MEDICAL POLICY STATEMENT

INDIANA MEDICAID

Policy Name	Policy Number	Date Effective
Metabolic and Bariatric Surgery in Adults 20 and Older	MM-0257	11/01/2019

Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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Table of Contents

A. Subject

Metabolic and Bariatric Surgery in Adults 20 and Older

B. Background

Obesity continues to be a major health threat in the United States affecting an increasingly larger proportion of adults and children. The Centers for Disease Control and Prevention (CDC) estimate that over 39.8% of adults in the United States older than the age of 20 are obese (2015-2016). Obesity in adults aged 40 to 59 is higher (42.8%) than those under aged 40 (35.7%), statistics indicate that there has been a significant increase in obesity from 1999 through 2016. Only tobacco has a higher modifiable risk factor in adult mortality. If continuing to trend at the current rate, obesity will become the number one modifiable risk factor in adult mortality. Obesity-related health problems include hypertension, Type II diabetes, hyperlipidemia, atherosclerosis, heart disease, and stroke, diseases of the gallbladder, osteoarthritis, sleep apnea and certain cancers.

The primary goals in achieving optimal health outcomes for our members are providing noninvasive approaches to reduce or prevent obesity by promoting healthy life styles that will improve long-term outcomes. For individuals not able to manage serve obesity though non-surgical interventions, metabolic and bariatric surgery options may be an effective intervention. Metabolic and bariatric surgery must not be experimental or investigational, must meet current standard of care guidelines, and any device utilized must be FDA approved.

Bariatric and metabolic surgery has been shown to have positive effects on psychosocial functioning; however, 20% of patients fail to achieve significant weight loss. A National Institutes of Health (NIH) consensus panel concluded that patients contemplating bariatric surgery should undergo pre-surgery psychological evaluation along with monitoring and addressing of psychological and behavioral factors pre- and post-surgery.

Obesity is clinically defined using body mass index (BMI), a mathematical formula that quantifies body fat by reflecting the presence of excess adipose tissue. Body mass index is weight in kilograms divided by height in meters squared (Kg/M^2). BMI is the most common measure used to measure relative weight in comparison in children and adults.

The National Heart, Lung, and Blood Institute (NHLBI) classify the ranges of BMI in adults as follows (NHLBI, 1998):

- <18.5 - Underweight
- 18.5 to 24.9 kg/m^2 - Normal
- 25-29.9 kg/m^2 - Overweight
- 30-34.9 kg/m^2 - Obesity Class I
- 35-39.9 kg/m^2 - Obesity Class II
- Greater than 40 kg/m^2 – Extreme Obesity Class III (The term extreme obesity is equivalent to morbid obesity.

In addition, individuals with a BMI greater than 50 are classified as “super–obese”.

Professional Societies

The following professional societies’ recommendations are derived from the latest guidelines and scientific based literature available.

American Diabetes Association (ADA):

The ADA recommends bariatric surgery should be a recommended option to treat type 2 diabetes in appropriate surgical candidates with a body mass index (BMI) of 40 or greater regardless of glycemic control (BMI of 37.5 or greater in Asian Americans), and patients with a BMI of 35.0 to 39.9 (32.5 to 37.4 in Asian Americans) with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy. Surgery should also be considered as an option to treat type 2 diabetic patients with a BMI of 30.0 to 34.9 (27.5 to 32.4 in Asian Americans) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with reasonable nonsurgical methods. (2019)

National Institute of Health, the American Society for Bariatric Surgery, the American Obesity Association, and Shape Up America:

Guidelines developed by these organizations and embraced by the American Medical Association and the American College of Surgeons recommends that patients who are morbidly obese receive responsible, affordable medical treatment for their obesity.

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

The ASMBS in a joint commission with the AACE and the TOS recommends bariatric surgery be offered for patients with a BMI of 40 or greater and without a coexisting medical condition and for whom the surgery would not be considered high risk and for patients with a BMI of 35 or greater and 1 or more co-morbidities (2013).

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES):
The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) recommend bariatric surgery for the following (2008):

- BMI 35 to 40 with obesity-related co-morbid medical conditions
- BMI ≥ 40 without co-morbidity if the weight adversely affects the patient
- Demonstration that dietary attempts at weight control have been ineffective
- Patients are motivated and well-informed
- Patients are free of psychological disease

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD):

The National Institutes of Diabetes and Digestive and Kidney Diseases recommend bariatric surgery for the following (2016):

- BMI of greater than 40
- BMI of greater than 35 with serious comorbidity including:
    - Type 2 Diabetes

  - Heart Disease
  - Sleep Apnea
- For the gastric band only: BMI of 30 or greater with a serious health problem liked to obesity

C. Definitions

- Adolescent: an individual aged 10 to 19 years of age.
- Body Mass Index (BMI) for Adults: Body Mass Index (BMI): a person's weight in kilograms divided by the square of height in meters.
- Morbid Obesity: a weight which is at least 100 pounds over or twice the ideal weight for frame, age, height, and gender as specified in the 1983 Metropolitan Life Insurance tables. Morbid obesity also means a body mass index (BMI) equal to or greater than 35 kilograms per meter squared with comorbidity or coexisting medical conditions such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes or a BMI of 40 kilograms per meter squared without such comorbidity.
- Laparoscopic Adjustable Gastric Banding (LAGB): a type of laparoscopic surgery to effect weight loss by gastric restriction only. An adjustable band is placed around the top part of the stomach causing the creation of a very small stomach pouch. The band can be adjusted by removing or adding fluid using a needle inserted into a port placed under the skin of the abdomen into the balloon around the band.
- Mini Gastric Bypass or Laparoscopic Loop (LMGBP): involves the construction of a gastric tube by dividing (segmenting) the stomach vertically, down to the antrum. As in the RYGB, food does not enter the distal stomach. A mini gastric bypass creates a long narrow tube of the stomach along its right border (the lesser curvature). A loop of the small gut is brought up and hooked to this tube at about 180 cm from the start of the intestine. However, unlike gastric bypass surgery, digestive enzymes and bile are not diverted away from the stomach after LMGBP.
- Roux-en Y Gastric Bypass (RYGB): a surgical procedure (either open or laparoscopic) with two components. The first component is the surgical creation of a small stomach pouch, approximately one ounce or 30 milliliters in volume, by dividing the top of the stomach from the rest of the stomach. The second component is the division of the small intestine where a Y-shaped bottom end of the small intestine is connected to the newly created small stomach pouch, allowing food to bypass the lower stomach and parts of the digestive tract where calories and nutrients are absorbed, creating a direct connection to the lower portion of the small intestine.
- Successful weight-loss therapy: the ability to reduce body weight by approximately 10% from baseline in a period of 8 months.
- Sleeve Gastrectomy or Stand-Alone Laparoscopic Sleeve Gastrectomy (LSG): involves the removal of approximately 70 to 80 percent of the stomach through a curvature (resembling the shape of a banana) gastrectomy. The continuity of the gastric lesser curve is maintained. This procedure used to be part of the RYGBP but is sometimes performed as stand-alone surgery. This procedure can be open or laparoscopic.
- Unsuccessful weight-loss therapy: a weight regain of more than 3 kilograms (6.6 pounds) in 2 years and the inability to reduction in waist circumference of at least 4 cm.

D. Policy

I. A prior authorization is required for all types of metabolic and bariatric surgery.

II. Metabolic and bariatric surgery is considered medically necessary when:

A. Primary diagnosis is obesity

B. Patient is at least 20 years of age (For individuals 19 years of age and younger, please refer to Metabolic and Bariatric Surgery in Adolescents, Policy MM-0258)

C. All of the following Body Mass Index (BMI^2) requirements must be met:

1. The member is morbidly obese as defined by either of the following:

a. Patient has Body Mass Index (BMI^2) of 40 (Obesity Class III) or greater without comorbidity; OR

b. Patient has Body Mass Index (BMI^2) of at least 35 with at least one comorbidity or coexisting medical conditions, such those listed below:

01. Obesity hypoventilation syndrome (OHS)
02. Obstructive sleep disorder diagnosis/Obstructive Sleep Apnea (OSA), not otherwise well-controlled by standard therapies
03. Non-alcoholic fatty liver disease
04. Nonalcoholic steatohepatitis (NASH)
05. Pseudotumor cerebri
06. Gastroesophageal reflux disease (GERD)
07. Asthma
08. Venous stasis disease
09. Severe urinary incontinence
10. Debilitating arthritis
11. Poorly controlled hypertension on multi-drug therapy
12. Coronary Artery Disease
13. Pulmonary Hypertension
14. Diabetes

2. Failed weight-loss therapy as meeting the following criteria:

a. Unsuccessfully weight-loss therapy:

01. Morbid obesity has persisted for at least 5 years **and**
02. Physician-supervised nonsurgical weight-loss program has been unsuccessful for at least 6 consecutive months OR

b. Unsuccessful weight-loss maintenance:

01. Member successfully achieved weight loss after participating in a physician-supervised nonsurgical weight-loss program, but has been unsuccessful at maintaining weight loss for 2 years (> 3-kilogram [6.6-pound] weight gain).

III. DOCUMENTATION:

A. Written clinical documentation and supporting information from the attending surgeon must include all of the following:

1. Signed documentation of informed consent from the member acknowledging an understanding of pre- and postoperative expectations
2. Letter of medical necessity from the Primary Care Physician (PCP) or appropriate specialist.
3. Evidence that the member has actively participated in a physician supervised structured nutrition and exercise weight loss program for at least a 6-month period within the last 2 years.
4. Evidence that member is participating in a multi-disciplinary program to prepare them for surgery as well as through the extended post-operative period.

5. Documentation illustrating the member has been evaluated from a psychological standpoint within the past 6 months by the treating behavioral health provider including consideration of all of the following:
   a. Evidence that any co-existing psychiatric condition is stable.
   b. Obesity surgery is contraindicated if any of the following conditions exist:
      01. Active suicidality
      02. Active psychosis
      03. Active substance abuse
   c. Obesity surgery is contraindicated if member has an ongoing substance abuse problem within the previous year
   d. Evidence the member can withstand the rigors of surgery.
   e. Evidence the member can adhere with preoperative and postoperative long-term follow-up care.
   f. Assessment, listing of diagnoses and treatment plan must be provided.
6. The intended procedure must not be experimental or investigational, must meet current standard of care guidelines, and any device utilized must be FDA approved.
7. The member should not have a current or planned pregnancy within 12 to 18 months of surgery.
8. Consultation reports from other practitioners (anesthesiologist, pulmonologist, cardiologist, and so on) who have seen the member for evaluation, if applicable.

IV. REVISION SURGERY:

A. Revision surgery is considered medically necessary when complications following metabolic or bariatric surgery occur including one or more of the following:
   1. Abdominal pain
   2. Anastomotic leak
   3. Bacterial overgrowth
   4. Bowel obstruction
   5. Chest pain
   6. Fever
   7. Persistent vomiting
   8. Heartburn (new or increased)
   9. Inadequate weight loss

B. Prior authorization is required for reoperation to repair a complication or to correct a technical failure. PA for revision or conversion to Roux-en-Y includes a medical review of documentation. Documentation of medical necessity must include the reason for the failure and the date of the original surgery.

C. PA for revision of bariatric surgery due to the noncompliant behavior of the member requires 6 months of documentation in the medical record, to include the following:
   1. Member participation in all preoperative and postoperative evaluations and sessions included in the treatment plan
   2. Member participation in the preoperative and postoperative sessions with a bariatric dietician included in the treatment plan

3. An evaluation by a psychiatrist or licensed HSPP that reflects the absence of behavioral health contraindications to a successful outcome to revision of the bariatric surgery

V. EXCLUSIONS:

A. The following items are excluded from coverage

1. Procedures that are considered investigational or not meeting safety or efficacy standards will not be covered. The following procedures are not covered by the IHCP (this list may not be all-inclusive):
2. Fobi-Pouch (limiting proximal gastric pouch)
3. Gastroplasty (stomach stapling)
4. Intestinal bypass (jejunoileal bypass)
5. Intragastric balloon
6. Loop gastric bypass
7. Mini-gastric bypass
8. Natural orifice transluminal endoscopic surgery (NOTES) such as StomaphyX.
9. Panniculectomy following gastric bypass procedures performed for cosmetic reasons, even if performed incidentally to a ventral herniorrhaphy

E. Conditions of Coverage

HCPCS
CPT

AUTHORIZATION PERIOD

F. Related Polices/Rules

Metabolic and Bariatric Surgery in Adolescents MM-0258

G. Review/Revision History

	DATES	ACTION
Date Issued	09/21/2004	New Policy.
Date Revised	10/17/2017	Annual update
Date Effective	11/01/2019	Changed title from Obesity Surgery and updated per 2018 guidelines.

H. References

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 5/2019