, or;
   B. BMI ≥ 35 and < 40 kg/m² with at least *one* of the following comorbidities that is unimproved or poorly controlled despite 6 months of adherence to lifestyle and (when appropriate) pharmacotherapy management:
      1. Type 2 diabetes mellitus (DM) on metformin and a GLP-1 agonist and/or SGLT2 inhibitor
      2. Poorly controlled hypertension
      3. Dyslipidemia
      4. Obstructive sleep apnea
      5. Obesity-hypoventilation syndrome/Pickwickian syndrome
      6. Nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH)
      7. Asthma
      8. Venous stasis disease
      9. Severe urinary incontinence
      10. Osteoarthritis (hip, knees and/or ankles)
      11. Pseudotumor cerebri (idiopathic intracranial hypertension)
      12. Psoriasis uncontrolled with topical agents and narrow band UVB
      13. Psoriatic arthritis
      14. Significant impairment of activities of daily living,
   C. Persistent obesity (BMI ≥ 40 kg/m² or BMI 35-39.9 kg/m² with comorbidities noted above) despite at least 6 months documented adherence to obesity management interventions (nutritional counseling for diet & exercise +/- medication).

II. **Preoperative evaluation and medical clearance** requirements within 6 months of the scheduled surgery include *all* of the following:
   A. Cardiac evaluation includes an electrocardiogram and *one* of the following categories (1 *or* 2):
      1. LOW CARDIAC RISK candidates, with *none* of the risk factors listed in section 2, need cardiac clearance by a PCP or cardiologist. If additional testing is needed, it should be conducted by a cardiologist.

      2. HIGH CARDIAC RISK candidates need consultation/evaluation and cardiac clearance from a cardiologist. High risk candidates include those with *any* of the following:
         a. History of ischemic heart disease;
         b. History of congestive heart failure;
         c. History of cerebrovascular disease;
         d. Glomerular filtration rate < 30 mL/min-1;
         e. High-grade arrhythmia;

f. Hemodynamically significant valvular heart disease.

B. To improve surgical outcomes, glycemic control should be optimized as evidenced by *one* of the following:
   1. HbA1c 6.5 - 7.0%;
   2. Fasting blood glucose level of ≤ 110 mg/dL;
   3. 2-hour postprandial blood glucose concentration of ≤ 140 mg/dL;
   4. HbA1c of 7 - 8% in candidates with advanced microvascular or macrovascular complications, extensive co-morbid conditions, or long-standing diabetes in which the general goal has been difficult to attain despite intensive efforts.
   5. If one of the glycemic control criteria (above) are not met despite documented adherence to intensive efforts, an explanation of how the risks of not doing the surgery exceed the increased risk of surgical complications from poor glycemic control.

C. Pulmonary Evaluation:
   1. Chest x-ray;
   2. Screening for obstructive sleep apnea;
   3. Pulmonary function testing and arterial blood gas analysis for candidates with intrinsic lung disease or disordered sleep patterns;
   4. Evaluation of obstructive sleep apnea (HST or PSG—see BI306) in members who meet at least *one* of the following criteria:
      a. Recurrent witnessed apnea during sleep > 10 seconds in duration;
      b. Excessive or inappropriate daytime sleepiness such as falling asleep while driving or eating;
      c. Sleepiness that interferes with daily activities not explained by other conditions, such as poor sleep hygiene, medication, drugs, alcohol, psychiatric or psychological disorders;
      d. Having an Epworth Sleepiness Scale score > 10;
      e. Persistent or frequent disruptive snoring, choking or gasping episodes associated with awakenings;
   5. Specialist should be consulted for interpretation of any abnormal findings.

D. Nutritional evaluation, including micronutrient measurements and treatment of insufficiencies/deficiencies prior to surgery.

E. Nutritional therapy/counseling
   1. Initial comprehensive diet history to include assessment of current pattern of nutrition and exercise and steps to modify problem eating behaviors;
   2. Monthly nutritional counseling until the date of the surgery;
   3. Prescribed exercise program;
   4. Must provide documentation that counseling has been conducted regarding the potential for success of weight loss surgery dependent on post-op diet modification.

F. Psychiatry/psychology consultation including all of the following:

1. An in-person psychological evaluation to assess for major mental health disorders which would contradict surgery and determine ability to comply with post-operative care and guidelines;
2. If history is positive for alcohol or drug abuse must provide documentation of alcohol and drug abstinence for ≥ 1 year prior to surgery.

G. Members with signs or symptoms of hypothyroidism (other than obesity) are screened with a TSH level and treated if found to be hypothyroid.

H. A fasting lipid panel must be obtained and, if necessary, treatment initiated for dyslipidemia.

I. Screening for *Helicobacter pylori* if signs or symptoms of active peptic ulcer disease are present, with documentation of treatment if positive for *H.pylori.*

J. Prophylactic treatment for gouty attacks in patients with a history of gout.

K. If tobacco user, must stop use > 6 weeks prior to surgery (documented with negative urine cotinine testing).

III. **Bariatric Surgery Accreditation**

The bariatric surgery will be performed through a facility/program that has MBSAQIP accreditation (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program) through the American College of Surgeons. This requirement will not apply to members employed by The City of Hot Springs.

IV. **Repeat Surgeries**

A. Repeat bariatric surgery is considered medically necessary for one of the following:
   1. To correct complications from a previous bariatric surgery, such as obstruction or strictures;
   2. Conversion from LAGB to a RYGB or BPD-DS; or revision of a primary procedure that has failed due to dilation of the gastric pouch when all of the following criteria are met:
      a. All criteria listed above for the initial bariatric procedure must be met again;
      b. Previous surgery for morbid obesity was at least 3 years prior to repeat procedure;
      c. Weight loss from the initial procedure was less than 50% of the member`s excess body weight at the time of the initial procedure;
      d. Documented compliance with previously prescribed postoperative nutrition and exercise program. If non-compliant with postoperative regimen, member will be required to take part in an established multidisciplinary bariatric program to meet all of the initial surgery criteria listed above;
      e. Supporting documentation from the provider should also include a clinical explanation of the circumstances as to why the procedure failed and if initial procedure failure was related to non-compliance with diet then why the requesting provider feels member will be compliant with diet after repeat surgery.

V. **Contraindications** for surgical weight loss procedures include:
   A. Medically correctable causes of obesity;
   B. An ongoing substance abuse problem within the preceding year;
   C. Untreated major depression or psychosis;
   D. Uncontrolled and untreated eating disorders (eg, bulimia);
   E. A medical, psychiatric, psychosocial, or cognitive condition that prevents adherence to post-operative dietary and medication regimens or impairs decisional capacity;
   F. Current or planned pregnancy within 12 to 18 months of the procedure;
   G. Severe cardiac disease with prohibitive anesthetic risks;
   H. Severe coagulopathy;
   I. Inability on the part of the patient to comprehend the risks and benefits of the surgical procedure.

Codes Used In This BI:

CPT®* Codes	CPT®* Codes
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 restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty

43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
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
00797	Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; gastric restrictive procedure for morbid obesity
HCPCS Codes	**Description**
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Limits

1) Members who have an uncontrolled severe psychiatric disorder or active substance use disorder are not eligible.

2) Surgery to correct complications from bariatric surgery, such as obstruction or stricture, wound infections or hernias is covered only when the original bariatric surgery was (is) eligible for coverage. For panniculectomy see BI284.

3) Obesity surgery for members under 18 is not covered as the safety and effectiveness have not been adequately documented

4) Members with uncontrolled severe medical problems such as active cancer, severe heart failure, or unstable angina may not be eligible until the medical condition is controlled.

5) Any of the following procedures are considered experimental and investigational because

the peer reviewed medical literature shows them to be either unsafe or inadequately studied:

a) Loop gastric bypass;
b) Gastroplasty, more commonly known as "stomach stapling" (see below for clarification from vertical band gastroplasty);
c) Biliopancreatic bypass without duodenal switch (Scopinaro procedure)
d) Mini gastric bypass;
e) Silastic ring vertical gastric bypass (Fobi pouch);
f) Intragastric balloon;
g) Distal gastric bypass (very long limb gastric bypass);
h) Laparoscopic re-sleeve gastrectomy (LRSG) performed after the resulting gastric pouch is primarily too large or dilates after the original LSG;
i) Laparoscopic greater curvature plication (Gastric Imbrication);
j) LAP-BAND when BMI is 30 to 35 with or without comorbid conditions;
k) AspireAssist;
l) Endoscopic Suture Revisions post bariatric surgery.

6) It is the policy of QualChoice that the following bariatric surgery procedures are considered **not medically necessary,** due to potential complications and a lack of positive outcomes:

A. Biliopancreatic diversion (BPD) procedure (also known as the Scopinaro procedure);
B. Jejunoileal bypass (jejuno-colic bypass);
C. Vertical Banded Gastroplasty (VBG);
D. Gastric balloon;
E. Gastric pacing;
F. Gastric wrapping.

Background

There is sufficient evidence in peer-reviewed medical literature to support the use of the above mentioned bariatric surgeries for the clinically obese individual. Persons with clinically severe obesity are at risk for increased mortality and multiple co-morbidities. These co-morbidities include hypertension, hypertrophic cardiomyopathy, hyperlipidemia, diabetes, cholelithiasis, obstructive sleep apnea, hypoventilation, degenerative arthritis and psychosocial impairments. The majority of severely obese patients losing weight through non-operative methods alone regain all the weight lost over the next five years. Surgical treatment is the only proven method of achieving long term weight control for the morbidly obese. Eating behaviors after surgery improve dramatically due to the restricted size of the stomach allowing only small amounts of food to be taken in at a time.

The success of the bariatric surgery does rely on the motivation and dedication to the program of the patient. The patient must be able to participate in the treatment and long-term follow up required after surgery. Studies have shown that about 10% of patients may have unsatisfactory weight loss or regain much of the weight they have lost. This may occur due to frequent snacking on high-calorie foods or lack of exercise. Technical problems that may occur include a

stretched pouch due to overeating following surgery. Ensuring patients are motivated to lose weight can help prevent some of these issues.
Maximum weight loss usually occurs between 18 and 24 months postoperatively. The average weight loss at five years ranges from 48 to 74% after gastric bypass and 50 to 60% following gastric banding. Several studies have follow-up from 5-15 years with these patients maintaining weight loss of 50-60% of excess weight.

The Lap Band is a small bracelet-like band placed around the top of the stomach to produce a small pouch about the size of a thumb. The size of the outlet is controlled by a circular balloon inside the band that can be inflated and deflated with saline solution through an access port placed under the skin. The more inflated the balloon, the narrower the opening and slower passage of food to the rest of the stomach.

Roux-en-Y gastric bypass (RYGB) creates a small stomach pouch, bypassing most of the stomach, duodenum, and upper intestine. Weight loss occurs through restriction of food intake and by decreasing the absorption of food by re-routing food directly from the pouch into the small intestine.

Biliopancreatic diversion with duodenal switch (BPD-DS) is a complex operation that includes 1) removing a large portion of the stomach to promote smaller meal sizes, 2) re-routing of food away from much of the small intestine to partially prevent absorption of food, and 3) re-routing of bile and other digestive juices which impair digestion. The operation bypasses most of the duodenum, but leaves a small portion for food and the absorption of some vitamins and minerals. BPD-DS produces significant weight loss, but has a greater risk of long-term complications due to decreased absorption of food, vitamins, and minerals.

There are both early and later complications associated with these operations. Early complications can include bleeding, infections, leaks from suture sites and blood clots. Strictures, hernias, and malnutrition, especially when not taking prescribed vitamins and minerals, are all late complications that can occur in addition to the above mentioned stretched pouch or separated stitches. A repeat surgery is at times required to repair some of these complications.

Investigational Procedures

Long-limb or Distal Gastric Bypass for Superobesity: An RCT has recently been completed by Svanevik et al., but only perioperative outcomes have been reported thus far. Svanevik et al. found that in superobese patients with BMI between 50 and 60 kg/m(2), distal gastric bypass was associated with longer operating time and more severe complications resulting in reoperation than proximal gastric bypass. There is increased risk of adverse nutritional outcomes with longer limb gastric bypass. At this time the long-limb or distal gastric bypass for superobesity is considered investigational, until more long-term studies can be done which reflect better outcomes than existing procedures.

Loop Gastric Bypass (Mini Gastric Bypass): The mini gastric bypass has not been universally accepted due to higher rates of alkaline bile reflux and limited long-term research. More long-term research is needed to solidify mini gastric bypass surgery's position as a viable bariatric surgery option.

Re-Sleeve Gastrectomy for Failed Laparoscopic Sleeve Gastrectomy: Iannelli et al. (2012) noted that laparoscopic sleeve gastrectomy (LSG) was rapidly accepted as a valuable bariatric procedure before its effectiveness on weight loss in the long-term is clearly demonstrated. The authors report a feasibility study including 13 patients undergoing a redo LSG for either progressive weight regain after initial weight loss of insufficient weight loss. AlSabah et al. describe 24 patients who underwent re-sleeve laparoscopic gastrectomy after an initial LSG. Compared to 12 patients that initially had LSG, which was converted to LRYGB, results were similar, with no significant differences in percent of excess weight loss at one year. They conclude that larger and longer follow-up studies are needed to verify results.

Fobi Pouch or Silastic® Ring: The Fobi Pouch bariatric operation for obesity is a combination of stomach reduction and gastric bypass. The Silastic ring is placed around the vertically constructed gastric pouch above the anastomosis between the pouch and the intestinal Roux limb. Possible long term nutritional deficiencies involve fat soluble vitamin deficiencies of Calcium, Iron, B12, and Folic Acid. Patients are placed on nutritional supplements for the rest of their lives, and yearly monitoring is needed. The Fobi Pouch gastric bypass takes about double the time that a vertical banded gastroplasty operation takes. There is limited research on the outcomes of the fobi pouch versus other bariatric surgery procedures.

Gastric Imbrication: Fried et al. (2011) completed a 3-year RCT on the safety and efficacy of laparoscopic adjustable gastric banding with and without imbrication sutures. The results of the RCT have demonstrated that SAGB combined with a conservative approach to band adjustments and limited retrogastric dissection is effective and safe with and without imbrication sutures. Not using imbrication sutures results in significant benefits in operative speed with comparable clinical weight loss and intermediate term safety. Sharma et al. conducted a randomized, double blinded trial comparing LSG and laparoscopic gastric imbrication (LGI). They found no differences in weight, age, or BMI preoperatively at 6 months or 3 years between the two groups.

The AspireAssist System (AspireAssist) was FDA approved in 2016. It is a weight loss device comprised of an endoscopically-placed percutaneous gastrostomy tube and an external device to facilitate drainage of about 30% of each meal consumed. It is meant to be used in conjunction with diet and exercise. Thompson et al. (2017) performed a 1-year RCT comparing results of 207 patients treated with AspireAssist. The treatment group (n=137) received AspireAssist and lifestyle counseling and the control group (n=70) received lifestyle counseling alone. Compared to the control group, those who received the AspireAssist and counseling lost more weight: 58.6% of participants in the AspireAssist group and 15.3% of participants in the Lifestyle Counseling group lost at least 25% of their excess body weight ($P<0.001$). Additionally, Noren et al. (2016) conducted a prospective observational study on 25 patients. By the end of

the 2-year observation period only 15 patients were still in the study. They concluded that AspireAssist is an efficient and safe treatment for obesity. There is no research on AspireAssist versus other bariatric surgery procedures.

Endoscopic Suture Revisions Post Bariatric Surgery: To enhance weight loss, endoscopic procedures to promote restriction of the pouch or stoma include sclerotherapy of the site using 6 to 30 mL of sodium morrhuate injected circumferentially; tissue plication systems to reduce the size of the gastrojejunostomy and the gastric pouch; revisional surgery using a tissue plication device known as StomaPhyX to reduce the pouch size; and application of the endoclip to reduce the size of the gastrojejunal anastomosis. There is a lack of long-term outcomes for endoscopic suture revisions post RYGB.

Not Medically Necessary Procedures

Biliopancreatic Diversion (BPD) Procedure (Scopinaro procedure): The biliopancreatic diversion (BPD) is a malabsorptive procedure that was introduced as a solution to the high rates of liver failure resulting from bowel exclusion in the jejunoileal bypass. The procedure consists of a partial gastrectomy and gastroileostomy with a long segment of Roux limb and a short common channel, resulting in fat and starch malabsorption. BPD also has a restrictive component. The BPD/DS procedure differs from the BPD in the portion of the stomach that is removed, as well as preservation of the pylorus. This allows more forward flow of the contents of the biliopancreatic limb and avoids the complications of stasis that plagued the jejunoileal bypass (JIB). It is associated with fewer complications than BPD alone. BPD/DS is a complex procedure that is only performed at a few centers in the U.S.

Jejunoileal Bypass or Jejunoileal Intestinal Bypass (JIB): The jejunoileal bypass (also called the intestinal bypass) is performed by dividing the jejunum close to the ligament of Treitz and connecting it a short distance proximal to the ileocecal valve, thereby diverting a long segment of small bowel, resulting in malabsorption. This procedure is no longer performed due to the high complication rate and frequent need for revisional surgery. Per the American Society for Metabolic & Bariatric Surgery, the JIB is no longer a recommended bariatric surgical procedure. The lessons learned from the JIB include the crucial importance of long-term follow-up and the dangers of a permanent, severe and global malabsorption.

Vertical Banded Gastroplasty (VBG): VBG has fallen out of favor as a restrictive procedure for severe obesity, due largely to the advantages of adjustable gastric banding. VBG requires division of the stomach or intestinal resection, while LAGB does not. In addition, the staples used in VBG may break down and cause weight regain, and VBG requires the use of prosthetic mesh that may increase the incidence of stomach stenosis. Thus, CMS says in their National Coverage Determination for Bariatric Treatment for Morbid Obesity that “VBG procedures are essentially no longer performed.”

Gastric Balloon: Previous endoscopic technologies used to treat obesity endoscopically, such as the gastric balloon, had limited exposure in the U.S. and were removed from the market

because of associated complications, such as balloon deflation with migration and resultant small intestinal obstruction.

Gastric Pacing: A number of procedures have been investigated for weight loss surgery but have not been totally accepted by the surgical community. Gastric pacing has been performed in several trials but has not been shown to have any long-term effect and has been abandoned.

Gastric Wrapping: A gastric wrap is minimally invasive surgery and involves folding the stomach in on itself and then the edges are stitched to turn the stomach into a narrow tube therefore restricting the amount of food that can be consumed. As this surgery is very new and not widely offered. There is a paucity of peer-reviewed scientific literature on this procedure.

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Addendums:
Effective 02/01/21: Anesthesia for bariatric procedures (00797) is covered without prior authorization (Internal).

Effective 05/01/21: Updated wording on the Bariatric Surgery Accreditation.

Resource Document:
Resource Document Link

Application to Products
This policy applies to all health plans administered by QualChoice, both those insured by QualChoice and those that are self-funded by the sponsoring employer, unless there is indication in this policy otherwise or a stated exclusion in your medical plan booklet. Consult the individual plan sponsor Summary Plan Description (SPD) for self-insured plans or the specific Evidence of Coverage (EOC) for those plans insured by QualChoice. In the event of a discrepancy between this policy and a self-insured customer's SPD or the specific QualChoice EOC, the SPD or EOC, as applicable, will prevail. State and federal mandates will be followed as they apply.

Changes: QualChoice reserves the right to alter, amend, change or supplement benefit interpretations as needed.