Gastric Surgery for Clinically Severe (Morbid) Obesity

Origination: 3/28/01	**Revised:** 08/03/17	**Annual Review:** 11/02/17

Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Gastric Surgery for Clinically Severe (Morbid) Obesity in order to determine inclusion in the benefit plan.

Compliance Status:

- Centers for Medicare & Medicaid Services (CMS)

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Definitions

- **Guideline**: an instruction guide or reference to indicate a course of action in a specified situation.[1]
  Guidelines are systematically developed statements to assist the Medical Department staff in making decisions about appropriate healthcare for specified clinical conditions. Guidelines reflect the state of knowledge, current at the time of development, on effective and appropriate care. Given the inevitable changes in the state of scientific information and technology, periodic review updating and revision will take place.

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

The following are descriptions of bariatric surgery procedures:

a. Roux-en-Y Gastric Bypass (RYGBP)
   The RYGBP achieves weight loss by gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. RYGBP procedures can be open or laparoscopic.

b. Biliopancreatic Diversion with Duodenal Switch (BPD/DS)
BPD achieves weight loss by gastric restriction and malabsorption. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantially malabsorption occurs. The partial BPD with duodenal switch is a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transaction of the duodenum above the ampulla of Vater with a duodeno-ileal anastamosis and a lower ileo-ileal anastamosis. BPD/DS procedures can be open or laparoscopic.

c. Adjustable Gastric Banding (AGB)
AGB achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15-30 cc's encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. ABG procedures are laparoscopic only.

d. Sleeve Gastrectomy
Sleeve gastrectomy is a 70-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing RYGBP. Sleeve gastrectomy procedures can be open or laparoscopic.

e. Vertical Gastric Banding (VGB)
VGB achieves weight loss by gastric restriction only. The upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less.

Gastric Surgery for Clinically Severe (Morbid) Obesity

Coverage Guidelines

1.0 Member Selection (must meet ALL requirements):

1.1 Certain designated surgical services for the treatment of obesity are covered for beneficiaries who have either a BMI ≥40 or a BMI ≥35, have at least one (1) co-morbidity related to obesity and have been previously unsuccessful with the medical treatment of obesity." Co-morbidities include:

1.1.1 Coronary artery disease such as history of stroke, myocardial infarction, stable or unstable angina pectoris, past history of coronary artery surgery or coronary artery procedures;

1.1.2 Clinically significant obstructive sleep apnea with a respiratory disturbance index (RDI) of 16 to 30 (moderate) or apnea-hypopnea index (AHI) >30 (severe);

1.1.3 Diabetes mellitus;

1.1.4 Medically refractory hypertension uncontrolled by pharmacotherapy (documented at least triple anti-hypertensive therapy);

1.2 Member has completed growth (18 years of age or documentation of bone growth completion);

1.3 Recent psychiatric/psychological evaluation by a licensed physician, Ph.D, or Psy.D to rule out eating disorder(s) or psychological disturbance, such as Binge Eating Disorder, active drug abuse, active suicidal ideations/thoughts, borderline personality disorder, schizophrenia, terminal illness or uncontrolled depression, which may impede post-operative recovery and dietary restrictions;

1.4 Documentation that Member will have high probability for post-operative compliance related to regimented dietary and exercise programs;

1.5 Documentation that no medically treatable causes of obesity are present and the Member has an acceptable operative risk for the procedure and has been medically cleared;

1.6 Documentation that the surgery is to take place within the context of a program providing extensive pre- and post-operative assessments/ counseling that include evaluations by a multidisciplinary team including the surgeon;

1.7 Documentation that the Member has been informed of both the risks and benefits of surgical and non-surgical treatments;

1.8 Documentation (e.g., type, duration, amount of weight loss) of all prior weight control/loss programs including:

- 1.8.1 Food supplements;
- 1.8.2 Appetite suppressants;
- 1.8.3 Dietary regimens/treatments;
- 1.8.4 Exercise programs;

1.9 Documentation of non-operative, physician supervised integrated weight reduction program consisting of dietary therapy, appropriate exercise, behavior modification and psychological support:

1.9.1 Four (4) independent practitioner visits are required over a six (6)-month period to document supervision;

1.9.2 The program must maintain at least a six (6)-month duration, within three (3) years of request for surgical intervention;

1.9.3 Weight loss attempts through programs such as Weight Watchers, Curves, personal trainers, etc., are insufficient to meet these criteria;

1.9.4 If the Member's Primary Care Physician is used to fulfill the requirement of 1.9, all of the following documentation must be submitted:

1.9.4.1 At least six (6) office visits during the continuous six (6) month period in which the obesity and weight-related conditions are addressed in the progress notes and records;

1.9.4.2 The progress notes and records must include:

a. An actual measured weight and calculated BMI;
b. The Member's history;
c. The physical findings;
d. The physician's assessment;
e. The physician's treatment recommendation;

1.9.4.3 A physician's summary letter of care, by itself, is insufficient documentation.

2.0 An integrated program must be in place to provide guidance on diet, physical activity, and behavioral and social support both prior to and after the surgery.2

3.0 Because of potential nutrient deficiencies resulting from some loss of absorptive function following surgery, the NIH guidelines recommend lifelong medical surveillance after surgery as a necessity, particularly with regard to vitamin B_{12}, folate, and iron.[3]

4.0 In addition, CMS has determined that covered bariatric surgery procedures are reasonable and necessary **only** when performed at facilities certified by:

4.1 The American College of Surgeons (ACS http://www.facs.org/cqi/bscn/) as a Level 1 Bariatric Surgery Center (BSC; program standards and requirements in effect on February 15, 2006);

OR

4.1 The American Society for Bariatric Surgery (ASBS http://www.asbs.org/) as a Bariatric Surgery Center of Excellence (BSCOE; program standards and requirements in effect on February 15, 2006).

Repeat Bariatric Surgery:

5.0 Surgery to correct complications from bariatric surgery, such as obstruction or stricture is covered only if coverage for bariatric surgery is available under the Member's current health benefit plan.

6.0 Repeat bariatric surgery is covered for Members whose:

6.1 Initial bariatric surgery was medically necessary and would have met AvMed's Obesity surgery criteria; and,

6.2 Coverage for bariatric surgery is available under the Member's current health benefit plan; and,

6.3 Member meets either one (1) of the following criteria:

6.3.1.1 Conversion to a Roux-en-Y Gastric Bypass or Biliopancreatic diversion with duodenal switch may be considered for members who have not lost of more than 50% of their excess body weight at least two (2) years following the primary bariatric surgery procedure. There must be documentation of compliance with a prescribed nutrition and exercise program following the procedure;

OR

6.3.1.1 Revision of a primary bariatric surgery procedure that has technically failed due to dilation of the gastric pouch may be considered if the primary procedure was successful in inducing weight loss prior to the pouch dilation. There must be documentation of compliance with a prescribed nutrition and exercise program following the procedure.

7.0 Conversion/revision procedures are limited to once (x1) per lifetime:

7.1 Inadequate weight loss due to individual non-compliance with post-operative nutrition and exercise recommendations is not a medically necessary indication for revision or conversion surgery and is not a covered benefit.

Exclusion Criteria

1.0 If any of the following medical conditions is present, gastric obesity surgery is not covered:

1.1 Pregnancy/lactation;
1.2 Severe psychopathology;
1.3 Medical conditions that make the Member an unacceptable high surgical risk;
1.4 End-stage disease (e.g. cancer, uremia, liver failure), associated with an estimated survival less than one (1) year;
1.5 Substance abuse including alcohol and other drugs of abuse;
1.6 Smoking.

2.0 The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary; therefore, the following procedures, which are not all inclusive, are non-covered for all beneficiaries:

2.1 Open vertical banded gastroplasty	2.7 Fobi-pouch (Silastic Ring Vertical Gastric Bypass)
2.2 Open sleeve gastrectomy	2.8 Natural Orifice Transluminal Endoscopic Surgery (i.e., NOTES or StomaphyX)
2.3 Open adjustable gastric banding	2.9 Transoral Gastroplasty (TOGA)
2.4 Gastric Balloon	2.10 Gastric Electrical Stimulation
2.5 Intestinal Bypass	2.11 Aspire Assist Drainage System
2.6 Mini-gastric Bypass	

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References:

1. *Taber's® Cyclopedic Medical Dictionary. (1997).* F.A. Davis Company Philadelphia. Edition 18.

2. *NIH* - NHLB Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight, and Obesity in Adults - Executive Summary, 1991.

3. *AACE/ACE Position Statement on the Prevention, Diagnosis and Treatment of Obesity, 1998 Revision.*

4. *Medical Technology Assessment Committee Recommendation November 4, 2004.*

5. *Medicare National Coverage Determination, NCD 100.11* - Gastric Balloon for Treatment of Obesity, 1987.

6. *Medicare National Coverage Analysis (CIAG-00108N):* Obesity as an Illness – Preliminary Findings, 2004.

7. *Medicare National Coverage Determination, NCD 40.5* – Treatment of Obesity, Feb. 2006.

8. *16th Annual Meeting American Society for Bariatric Surgery June 9-12, 1999.* Obes. Surg 1999:9(2).

9. *National Institute for Clinical Excellence (NICE).* Guidance on the Use of Surgery to Aid in the Reduction for People with Morbid Obesity. Technology Appraisal Guidance No. 46. London UK. 2002.

10. *National Institute of Health* – Practical Guide to the Identification, Evaluation, and Treatment of Obesity, 2000.

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<u>Disclaimer Information</u>:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.