Keywords: Adolescent Bariatric Surgery, Adult Bariatric Surgery, Bariatric Surgery, Repeat Bariatric Surgery

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I. ACTION

New Policy

x Revising Policy Number CMS02.02

Superseding Policy Number

Archiving Policy Number

Retiring Policy Number

II. POLICY DISCLAIMER

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement.

Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

III. POLICY

For Advantage MD, see Medicare Coverage Database:

- National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)

For USFHP see:


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IV. POLICY CRITERIA

A. When benefits are provided under the member’s contract, JHHC considers initial Bariatric Surgery (weight reduction surgery) medically necessary when ALL of the following modified InterQual criteria are met:

1. For adults aged 18 years or older: Clinically severe obesity:
   a. Body Mass Index (BMI) > 40 kg/m², OR;
   b. Body Mass Index (BMI) > 35 kg/m² and < 40 kg/m² with at least ONE of the following documented comorbidities:
      i. Type 2 diabetes mellitus (DM) by history,
      ii. Type 1 diabetes mellitus (case by case basis),
      iii. Hypertension (HTN) systolic BP >140mmHg or diastolic BP>90mmHg,
      iv. Coronary artery disease (CAD) by history
      v. Heart failure by history or physical examination
      vi. Dyslipidemia by history
      vii. Obstructive sleep apnea documented with sleep study,
      viii. Gastroesophageal reflux disease (GERD) by history,
      ix. Non-alcoholic fatty liver disease (NAFLD) or non-alcoholic steatohepatitis by history
      x. Obesity-hypoventilation syndrome (Pickwickian syndrome) confirmed by sleep study
      xi. Osteoarthritis by history,
      xii. Pseudotumor cerebri by history, AND;

2. For adolescents who have achieved greater than 95% of estimated adult height based on documented individual growth pattern and a minimum Tanner Stage of 4: Clinically severe obesity:
   a. Body Mass Index (BMI) > 35 kg/m² with at least ONE of the following documented comorbidities:
      i. Type 2 diabetes mellitus (DM) by history, OR;
      ii. Obstructive sleep apnea documented with sleep study, OR;
      iii. Pseudotumor cerebri by history, AND;
   b. Body Mass Index (BMI) > 40 kg/m² with at least ONE of the following documented less comorbidities or any of the comorbidities from section 1 above:
      i. Refractory hypertension, OR;
      ii. Dyslipidemia, OR;
      iii. Non-alcoholic fatty liver disease (NAFLD) or Non-alcoholic steatohepatitis by history, OR;
      iv. Significant impairment in activities of daily living, OR;
      v. Venous stasis disease, OR;
      vi. Intertriginous soft-tissue infections, OR;
      vii. Stress urinary incontinence, OR;
      viii. Gastroesophageal reflux disease (GERD), OR;
      ix. Weight-related arthropathies that impair physical activity, OR;
      x. Obesity-related psychosocial distress, AND;

3. Continued obesity despite a supervised weight loss program of a minimum of six (6) months.
   a. The information in this section is required in all cases of bariatric surgery (sections A and B above), AND;
   b. The member must demonstrate engagement in the process of eating behavior change by EITHER:
      i. Documentation that the member has achieved a minimum of 5% weight reduction (from recorded weight at first visit with the bariatric program staff) during the supervised weight loss program which should include use of a food and exercise diary.*, OR;
      ii. Documented active participation in a non-surgical weight reduction regimen for 6 months, to enable both behavioral changes and adequate assessment of anticipated postoperative dietary maintenance which should include food and exercise diary.*
c. *Documentation to include evidence that a daily food and activity diary has been kept by the member and reviewed by a professional of the bariatric team. Contents of a food/activity log typically include the following:
   i. For activity: List type and duration, e.g., brisk walk for 30 minutes.
   ii. For food/beverage: Place, time, food/beverage type, amount by weight or volume, calories per meal and total calories consumed for the day.
   iii. Other information: List hunger rating before food or drink consumption, feelings/mood rating. List trigger for eating (i.e., hunger, stress, time of day, event).

d. Commercially available diet programs or plans are acceptable methods of dietary management, if there is concurrent documentation of at least monthly clinical encounters with the physician and ongoing encounters with the dietitian/nutritionist where food and activity logs are reviewed.

B. Preoperative evaluation, including ALL of the following:
1. Cardiac and pulmonary evaluation with formal specialty consultation in members with significant cardiac or pulmonary diagnoses, AND;
2. Nutrition consult to do the following:
   a. Develop nutritional care plan for member, and;
   b. Provide resources to members on their specific care plan, and;
   c. Provide additional resources and information to members to accurately log their progress on meal and activity log as noted in documentation requirements (refer to section (c above*); AND;
3. Endocrinopathy excluded or adequately treated, AND;
4. Gastrointestinal evaluation, disease excluded or adequately treated. AND;
5. Psychiatry/Psychology consultation that includes at a minimum ALL of the following:
   a. Comprehensive psychiatric interview (initial visit requirement : in-person (face to face) evaluation, for identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome), AND;
   b. Complete Mental Status Examination (MSE), AND;
   c. Documentation of all current and previous psychiatric diagnoses, AND; EITHER:
      i. No behavioral health disorder by history, supported by 18 month claims and pharmacy activity, OR;
      ii. If behavioral health disorder by history and/or claims and pharmacy activity, documentation must indicate ALL of the following:
         • No active psychosis and
         • If binge eating disorder diagnosis or symptoms, these have been fully evaluated, treated and monitored;

d. Completion of drug and alcohol screen which documents ALL of the following:
   i. No drug or alcohol abuse by history supported by an eighteen (18) month claims and pharmacy look back, OR;
   ii. Alcohol and drug free period of a minimum of 1 year.
   iii. Members on methadone or suboxone maintenance must have an explicit postoperative pain management plan developed in coordination with their substance abuse provider

C. Procedure must be performed at an accredited Bariatric Surgery Center, which has been recognized as a member of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), AND;
D. Member understanding of surgical risk, post procedure compliance, and follow-up documented by bariatric surgeon.
E. Repeat Bariatric Surgery:
1. When benefits are provided under the member’s contract, JHHC considers removal or replacement of a gastric band medically necessary when recommended by the member's physician. Conversion to an alternative bariatric procedure at the time of band removal is not considered medically necessary unless all criteria in ILC below are met
2. When benefits are provided under the member’s contract, JHHC considers surgery to correct complications from bariatric surgery, such as obstruction, stricture, erosion, or band slippage, medically necessary.
3. When benefits are provided under the member’s contract, JHHC considers repeat bariatric surgery medically necessary for members whose initial bariatric surgery was medically necessary (i.e., who met medical necessity criteria for their initial bariatric surgery), AND; who qualify for ANY of the following:
   a. Revision of a primary bariatric surgery procedure that has failed due to dilation of the gastric pouch, dilated gastrojejunal stoma, or dilation of the gastrojejunostomy anastomosis is considered medically necessary IF the primary procedure was successful in inducing weight loss prior to the dilation of the pouch or GJ anastomosis AND the member has been fully compliant with all post-operative follow-up care, nutrition and exercise requirements, OR;
   b. Conversion from an adjustable band to a sleeve gastrectomy, Roux-en-Y Gastric Bypass (RYGB) or Biliopancreatic Diversion with Duodenal Switch (BPD/DS) is considered medically necessary for members who have been fully compliant with all post-operative follow-up care, nutrition, and exercise requirements following the band procedure and there are complications that cannot be corrected with band manipulation, adjustments or replacement, OR;
   c. Conversion to a sleeve gastrectomy, RYGB or BPD/DS is considered medically necessary for members who have not had adequate success (defined as loss of more than 50% of excess body weight) 3 years following the primary bariatric surgery procedure and the member has been fully compliant with all post-operative follow-up care, nutrition and exercise requirements.

4. Revision or repeat of gastric restrictive surgery will not be authorized for inadequate weight loss or weight regain due to individual noncompliance with postoperative nutrition and exercise recommendations.

F. Unless specific benefits are provided under the member’s contract, JHHC considers all other treatments and surgeries, including but not limited to the following, experimental and investigational, as they do not meet Technology Evaluation Criteria (TEC). Refer to CMS01.00 Medical Policy Introduction Technology Evaluation Criteria.
   1. Loop Gastric Bypass,
   2. Gastroplasty using staples to create a small pouch,
   3. Biliopancreatic bypass, Intestinal/Jejunoileal Bypass
   4. Intragastric balloon,
   5. Vagal blocking therapy (VBLOC), AND/OR;
   6. Gastrointestinal electrical stimulation (GES)

V. DEFINITIONS

Body Mass Index (BMI): A person’s weight in kilograms divided by the square of height in meters. BMI can be used as a screening tool but is not diagnostic of the body fatness or health of an individual. (Centers for Disease Control and Prevention, CDC, 2017.

Bariatric Surgery Procedures:

Gastric Bypass: The Roux-en-Y Gastric Bypass- often called gastric bypass is considered the gold standard of weight loss surgery. There are two components to the procedure. First, a small stomach pouch, approximately one ounce or 30 milliliters in volume, is created by dividing the top of the stomach from the rest of the stomach. Next, the first portion of the small intestine is divided, and the bottom end of the divided small intestine is brought up and connected to the newly created small stomach pouch. The procedure is completed by connecting the top portion of the divided small intestine to the small intestine further down so that the stomach acids and digestive enzymes from the bypassed stomach and first portion of small intestine will eventually mix with the food. The gastric bypass works by several mechanisms. First, similar to most bariatric procedures, the newly created stomach pouch is considered smaller and facilitates significantly smaller meals, which translates into less calories consumed. Additionally, because there is less digestion of food by the smaller stomach pouch, and there is a segment of small intestine that would normally absorb calories as well as nutrients that no longer has food going through it, there is probably to some degree less absorption of calories and nutrients. Most importantly, the rerouting of the food stream produces
changes in gut hormones that promote fullness, suppress hunger, and reverse one of the primary mechanisms by which obesity induces type 2 diabetes.

A. Advantages
1. Produces significant long-term weight loss (60-80 percent excess weight loss)
2. Restricts the amount of food that can be consumed
3. May lead to conditions that increase energy expenditure
4. Produces favorable changes in gut hormones that reduce appetite and enhance fullness
5. Typical maintenance of >50% excess weight loss

B. Disadvantages
1. Is technically a more complex operation than the Adjustable Gastric Band (AGB) or Laparoscopic Sleeve Gastrectomy (LSG) and potentially could result in greater complication rates
2. Can lead to long-term vitamin/mineral deficiencies particularly deficits in vitamin B12, iron, calcium, and folate
3. Generally has a longer hospital stay than the AGB
4. Requires adherence to dietary recommendations, life-long vitamin/mineral supplementation, and follow-up compliance. (ASMBS 2018)

Adjustable Gastric Band: The Adjustable Gastric Band – often called the band – involves an inflatable band that is placed around the upper portion of the stomach, creating a small stomach pouch above the band, and the rest of the stomach below the band. The common explanation of how this device works is that with the smaller stomach pouch, eating just a small amount of food will satisfy hunger and promote the feeling of fullness. The feeling of fullness depends upon the size of the opening between the pouch and the remainder of the stomach created by the gastric band. The size of the stomach opening can be adjusted by filling the band with sterile saline, which is injected through a port placed under the skin. Reducing the size of the opening is done gradually over time with repeated adjustments or “fills.” The notion that the band is a restrictive procedure (works by restricting how much food can be consumed per meal and by restricting the emptying of the food through the band) has been challenged by studies that show the food passes rather quickly through the band, and that absence of hunger or feeling of being satisfied was not related to food remaining in the pouch above the band. What is known is that there is no malabsorption; the food is digested and absorbed as it would be normally. The clinical impact of the band seems to be that it reduces hunger, which helps the patients to decrease the amount of calories that are consumed.

A. Advantages
1. Reduces the amount of food the stomach can hold
2. Induces excess weight loss of approximately 40 – 50 percent
3. Involves no cutting of the stomach or rerouting of the intestines
4. Requires a shorter hospital stay, usually less than 24 hours, with some centers discharging the patient the same day as surgery
5. Is reversible and adjustable
6. Has the lowest rate of early postoperative complications and mortality among the approved bariatric procedures
7. Has the lowest risk for vitamin/mineral deficiencies

B. Disadvantages
1. Slower and less early weight loss than other surgical procedures
2. Greater percentage of patients failing to lose at least 50 percent of excess body weight compared to the other surgeries commonly performed
3. Requires a foreign device to remain in the body
4. Can result in possible band slippage or band erosion into the stomach in a small percentage of patients
5. Can have mechanical problems with the band, tube or port in a small percentage of patient
6. Requires strict adherence to the postoperative diet and to postoperative follow-up visits (ASMBS 2018)
Sleeve Gastrectomy: The Laparoscopic Sleeve Gastrectomy (often called the sleeve) is performed by removing approximately 80 percent of the stomach. The remaining stomach is a tubular pouch that resembles a banana. This procedure works by several mechanisms. First, the new stomach pouch holds a considerably smaller volume than the normal stomach and helps to significantly reduce the amount of food (and thus calories) that can be consumed. The greater impact, however, seems to be the effect the surgery has on gut hormones that impact a number of factors including hunger, fullness, and blood sugar control. Short term studies show that the sleeve is as effective as the roux-en-Y gastric bypass in terms of weight loss and improvement or remission of diabetes. There is also evidence that suggest the sleeve, similar to the gastric bypass, is effective in improving type 2 diabetes independent of the weight loss. The complication rates of the sleeve fall between those of the adjustable gastric band and the roux-en-y gastric bypass.

A. Advantages
   1. Restricts the amount of food the stomach is able to hold
   2. Induces rapid and significant weight loss that comparative studies find similar to that of the Roux-en-Y gastric bypass (RYGB). Weight loss of >50% for 3-5+ year data, and weight loss comparable to that of the bypass with maintenance of >50%
   3. Requires no foreign objects Adjustable Gastric Banding (AGB), and no bypass or re-routing of the food stream (RYGB)
   4. Involves a relatively short hospital stay of approximately 2 days
   5. Causes favorable changes in gut hormones that suppress hunger, reduce appetite and improve fullness

B. Disadvantages
   1. It is a non-reversible procedure
   2. It has the potential for long-term vitamin deficiencies
   3. It has a higher early complication rate than the (AGB) (ASMB 2018)

Biliopancreatic Diversion with Duodenal Switch (BPD/DS) Gastric Bypass: The Biliopancreatic Diversion with Duodenal Switch (abbreviated as BPD/DS) is a procedure with two components. First, a smaller, tubular stomach pouch is created by removing a portion of the stomach, very similar to the sleeve gastrectomy. Next, a large portion of the small intestine is bypassed. The duodenum, or the first portion of the small intestine, is divided just past the outlet of the stomach. A segment of the distal (last portion) small intestine is then brought up and connected to the outlet of the newly created stomach, so that when the patient eats, the food goes through a newly created tubular stomach pouch and empties directly into the last segment of the small intestine. Roughly three-fourths of the small intestine is bypassed by the food stream. The bypassed small intestine, which carries the bile and pancreatic enzymes that are necessary for the breakdown and absorption of protein and fat, is reconnected to the last portion of the small intestine so that they can eventually mix with the food stream. The BPD/DS initially helps to reduce the amount of food that is consumed; however, over time this effect lessens and patients are able to eventually consume near “normal” amounts of food. Unlike the other procedures, there is a significant amount of small bowel that is bypassed by the food stream. In addition, the food does not mix with the bile and pancreatic enzymes until very far down the small intestine. This results in a significant decrease in the absorption of calories and nutrients (particularly protein and fat) as well as nutrients and vitamins dependent on fat for absorption (fat soluble vitamins and nutrients). Lastly, the BPD/DS, similar to the gastric bypass and sleeve gastrectomy, affects gut hormones in a manner that impacts hunger and fullness as well as blood sugar control. The BPD/DS is considered to be the most effective surgery for the treatment of diabetes among those that are described above in the definitions.

A. Advantages
   1. It results in greater weight loss than RYGB, LSG, or AGB, i.e. 60-70% excess weight loss or greater, at 5 year follow up
   2. It allows patients to eventually eat near “normal” meals
   3. The absorption of fat will be reduced by 70% or more

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4. It causes favorable changes in gut hormones to reduce appetite and improve fullness
5. It is the most effective against diabetes compared to RYGB, LSG, and AGB

B. Disadvantages
1. It has higher complication rates and risk for mortality than the AGB, LSG, and RYGB
2. It requires a longer hospital stay than the AGB or LSG
3. Greater potential to cause protein deficiencies and long-term deficiencies in a number of vitamin and minerals, i.e. iron, calcium, zinc, fat-soluble vitamins such as vitamin D
4. In order to avoid serious complications from protein and certain vitamin deficiencies it is critical to be compliant with follow-up visits and care and to have strict adherence to dietary and vitamin supplementation guidelines. (ASMBS 2018)

VI. BACKGROUND

Bariatric surgery is an increasingly popular approach for treating obesity. The term “bariatric surgery” refers to several procedures that involve the stomach and/or intestine. Such procedures include Roux-en-Y Gastric Bypass (RYGB) Surgery, Laparoscopic Adjustable Gastric Banding, Biliopancreatic Diversion (BPD/DS), and Vertical Banded Gastroplasty and Sleeve Gastrectomy. The theory behind how bariatric surgery promotes weight loss is that when the size of the stomach is decreased by an intervention such as gastric banding or a surgical reduction in stomach size, an individual feels satiated after consuming a small amount of food and therefore limits the amount of calories consumed. Excess calories are additionally limited when the surgery involves bypass of a portion of the small intestine because the area available for absorption of nutrients is decreased. RYGB currently ranks among the most popular bariatric procedures and is considered the gold standard of weight loss surgery. Involving creation of a small stomach pouch in combination with connecting the new pouch with the middle portion of the small intestine, RYGB is a procedure that seeks to accomplish weight loss via both theorized weight loss mechanisms.

Because obesity is a health condition that involves multiple body systems, evaluation of candidates for bariatric surgery typically involves collaboration between health professionals that transcends many disciplines of medicine. Individuals must be physically able to endure surgery and psychiatrically prepared for post-surgical changes in eating habits that are mandatory for achieving optimal outcomes. As with most medical interventions, bariatric surgery possesses a combination of potential risks and benefits that require evaluation when deciding upon whether to include bariatric surgery in an individual’s plan of care.

Psychosocial factors have great potential to affect long-term outcomes of bariatric surgery, including emotional adjustment, sticking to the recommended postoperative lifestyle regimen, weight loss outcomes, and co-morbidity improvement and or resolution. Therefore, it is 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. The clinician who evaluates the patient has a major role in the multidisciplinary treatment of the bariatric patient. One of the main roles is to identify factors that may pose challenges to optimal surgical outcomes and to provide recommendations to the patient and bariatric team on how to address these issues. (ASMBS, 2016).

Additional guidance and general education on nutrition is available through the JHHC Health Promotion and Wellness Unit of the Care Management Department. For additional information refer to medical policy CMS14.02 Nutritional Counseling

VII. CODING DISCLAIMER

CPT Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage and referral requirements. All inpatient admissions require preauthorization.
Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits

Employer Health Programs (EHP) refer to specific Summary Plan Description (SPD). If there is no criteria in the SPD, apply the Medical Policy criteria.

Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply the Medical Policy criteria.

US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria.

Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria.

VIII. CODING INFORMATION

PRE-AUTHORIZATION REQUIRED

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<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
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<td>Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only</td>
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### ICD10 AND REVENUE CODES ARE FOR INFORMATIONAL PURPOSES ONLY

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IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

X. REFERENCES


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XI. APPROVALS