

Subject: Surgery for Clinically Severe Obesity
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Description/Scope

Clinically severe obesity is a result of persistent and uncontrollable weight gain that constitutes a present or potential threat to life. There are a variety of surgical procedures intended for the treatment of clinically severe obesity. This policy addresses those procedures.

Policy Statement

Medically Necessary:

Gastric bypass with a Roux Y procedure up to 150 cm, laparoscopic adjustable gastric banding (the Lap-Band[®] System), vertical banded gastroplasty, or biliopancreatic bypass with duodenal switch as a single surgery, is considered **medically necessary** for the treatment of clinically severe obesity for selected adults (18 years and older) who meet the following criteria:

1. BMI of 40 or greater, or BMI of 35 or greater with co-morbid conditions including, but not limited to, life threatening cardio-pulmonary problems (severe sleep apnea, Pickwickian syndrome and obesity related cardiomyopathy), severe diabetes mellitus, cardiovascular disease or hypertension.
***Note:** Individuals considering the laparoscopic adjustable gastric banding (Lap-Band[®]) procedure must meet the above minimum BMI requirement and, in addition, have a maximum BMI of less than 50.
2. The patient must have actively participated in non-surgical methods of weight reduction; these efforts must be fully appraised by the physician requesting authorization for surgery.
3. The physician requesting authorization for the surgery must confirm the following:
 - The patient's psychiatric profile is such that the patient is able to understand, tolerate and comply with all phases of care and is committed to long-term follow-up requirements;
 - The patient's post-operative expectations have been addressed;
 - The patient has undergone a preoperative medical consultation and is felt to be an acceptable surgical candidate;
 - The patient has undergone a preoperative mental health assessment and is felt to be an acceptable candidate;
 - The patient has received a thorough explanation of the risks, benefits, and uncertainties of the procedure;
 - The patient's treatment plan includes pre- and post-operative dietary evaluations and nutritional counseling;
 - The patient's treatment plan includes counseling regarding exercise, psychological issues and the availability of supportive resources when needed.

For revision of a gastric restrictive procedure for clinically severe obesity, there must be documentation of a failure secondary to a surgical complication such as fistula, obstruction or disruption of a suture/staple line, and is subject to the same criteria listed above.

Not Medically Necessary:

Stretching of a stomach pouch formed by a previous gastric restrictive surgery, due to the patient overeating, does not constitute a surgical complication and the revision of this condition is considered **not medically necessary**.

Investigational/Not Medically Necessary:

Gastric bypass, using a Billroth II type of anastomosis (also known as a "mini gastric bypass") is considered **investigational/not medically necessary** as a treatment of clinically severe obesity.

Malabsorptive procedures including, but not limited to, jejunioileal bypass, biliopancreatic bypass without duodenal switch, or very long limb (>150 cm) gastric bypass (other than the biliopancreatic bypass with duodenal switch) are considered **investigational/not medically necessary** as a treatment of clinically severe obesity.

All other procedures not listed above as medically necessary are considered **investigational/not medically necessary**.

Further Consideration:

A bariatric surgeon with experience in the pediatric population may request further consideration of a case of an individual under 18 years old with severe morbid obesity and unique circumstances by contacting a Medical Director.

Rationale

At this time, there is sufficient evidence in the peer-reviewed medical literature to support the use of gastric bypass with a Roux Y procedure up to 150cm and/or vertical banded gastroplasty for the indication of clinically severe obesity. The evidence suggests that these procedures are beneficial both in terms of clinical effectiveness and safety for this indication in a selected group of individuals. The most compelling evidence for an improvement in comorbid conditions comes from the Swedish Obese Subjects (SOS) intervention trial that reported a large reduction in diabetes over a 5.5 year mean follow-up for the surgery group. While there is substantial evidence that these procedures can facilitate significant weight loss and improve co-morbidities in clinically severe obese individuals, perioperative mortality may occur in such individuals as well, occurring at a rate of approximately 1 in 200 procedures. In order to minimize potential morbidity and mortality, individuals who undergo such treatment should meet specific criteria prior to undergoing the procedure. The evidence supporting this conclusion includes properly randomized controlled trials.

There is also sufficient evidence to support the use of the biliopancreatic bypass with duodenal switch for individuals who have clinically severe obesity. Mortality is similar to the Roux Y procedure, and the evidence suggests that up to 70% excess weight loss (EWL) can be maintained over long-term follow-up (up to 6 years post-surgery). The evidence supporting this conclusion includes multiple large case series.

There is now sufficient U.S. data available supporting the safety and efficacy of laparoscopic adjustable gastric banding, using the Lap-Band® system, for the treatment of clinically severe obesity. At this time, this would only apply to individuals with a BMI of less than 50 as there is very little data in the literature addressing the safety and efficacy of this procedure for individuals with a BMI of greater than 50. While EWL with a laparoscopic adjustable gastric banding procedure is more gradual than with other bariatric surgical procedures, studies with up to three years follow-up have shown that an EWL of 40% to 60% can be achieved. This is accompanied by improvements in quality of life scores. Recent improvements in the band design and use of the "pars flaccida" surgical approach have resulted in a lower complication rate. Both international and U.S. case studies have consistently reported mortality rates for the laparoscopic gastric banding procedure that are lower than the mortality rates found for most other bariatric procedures, including the gold standard Roux Y gastric bypass. The evidence supporting this conclusion includes large case studies.

There are relatively few randomized comparative studies evaluating the relative risk and benefit of each of the surgical options. Furthermore, long-term results (>6 years) are not abundant for any of the bariatric procedures. Thus, the quality of evidence to guide operative choice by surgeon and patient is fair at best, based primarily on single-institution case series.

At this time, there is insufficient convincing evidence in the peer-reviewed medical literature, in terms of safety, to support the use of "mini gastric bypass" and malabsorptive procedures other than the biliopancreatic bypass with duodenal switch in individuals with clinically severe obesity. Therefore, these procedures cannot be recommended for such individuals. The investigational status of these procedures is based on the judgment that there is insufficient evidence to demonstrate that the increased risks of these procedures, compared specifically to the

gastric bypass with the Roux Y procedure, is outweighed by a significantly greater reduction in obesity-related morbidities and excess weight loss.

There is at present insufficient evidence to support the use of bariatric surgery for the pediatric and adolescent population. Several small case series have shown some promising results. However, in one case series of 33 patients, 5 individuals (15%) regained most or all of their weight 5 to 10 years post-surgery. Concerns about possible nutritional deficiency in growing individuals also exist, and patient and procedure selection criteria are unclear. Further results are required before it is clearly known whether the benefits of surgery outweigh the risks in this population. However, in a small subset of adolescents with severe morbid obesity, the risks from comorbidities and complications are sufficiently high that bariatric surgery may be indicated. Consequently, special consideration for such surgery may be given for an adolescent with severe morbid obesity presenting with unique circumstances.

Gastric wrapping and the Garren Gastric Bubble represent obsolete techniques. The jejunoileal bypass has also been abandoned due to severe metabolic complications.

Background/Overview

Surgery for clinically severe obesity (bariatric surgery) falls into two categories: Gastric restrictive procedures and malabsorptive procedures. The first category, gastric restrictive procedures, includes procedures in which a small pouch is created in the stomach. Weight loss occurs as the individual feels fuller sooner, having eaten much less than usual. The second category, malabsorptive procedures, includes procedures that rearrange the connections between the stomach and intestines, causing the food to be poorly digested and incompletely absorbed. Weight loss is due to malabsorption without necessarily requiring dietary modification.

Surgery for the treatment of clinically severe obesity may be appropriate in a select group of individuals. According to the National Institutes of Health (NIH), weight loss surgery should be reserved for individuals suffering from the complications of extreme obesity, for whom efforts of medical therapy have failed. Possible surgical candidates are those with severe obesity, defined as a body mass index (BMI*) of 40 or greater, or 35 or greater with other medical complications. Such complications include the following:

- Diabetes mellitus
- Hypertension
- Coronary artery disease
- Obstructive sleep apnea
- Pulmonary hypertension of obesity

*BMI is calculated by dividing an individual's weight (in kilograms) by height (in meters) squared. To convert pounds to kilograms, multiply pounds by 0.45; to convert inches to meters, multiply inches by 0.0254.

According to the National Institutes of Health (NIH), an increase of 20 percent or more above an individual's ideal body weight is the point at which excess weight becomes a health risk. Today, nearly two-thirds of Americans are overweight or obese. Nearly 15 million of those are considered to have clinically severe obesity, in which there is higher risk of one or more obesity-related health conditions that result either in significant physical disability or even death. While medical complications of obesity may occur in moderately obese people, the frequency increases dramatically as weight increases.

The first line treatment of clinically severe obesity is dietary and lifestyle changes, including regular exercise.

In order to lose weight, an individual must have a caloric deficit; calories out must be greater than calories in. This can be accomplished by decreasing the calories ingested with some form of dietary restriction and by increasing the calories expended through exercise. All available therapies (dietary, behavioral, pharmacologic, and surgical) help patients lose weight by changing the calories ingested, absorbed, or expended.

Surgery for clinically severe obesity is performed in a hospital setting. The number of days the individual is hospitalized is dependent on the type of surgery performed. When surgery is required for clinically severe obesity, the following are some of the more common procedures:

Gastric Restrictive Procedures

1. Vertical Banded Gastroplasty

Vertical banded gastroplasty is a purely restrictive procedure. The stomach is divided vertically, and a band is stapled around the top portion of the stomach to decrease its size. Because the normal flow of food is preserved, metabolic complications are rare. Complications of this procedure include esophageal reflux, as well as either widening or blockage of the narrow portion, which may require re-operation. Vertical banded gastroplasty may be performed using an open or laparoscopic approach. Many surgeons have abandoned this approach because of unsatisfactory long-term maintenance of weight loss.

2. Adjustable Gastric Banding

Adjustable gastric banding is also a purely restrictive procedure. It involves placing a gastric band around the exterior of the stomach. A thin flexible tube attaches the band to a reservoir that is implanted subcutaneously in the rectus sheath so that the band can be adjusted without further surgery. The size of the stomach can be progressively reduced to induce greater weight loss, or expanded if complications such as vomiting develop. Because the stomach is never entered, the surgery and any revision, if necessary, are proposed to be safer than conventional surgical treatments. Additional proposed advantages include reversibility of the procedure and maintenance of gastrointestinal anatomic integrity. However, serious complications may include slippage of the external band or band erosion through the stomach wall. Furthermore, incorrect positioning of the band may result in vomiting as well as ineffective weight loss. Recent improvements in surgical technique have decreased the incidence of such complications in some series, based on preliminary results, with erosions becoming rare and slippage (necessitating re-operation) occurring in about 2–5% of surgeries. Mortality is also generally less than other bariatric surgery procedures, amounting to about 1 in 1,000 to 1 in 2,000 procedures. Currently there is only one device approved by the FDA (in June, 2001) for marketing in the United States, called Lap-Band® (Inamed Health, formerly BioEnterics®).

3. Gastric Bypass

The most commonly performed restrictive approach is the Roux Y gastric bypass, which combines gastric restrictive and malabsorptive features. It involves a horizontal or vertical partitioning of the stomach, which results in a 90% restriction. It is followed by a Roux Y procedure in which the small intestine is reconfigured into a Y consisting of two limbs and a common channel. The proximal small bowel remains attached to the stomach and duodenum below the gastric division or partition. This limb is called the pancreatico-biliary conduit (or limb) and it drains bile, digestive enzymes, and gastric secretions. The other limb, sometimes called the Roux limb, is attached to and drains the small proximal gastric pouch, and so carries only food. The Y is created at the point where the pancreatico-biliary conduit and the Roux limb are connected. At this point the digestive juices and food mix and go on together, passing through the remaining arm of the Y, known as the common channel. Gastric bypass not only prevents the ability to ingest larger volumes at any one meal, but also induces a “dumping syndrome” if the patient ingests too much food or a high-sugar liquid meal. This unpleasant “dumping syndrome” occurs when a large amount of partially digested food is delivered directly to part of the small intestine from the stomach and can cause nausea, weakness, sweating, faintness, abdominal pain and vomiting. The dumping syndrome may further reduce intake particularly among “sweet eaters”. Surgical complications include leakage and stomal stricture. Since a major portion of digestion occurs in the stomach – specifically the process of breaking down food into nutrients – the amount of nutrients available for absorption is also reduced. As a result, this procedure requires that individuals take vitamin and mineral supplements. Gastric bypass may be performed using an open or laparoscopic approach.

4. Mini Gastric Bypass

Recently a variant of the gastric bypass, called the “mini gastric bypass” has been popularized. Using a laparoscopic (periscope-type) approach, the stomach is divided, similar to a traditional gastric bypass, but instead of creating a Roux Y connection, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure to the stomach. The unique aspect of this procedure is not based on its laparoscopic approach, but rather the type of anastomosis used. While this surgical approach may result in shorter operating time, it creates the risk of biliary reflux gastritis, in which bile flows back into the stomach and causes irritation. That is one of the reasons that this procedure has been abandoned in favor of a Roux Y gastric bypass.

Malabsorptive Procedures

1. Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure)

Biliopancreatic bypass (BPB) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to

unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the bypassed segment of the intestine. In contrast, BPB consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the small intestine by a long Roux Y procedure. This results in a 200 cm long alimentary tract and a 300 to 400 cm biliary tract. After these two tracts are joined at the distal anastomosis, there is only a 50 cm common absorptive alimentary tract. Because of the high incidence of gallstones associated with the procedure, patients typically have their gall bladders removed at the same time as the surgery. There are many potential complications related to biliopancreatic bypass, including iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parental nutrition. In addition, there have been several case reports of liver failure resulting in death or requiring liver transplant.

2. Biliopancreatic Bypass with Duodenal Switch

The duodenal switch procedure is essentially a variant of the biliopancreatic bypass described above. However, instead of performing a distal gastrectomy, a “sleeve” gastrectomy is performed along the vertical axis of the stomach, preserving the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum to create the alimentary limb. Preservation of the pyloric sphincter is designed to be more physiologic. The sleeve gastrectomy decreases the volume of the stomach and also decreases the parietal cell mass, with the intent of decreasing the incidence of ulcers at the duodenoileal anastomosis. The basic principle of this procedure is similar to that of the biliopancreatic bypass, which promotes weight loss by producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment. The potential for metabolic complications still exist with this procedure; however, this potential is not as great as with BPB. Individuals undergoing the duodenal switch procedure require long-term medical follow-up and regular monitoring of fat soluble vitamins, vitamin B-12, iron and calcium. There is some disagreement among surgeons about how long to make the alimentary and common channels. In some series, the common channel was created to be 100 cm for all patients. In another series that obtained good results, the small bowel segments varied according to the original length of the bowel. In that series, the alimentary limb segment (excluding the common channel) is about 40% of the total length of the small bowel, with the common limb being about 10% of the length of the total original small bowel length in increments of 25 cm. The common limb, therefore, is usually 50 cm, 75 cm, or 100 cm long depending on the individual. The important consideration is to make the channels long enough to prevent malnutrition and short enough to result in effective EWL.

3. Long Limb Gastric Bypass (i.e. >150cm)

Recent variations of gastric bypass procedures have been described, primarily consisting of long limb Roux Y procedures. The stomach may be bypassed in a variety of ways, i.e. either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially a gastric restrictive procedure, these very long limb Roux Y gastric bypasses function essentially as a malabsorptive procedure, more similar in concept to the biliopancreatic bypass. In the biliopancreatic bypass, the ileum is used as the alimentary limb, while in long limb gastric bypass, the jejunum functions as the alimentary limb. The long limb gastric bypass is designed to reduce the incidence of metabolic complications, but the potential complications are similar to those of the biliopancreatic bypass.

Operator Dependence in the Safety and Efficacy of Bariatric Procedures

Furthermore, strong evidence from a number of reports and case series exists for “operator dependence” in determining the risks and benefits of any bariatric procedure. It is important that the surgeon be extensively trained in the respective procedure and that the initial surgeries are supervised by an experienced bariatric surgeon until the “learning curve” is passed.

Definitions

Anastomosis: the connection of normally separate parts or spaces so that they intercommunicate. An anastomosis may develop naturally, or be artificially constructed during a surgical procedure

Body mass index (BMI): a key index for relating body weight to height. The BMI is a person's weight in kilograms (kg) divided by their height in meters (m) squared

Duodenal: related to the duodenum, which is the first part of the small intestine

Fistula: an abnormal passageway in the body. A fistula may go from the body surface into a blind pouch or into an internal organ or between two internal organs

Gastric: having to do with the stomach

Gastric banding: a surgical procedure used to help a person lose weight. A band is placed around the upper part of the stomach, creating a small pouch that can hold only a small amount of food. The narrowed opening between the stomach pouch and the rest of the stomach controls how quickly food passes from the pouch to the lower part of the stomach. The system helps the patient eat less by limiting the amount of food that can be eaten at one time and increasing the time it takes for food to be digested

Gastric bypass: a surgical procedure that reduces stomach capacity and diverts partially digested food from the duodenum to the jejunum (section of the small intestine extending from the duodenum)

Gastroplasty: a surgical procedure that decreases the size of the stomach

Jejunum: the portion of the small intestine that extends from the duodenum to the ileum

Obesity: the state of being well above one's normal weight because of an excessive accumulation of fat

Sleep apnea: temporary stoppage of breathing during sleep, often resulting in daytime sleepiness

Coding

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

00797	Anesthesia for intraperitoneal procedures in upper abdomen, including laparoscopy, gastric restrictive procedure for morbid obesity
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 band (gastric band and subcutaneous port components) (code effective 01/01/2006)
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 (less than 100cm) 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 band (separate procedure)

HCPCS

S2082	Laparoscopy, surgical; gastric restrictive procedure, adjustable gastric band, (includes placement of subcutaneous port) (code deleted 12/31/2005)
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline Note: medical necessity criteria for adjustments are based on whether or not the original surgery was considered medically necessary
S2085	Laparoscopy, gastric restrictive procedure, with gastric bypass for morbid obesity, with short limb (less than 100 cm), Roux-en-Y gastroenterostomy (deleted 12/31/2004)

ICD-9 Procedure

44.31	High gastric bypass
44.38	Laparoscopic gastroenterostomy (Roux-en-Y)
44.39	Other gastroenterostomy (open approach Roux-en-Y)
44.68	Laparoscopic gastropasty [Vertical banded gastropasty (VBG)]
44.95	Laparoscopic gastric restrictive procedure
44.96	Laparoscopic revision of gastric restrictive procedure
44.97	Laparoscopic removal of gastric restrictive device(s)

ICD-9 Diagnosis

All diagnoses

When services are considered Investigational/Not Medically Necessary:

For the procedure codes listed above, when criteria are not met, or when the code describes a procedure indicated in the Policy section as Investigational/Not Medically Necessary.

ICD-9 Procedure

44.93	Insertion of gastric bubble (balloon)
44.94	Removal of gastric bubble (balloon)

ICD-9 Diagnosis

All diagnoses

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Policy History

Status	Date	Action	
Revised	01/01/2006 11/22/2005	Updated coding section with 01/01/2006 CPT/HCPCS changes Added references for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).	
Revised	09/22/2005	Medical Policy & Technology Assessment (MPTAC) review. Revised Policy Statement: Included under medical necessity statement that the physician requesting authorization for the surgery must also confirm the following: <ul style="list-style-type: none"> • The patient has undergone a preoperative medical consultation and is felt to be an acceptable surgical candidate; • The patient has undergone a preoperative mental health assessment and is felt to be an acceptable candidate; • The patient’s treatment plan includes nutritional counseling; • The patient’s treatment plan includes counseling regarding exercise, psychological issues and the availability of supportive resources when needed. 	
Reviewed	04/28/2005	Added Physician Verification Form as attachment. Medical Policy & Technology Assessment Committee (MPTAC) review. Revision based on Policy Harmonization: Pre-merger Anthem and Pre-merger WellPoint.	
Pre-Merger Organizations	Last Review Date	Policy Number	Title
Anthem, Inc.	01/29/2004	SURG.00024	Surgery for Clinically Severe Obesity
WellPoint Health Networks, Inc	09/23/2004	3.06.02	Surgical Treatment of Morbid Obesity

Surgery for Morbid Obesity Physician Verification Form

Member: _____ **Member ID:** _____

BMI: _____ Weight: _____ Height: _____

1. Patient has failed conservative therapy: Yes No
2. Please outline previous conservative therapy: (attach additional pages as necessary)

3. Has the patient undergone a preoperative medical consultation and is felt to be an acceptable candidate? Yes No
4. Does the patient have any psychiatric conditions that would make it difficult for the patient to understand, tolerate, and comply with all phases of care? (attach notes) Yes No
5. Has the patient undergone a preoperative mental health assessment and is felt to be an acceptable candidate? Yes No
6. Has the patient been given information about the reasonable outcomes of surgery? Yes No
7. Has the patient received a thorough explanation of the risks, benefits, and uncertainties of the procedure? Yes No
8. Has the patient been evaluated by a dietician/nutritionist? (attach notes) Yes No
9. Does the dietician/nutritionist consider the patient a good candidate for surgery? Yes No
10. Does the current treatment plan include pre- and post-op dietary evaluations and nutritional counseling? Yes No
11. Does the current treatment plan include counseling regarding exercise, psychological issues and the availability of supportive resources when needed? Yes No
12. Proposed surgery with codes:
 - Gastric bypass length ____ cm codes: _____
 - Gastroplasty codes: _____
 - Biliopancreatic bypass with duodenal switch codes: _____
 - Laparoscopic adjustable gastric banding codes: _____

I do attest that the above is true and accurate to the best of my knowledge.

Print Name

Signature

Date

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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