Subject: Bariatric Surgery

Background: Morbid obesity (also called clinically severe obesity) is a serious health condition that can interfere with basic physical functions such as breathing or walking, and reduce life expectancy. Individuals who are morbidly obese are at greater risk for serious medical complications including hypertension, coronary artery disease, type 2 diabetes mellitus, sleep apnea, gastroesophageal reflux disease and osteoarthritis. While the immediate cause of obesity is caloric intake that persistently exceeds caloric output, a limited number of cases may also be caused by illnesses such as hypothyroidism, Cushing's disease, and hypothalamic lesions. Nonsurgical strategies for achieving weight loss and weight maintenance (e.g., caloric restriction, increased physical activity, behavioral modification) are recommended for most overweight and obese persons.

Bariatric (weight loss) surgery is a major surgical intervention, and is indicated for adults and adolescents who have completed bone growth, and are morbidly obese.

Bariatric surgery procedures modify the anatomy of the gastrointestinal tract and cause weight loss by restricting the amount of food the stomach can hold, causing malabsorption of nutrients. Bariatric procedures can often cause hormonal and metabolic changes that result from gastric and intestinal surgery.

The most common bariatric surgery procedures are gastric bypass, sleeve gastrectomy, adjustable gastric band, and biliopancreatic diversion with duodenal switch. Restrictive procedures (e.g., adjustable gastric banding, vertical banded gastroplasty) cause weight loss by limiting the stomach's capacity and slowing the flow of ingested nutrients. Expected weight loss with restrictive procedures is approximately 50-70% of the individual's pre-surgery body weight.

The following are descriptions of bariatric surgery procedures:

- Adjustable Gastric Banding (AGB) – AGB achieves weight loss through gastric restriction only. An inflatable doughnut-shaped balloon band creates a gastric pouch of approximately 15 to 30 cc's in the uppermost portion of the stomach. The diameter of the band can be adjusted in the clinic by adding or removing saline through a port that is positioned beneath the skin and allows the size of the gastric outlet to be modified. AGB procedures are laparoscopic only.
- Biliopancreatic Diversion with Duodenal Switch (BPD/DS) – BPD/DS partially resects the stomach and achieves weight loss through gastric restriction and malabsorption. Meal intake does not need to be restricted radically and patients eat relatively normal-sized meals, as the proximal areas of the small intestine (e.g. duodenum and jejunum) are bypassed and substantial malabsorption occurs. Partial BPD/DS involves resection of the greater curvature of the stomach. It preserves the pyloric sphincter and transects the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis. BPD/DS can be open or laparoscopic.
- Roux-en-Y Gastric Bypass (RYGBP) – RYGBP reduces the stomach to a small gastric pouch (30 cc), which results in feelings of satiety following smaller meals. This procedure achieves weight loss through gastric restriction and malabsorption. The small gastric pouch is joined to a segment of the jejunum, bypassing the

duodenum and very proximal small intestine, ultimately reducing absorption. RYGBP can be open or laparoscopic.
- Sleeve Gastrectomy – The greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a tube or sleeve shaped stomach. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum. This prevents the dumping syndrome, which occurs when there is an overly rapid transport of food through the stomach into the intestines.
- Vertical Gastric Banding (VGB) – VGB achieves weight loss by gastric restriction only. The upper part of the stomach is stapled, which creates a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. A non-adjustable band is placed around the inlet to prevent future enlargement of the opening. This creates a sense of fullness after eating smaller meals. Weight loss from this procedure solely depends on eating less. VGB procedures are essentially no longer performed.

Contraindications for bariatric surgeries include cardiac complications, significant respiratory dysfunction, non-compliance with medical treatment, psychological disorders that a psychologist/psychiatrist determines are likely to exacerbate or interfere with long-term management, significant eating disorders, and severe hiatal hernia/gastroesophageal reflux.

Authorization: Prior authorization is required for bariatric surgeries provided to members enrolled in commercial (HMO, POS, PPO) products.

Policy and Coverage Criteria:

Weight Loss Surgery Centers of Excellence

Harvard Pilgrim Health Care (HPHC) has designated selected in-network facilities as Weight Loss Surgery Centers of Excellence (COE); these facilities provide access to integrated programs focused on patient health, safety and cross-functional team support, and have met stringent quality criteria established by the American College of Surgeons and/or the American Society for Metabolic and Bariatric Surgery.
- A list of designated Weight Loss Surgery Centers of Excellence is published on HPHC's public website: https://www.harvardpilgrim.org/public/plan-details/weight-loss-surgery-centers-of-excellence

To ensure quality of care, HMO members should be directed to a designated Weight Loss Surgery Center of Excellence.
- For POS and PPO members, medically necessary procedures performed at designated Centers of Excellence facilities are covered at in-network cost; procedures performed at non-COE facilities may be covered at out-of-network benefits levels.

Initial Procedures:
Harvard Pilgrim Health Care (HPHC) considers bariatric surgeries as medically necessary for adults and adolescents over 15 years of age when ALL of the following criteria and all-age specific criteria are met:
- The bariatric surgeon has determined the member is an appropriate candidate for ONE of the following procedures:
  - Sleeve Gastrectomy
  - Short Limb Gastric Bypass/Roux-en-Y (RYGB)- Roux Limb, 150 cm or less
  - Adjustable Silicone Gastric Banding (e.g., LAP-BAND®, REALIZE™ Adjustable Gastric Band)
  - Biliopancreatic diversion with duodenal switch (BPD/DS)

- All of the following age-specific criteria are met:
  - Adults: Medical record documentation confirms EITHER of the following below:
    - Body Mass Index (BMI) of 40 or more; OR
    - BMI above 35 and ANY of the following high-risk comorbid conditions confirmed by a PCP and/or a specialist:
      - □ Type II Diabetes, with documentation of diabetes diagnosis consistent with the American Diabetic Association (diagnosis must be confirmed by an endocrinologist or primary care physician/provider)
      - □ Documented confirmation of obstructive sleep apnea (OSA) within the last 12 months
      - □ Coronary artery disease
      - □ Significant obesity-related cardiopulmonary conditions (e.g., Hypoventilation Syndrome, Cardiomyopathy, Pulmonary Hypertension)
      - □ Pseudotumor cerebri (diagnosis confirmed, and treatment plan supported by neurologist)
      - □ Pickwickian Syndrome
      - □ Severe, weight-bearing back or joint disease evaluated by an orthopedic or neurosurgeon
      - □ Severe arthropathy of spine and/or weight-bearing joints (when obesity prohibits appropriate surgical management of joint dysfunction treatable but for the obesity; (diagnosis must be confirmed by an orthopedic surgeon)
      - □ Continued hypertension requiring pharmacological treatment (i.e. blood pressure 140 mmHg systolic and/or 90 mmHg diastolic, despite use of 3 anti-hypertensive agents of different classes, unless contraindicated
      - □ Obesity induced cardiomyopathy (diagnosis must be confirmed by a cardiologist)
      - □ Obesity-related hypoventilation (diagnosis must be confirmed by a pulmonologist)

    The medical conditions need not be immediately life-threatening, but must be of sufficient severity as to pose considerable short-or long-term risk to function and/or survival, and must not be trivial or easily controlled with non-invasive intervention (e.g., medication). Consideration of the risk-benefit for each individual patient must be used to determine that surgery is the best option for treatment for the individual patient, and no contraindications to bariatric surgery may exist.

  - Adolescents: Bariatric surgery for morbid obesity is considered medically necessary for adolescents between 15-17 years of age when medical record documentation confirms the below criteria:
    - Member has attained (or nearly attained) physiological and skeletal maturity;
    - The individual has adequate cognitive, social, and emotional development to support his/her independent role in the decision-making process;
    - Member has adequate family/social support to ensure compliance with long-term follow-up and support a successful long-term outcome
    - EITHER of the following below:
      - □ Body Mass Index (BMI) of 40 or more AND any of the following high-risk comorbid conditions:
        - ♦ Type II Diabetes
        - ♦ Hypertension requiring pharmacological treatment
        - ♦ Obstructive Sleep Apnea (OSA)
        - ♦ Coronary artery disease
        - ♦ Pseudotumor cerebri (diagnosis confirmed and treatment plan supported by neurologist)
      - □ BMI of 50 or more AND any of the following less serious co-morbidities:
        - ♦ Dyslipidemias

- Gastroesophageal reflux disease
- Hypertension
- Insulin resistance
- Intertriginous soft-tissue infections
- Nonalcoholic steatohepatitis
- Stress urinary incontinence
- Venous stasis disease
- Weight-related arthropathies that impair physical activity

The medical conditions need not be immediately life-threatening, but must be of sufficient severity as to pose considerable short-or long-term risk to function and/or survival, and must not be trivial or easily controlled with non-invasive intervention (e.g., medication). Consideration of the risk-benefit for each individual patient must be used to determine that surgery is the best option for treatment for the individual patient, and no contraindications to bariatric surgery may exist.

- The member is motivated to achieve substantial weight loss, is a good candidate for the procedure and long-term follow-up, and is well-informed about potential operative risks, realistic expectations of surgery, and the need for lifelong medical follow up
- Member does not have ANY of the following contraindications:
  - Cardiac complications (prohibitive perioperative risk of cardiac complications due to cardiac ischemia or myocardial dysfunction)
  - Severe chronic obstructive pulmonary disease (COPD) or respiratory dysfunction
  - Failure to cease tobacco use
  - History of significant eating disorders
  - Documented hepatic disease with inflammation
  - Portal hypertension
  - Ascites
  - Behavioral health condition that imparts significant risk of psychological/psychiatric decompensation or is expected to interfere with long-term postoperative management.

  Note: A history or presence of mild, uncomplicated, and adequately treated depression due to obesity is not normally considered an absolute contraindication to bariatric surgery. Requests for bariatric surgery for patients with compensated cirrhosis and mild portal hypertension may be approved on a case-by-case basis. Medical record documentation must confirm that location and severity of the varices will not adversely impact likelihood that the member can reasonably be expected to benefit from the requested procedure (e.g., sleeve gastrectomy in a patient with stable gastric varies located in the fundus).

- In addition, all covered procedures must be provided as part of a comprehensive multidisciplinary program that includes a comprehensive pre-operative evaluation (including medical, nutritional and behavioral health assessment), and appropriate post-operative follow-up including nutritional and exercise counseling. Requests for bariatric surgeries must include medical record documentation that contains ALL the following:
  - Assessment and history of repeated attempts to lose weight (with failure to achieve sustained weight loss) through established non-surgical weight loss programs and/or clinician supervised approaches to long-term weight loss (e.g., diet/nutrition regimens, behavioral modification, exercise, and/or pharmacologic agents). Member must have documentation confirming completion of at least 6 months of medically supervised weight loss and exercise program, with at least 3 of those months being consecutive; AND

- Behavioral health history indicating no issues (e.g., active substance abuse, untreated major depression or anxiety, other serious psychological disorders) that could reasonably be expected to complicate the recuperative process or member's compliance with diet and post-surgery follow-up; AND
- Evaluation of member's ability to incorporate nutritional and behavioral changes (i.e. exercise programs based on the individual's capability) before and after bariatric surgery.

Repeat Procedures:
Repeat/Revision procedures after bariatric surgery may be authorized for eligible members over 15 years of age when complications are associated with the initial procedure that was considered medically necessary. Medical record documentation must also confirm ANY of the following:

- Individual's physician requires removal of a gastric band as medically necessary, OR
- Member requires replacement of an adjustable band due to complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments, OR
- Individual has a symptomatic anatomic abnormality resulting from the prior bariatric procedure (e.g., obstruction, stricture, band erosion, anastomotic stenosis or ulcer), and surgery is necessary to correct complications necessary to resolve symptoms, OR
- Member failed gastric bypass surgery, due to dilation of the gastric pouch, dilation of the gastrojejunostomy anastamosis. Member must have remained compliant with prescribed nutrition and exercise programs and the primary procedure must have been successful in inducing weight loss prior to the pouch/anastamotic dilation, OR
- Member has failed to lose at least 50% of excess weight within 2 years of authorized bariatric surgery despite compliance with prescribed nutrition and exercise programs. (All other requirements for coverage of bariatric surgery must be met.)

Exclusions:

Harvard Pilgrim Health Care (HPHC) does not cover bariatric surgeries when criteria above are not met. In addition, HPHC does not cover:

- Repeat or revisional procedures when member has not remained compliant to prescribed nutritional and exercise programs
- Adults and adolescents with Body Mass Index (BMI) less than 35
- Roux-en-Y gastric bypass as treatment for gastroesophageal reflux in non-obese persons
- Open adjustable gastric banding
- Open sleeve gastrectomy
- Open or laparoscopic vertical banded gastroplasty
- Intestinal bypass surgery (Jejunoileal bypass)
- Gastric balloon for treatment of obesity (e.g. Obalon ® Balloon, swallowable intragastric balloon system)
- Gastric bypass using a Billroth II type of anastomosis (Mini-gastric bypass, laparoscopic)
- Exercise programs other than those included in a comprehensive multi-disciplinary bariatric program
- Restorative obesity surgery endoscopy (ROSE) procedure
- Gastric electrical stimulation
- Silastic ring vertical gastric banding (e.g. Fobi Pouch)
- Multiple bariatric surgical procedures

Guidelines:

The American Diabetic Association considers criteria for the diagnosis of diabetes as follows:

1. Glycated hemoglobin (A1C) ≥ 6.5%. The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardized Program (NGSP) certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay, OR
2. Fasting plasma glucose (FPG) ≥ 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least eight hours, OR
3. Two-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization using a glucose load containing the equivalent of 750gram anhydrous glucose dissolved in water, OR
4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200 mg/dL (11.1 mmol/L).

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

CPT® Codes	Description
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
43659	Unlisted laparoscopy procedure, stomach
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., 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 (i.e., sleeve gastrectomy)
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)
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

Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

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Summary of Changes:

Date	Change
4/19	Annual review; criteria and coding updated
2/18	Policy coverage criteria reviewed and refined
4/17	Background, references and supporting information updated. Per LCD guidelines, policy criteria was updated to include added contraindications and comorbidities for adults and adolescents.
1/17	Added Criteria requiring no contradictions to major surgical intervention. Clarified that co-morbidities. Expanded CPT coding and added ICD 10 codes.
12/15	Coding added. Formatting and references updated. Update format and references. Delete Vertical Banded Gastroplasty (VBG) from list of covered procedures; add to list of exclusions. Add footnote re: coverage for bariatric surgery in patients with compensated cirrhosis and mild portal hypertension.

Approved by Medical Policy Committee: 4/9/19
Approved by Clinical Policy Operational Committee: 1/03, 12/03, 1/05, 1/06, 3/06, 5/07, 12/07, 2/08, 6/08, 5/09, 7/09, 5/10, 4/11, 5/12, 6/13, 7/14, 10/14, 12/15, 1/17, 4/17, 2/18; 4/19

Policy Effective Date: 4/11/19
Initiated: 11/01