



CLINICAL MEDICAL POLICY	
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Products:	Highmark Wholecare SM Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
05/01/2024	Provider Effective date
02/29/2024	PARP approval
01/17/2024	QI/UM Committee review
01/17/2024	Annual Review: Reformatted and revised 'Procedures' section. Updated bariatric surgery coverage criteria. Removed Group 2 & Group 3 Diagnosis Codes from 'Coding Requirements' section. Added the following Non-covered Diagnosis Codes: E66.1, E66.3, E66.8, E66.9, E66.09, K21.00, & K21.01. Removed the following covered Diagnosis Codes: A18.84, E11.00, E11.01, E11.21, E11.22, E11.29, E11.311, E11.319, E11.3211, E11.3212, E11.3213, E11.3219, E11.3291, E11.3292, E11.3293, E11.3299, E11.3311, E11.3312, E11.3313, E11.3319, E11.3391, E11.3392, E11.3393, E11.3399, E11.3411, E11.3412, E11.3413, E11.3419, E11.3491, E11.3492, E11.3493, E11.3499, E11.3511, E11.3512, E11.3513, E11.3519, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.353, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E11.3591, E11.3592, E11.3593, E11.3599, E11.36, E11.37X1, E11.37X2, E11.37X3, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9, E13.00, E13.01, E13.10, E13.11, E13.21, E13.22, E13.29, E13.311, E13.319, E13.3211,

Date	Activity
	E13.3212, E13.3213, E13.3219, E13.3291, E13.3292, E13.3293, E13.3299, E13.3311, E13.3312, E13.3313, E13.3319, E13.3391, E13.3392, E13.3393, E13.3399, E13.3411, E13.3412, E13.3413, E13.3419, E13.3491, E13.3492, E13.3493, E13.3499, E13.3511, E13.3512, E13.3513, E13.3519, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, E13.3591, E13.3592, E13.3593, E13.3599, E13.36, E13.37X1, E13.37X2, E13.37X3, E13.37X9, E13.39, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E13.622, E13.628, E13.630, E13.638, E13.641, E13.649, E13.65, E13.69, E13.8, E13.9, E66.2, E78.00, E78.1, E78.2, E78.3, E78.49, E78.5, G47.33, G47.36, G93.2, I10, I27.29, I27.89, I43, K75.81, K76.0, K76.89, M15.3, M15.8, M16.0, M16.10, M16.11, M16.12, M16.2, M16.30, M16.31, M16.32, M16.4, M16.50, M16.51, M16.52, M16.6, M16.7, M16.9, M17.0, M17.10, M17.11, M17.12, M17.2, M17.30, M17.31, M17.32, M17.4, M17.5, M19.071, M19.072, M19.079, M19.171, M19.172, M19.179, M19.271, M19.272, M19.279, M48.062, M48.07, M51.06, M51.36, M51.37, M99.23, M99.33, M99.43, M99.53, M99.63, & M99.73.
05/01/2023	Provider Effective date
03/16/2023	PARP approval
01/18/2023	QI/UM Committee review
01/18/2023	Annual Review: No changes to clinical criteria. Added procedure code 43659. Removed the following CPT codes: 43860, 43865, S9449, S9451, S9452, 97802, 97803, & 97804, per CMS guidance. Reformatted Diagnosis Code requirements. Removed the following ICD-10 codes: E66.09, E66.3, E66.8, I27.20, I27.21, I27.22, I27.23, & I27.24, all per CMS guidance. Per CMS guidance, ICD-10 code E66.01 must be billed for bariatric surgery, along with at least one Group 1 diagnosis code, and at least one Group 2 diagnosis code.
12/01/2022	Provider Effective date
10/19/2022	PARP Approval
09/21/2022	QI/UM Committee review
09/21/2022	Urgent Review: Corrected sleeve gastrectomy (laparoscopic) performed as part of a two-staged procedure guidelines under Eligible Bariatric Procedures section from "BMI is greater than or equal to 50" to "BMI is greater than or equal to 40". Updated 'Summary of Literature' and 'Reference Sources' sections.
05/01/2022	Provider Effective date
03/07/2022	PARP Approval
01/19/2022	QI/UM Committee review
01/19/2022	Annual Review: No changes to clinical criteria. Minor wording changes to Procedures section. Updated Summary of Literature and Reference Sources sections. Added the following diagnosis codes: K21.00, K21.01.
04/19/2021	Provider Effective Date
03/05/2021	PARP Approval
01/20/2021	QI/UM Committee review
01/20/2021	Annual Review: Removed criteria and diagnosis codes (N46.11, N46.12, N46.121-N46.129, N46.8, N46.9, N97.0-N97.9) related to infertility as ACOG no longer explicitly states that bariatric surgery for infertility is experimental investigational. Updated Summary of Literature and References.
02/17/2016	Policy approved at QI/UM Meeting

Disclaimer

Highmark WholecareSM medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark WholecareSM may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary bariatric surgical procedures for patients who are 18 years of age or older and are diagnosed with persistent morbid obesity for at least two years (24 months).

Routine cholecystectomy performed in conjunction with bariatric surgery is considered medically necessary. A liver biopsy, upper gastrointestinal (UGI) endoscopy, and esophagogastroduodenoscopy (EGD) are considered integral components of all bariatric procedures and are not eligible for separate payment when reported on the same day as the bariatric surgical procedure.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records. Bariatric surgery in children and adolescents may be covered under the Pennsylvania Medicaid fee schedule, if medically necessary. Requests are considered on a case-by-case basis.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Commonwealth of Pennsylvania (PA) Department of Human Services (DHS) and all applicable state and federal regulations.

(Current applicable PA HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

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.

Sleeve Gastrectomy (SG) – A procedure performed by removing approximately 80% of the stomach. The remaining stomach is a tubular pouch that resembles a banana.

Biliopancreatic Diversion with Duodenal Switch (BPD/DS) – 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.

Adjustable Gastric Banding (AGB) – Also called a lap-band, an inflatable silicone device placed around the top portion of the stomach to treat obesity, intended to slow consumption of food and thus reduce the amount of food consumed.

Vertical Banded Gastroplasty (VBG) – Also known as stomach stapling, a form of bariatric surgery for weight control. The VBG involves using a band and staples to create a small stomach pouch.

Body Mass Index (BMI) – A person's weight in kilograms divided by the square of height in meters. A BMI is useful as a screening measure.

Extreme Obesity – A condition in which the person has a body mass index of $\geq 40 \text{ kg/m}^2$. This condition has been referred to as Class III obesity.

Gastric Balloon – A device developed as a temporary adjunct to diet and behavior modification to reduce weight of patients who fail to lose with diet and behavior modification. The device is inserted into the stomach in order to reduce the capacity of the stomach and to affect early satiety.

Metabolic Surgery – Bariatric surgery performed with the primary intent to treat Type 2 diabetes or metabolic syndrome.

Procedures

1. Bariatric surgery should be performed in appropriately selected individuals by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up post-surgery. The following bariatric procedures may be considered medically necessary for the surgical treatment of morbid obesity:
 - Laparoscopic adjustable gastric banding using an FDA-approved adjustable gastric band
 - Biliopancreatic bypass with duodenal switch (or open procedure) for individuals with a BMI of 50 kg or greater
 - Roux-en-Y gastric bypass (RYGB) (laparoscopic or open procedure)
 - Sleeve Gastrectomy (laparoscopic or open procedure):
 - Sleeve gastrectomy is an eligible procedure as a first stage of a two-stage procedure or as a sole definitive procedure.
 - For high BMI individuals in whom the duodenal switch may be difficult, it is reasonable to do a sleeve gastrectomy as the first stage of an intended two-stage duodenal switch. This does permit subsequent assessment of both the efficacy of the sleeve (to see whether the second stage is really needed), assessment of the compliance of the individual (to see whether the more complicated procedure is justified), or to examine the metabolic and nutritional effects of the sleeve (to see whether potential further.

2. Selection Criteria for Adults:

- A. The individual is at least 18 years of age and is considered morbidly obese with a BMI greater than or equal to 40; OR
- B. The individual has a BMI of 35 to 39.9, along with ANY of the following comorbidities:
 - 1) Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and/or 90 mmHg diastolic despite concurrent use of three (3) anti-hypertensive agents of different classes); OR
 - 2) Cardiovascular heart disease (with objective documentation by exercise stress test, radionuclide stress test, pharmacologic stress test, stress echocardiography, CT angiography, coronary angiography, heart failure or prior myocardial infarction); OR
 - 3) Hyperlipidemia; OR
 - 4) Diabetes mellitus type II; OR
 - 5) Obstructive sleep apnea (OSA); OR
 - 6) Obesity-hypoventilation syndrome (OHS); OR
 - 7) Pickwickian syndrome (a combination of OSA and OHS); OR
 - 8) Nonalcoholic fatty liver syndrome (NAFLD); OR
 - 9) Nonalcoholic steatohepatitis (NASH); AND
- C. There is a documented history of failure of medical weight loss recognized as either participation in a physician-supervised nutrition and exercise program, OR a multi-disciplinary surgical preparatory regimen for at least 6 (six) consecutive months' duration, within 2 (two) years before the proposed weight loss surgery; AND
- D. The individual must complete a psychological evaluation performed by a licensed mental health care professional and be recommended for bariatric surgery. The individual's medical record documentation should indicate that all psychosocial issues have been identified and addressed; AND
- E. Individual selection is a critical process requiring psychiatric evaluation and a multidisciplinary team approach. The individual's understanding of the procedure and ability to participate and comply with life-long follow-up and the lifestyle changes (e.g., changes in dietary habits, and beginning and exercise program) are necessary to the success of the procedure.

3. Repeat or Revised Bariatric Surgical Procedures

Surgical repair to correct perioperative or late chronic complications of a bariatric procedure may be considered medically necessary when there is documentation of a surgical complication related to the perioperative or late chronic complications of a bariatric procedure. These include but are not limited to:

- Enteric fistula that does not close with bowel rest and nutritional support
- Gastrogastric fistula associated with ulcers, gastroesophageal reflux disease (GERD) and weight gain
- Band erosion
- Disruption/anastomotic leakage of a suture/staple line
- Tubing leak or port dislocation
- Small bowel obstruction
- Band intolerance with obstructive symptoms (e.g., vomiting, esophageal spasm)
- Band slippage and/or prolapse that cannot be corrected with manipulation or adjustment
- Stricture/stenosis with dysphagia, solid food intolerance and/or severe reflux

- Stomal stenosis
- Refractory marginal ulcers
- Non-absorption resulting in hypocalcemia or malnutrition
- Weight loss of 20% or more below ideal body weight

Repeat surgical procedures for revision or conversion to another surgical procedure may be considered medically necessary when the initial bariatric surgery was medically necessary (and the individual continues to meet of the medical necessity criteria for bariatric surgery), and when ANY ONE of the following criteria is met:

- A conversion to a sleeve gastrectomy, RYGB, or biliopancreatic bypass with duodenal switch (BPD/DS) for individuals who have not had adequate weight loss success (defined as less than 50% of excess body weight) two (2) years following the primary bariatric surgery procedure and the individual has been compliant with a prescribed nutrition and exercise program following the procedure; OR
- A revision of a primary bariatric surgery procedure that has failed due to dilatation of the gastric pouch, dilated gastrojejunal stoma, or dilation of the gastrojejunostomy (GJ) anastomosis of the primary procedure was successful in inducing weight loss prior to the dilation of the pouch or GJ anastomosis, and the individual has been compliant with a prescribed nutrition and exercise program following the procedure; OR
- Replacement of an adjustable band if there are complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments; OR
- A conversion from an adjustable band to a sleeve gastrectomy, RYGB, or BPD/DS for individuals who have been compliant with a prescribed nutrition and exercise program following the band procedure and have experienced complications that cannot be corrected with band manipulation, adjustments, or replacement.

Note: Conversion or revision surgery is considered not medically necessary when due to inadequate weight loss related to non-compliance with post-operative nutrition and exercise recommendations.

Note: Prior to consideration of a second bariatric procedure, individuals who have undergone adjustable gastric banding must demonstrate that appropriate band manipulation/adjustments in conjunction with regular postoperative visits and nutritional compliance have failed to result in adequate weight loss.

4. The following bariatric procedures are considered experimental/investigational, and therefore, non-covered:

- Any conditions other than those listed above
- Endoscopic procedures including but not limited to:
 - StomaphyX™ device or restorative obesity surgery (ROSE) procedure
 - Aspiration therapy devices
 - Endoscopic gastroplasty
 - Gastrointestinal Liners (e.g., the EndoBarrier)
 - Gastric balloons
 - Transoral outlet reduction (TORe)
- Biliopancreatic bypass (the Scopinaro procedure) or laparoscopic

- The long-limb gastric bypass
- Intestinal bypass
- Laparoscopic gastric plication
- Vagal nerve blocking (VBLOC) therapy (neuromodulation non-metabolic), also known as the Maestro implant or Maestro rechargeable system
- Mini-gastric bypass
- Vertical banded gastroplasty

5. Contraindications

- Prohibitive perioperative risk of cardiac complications due to cardiac ischemia or myocardial dysfunction
- Severe chronic obstructive airway disease or respiratory dysfunction
- Failure to cease tobacco use for at least 6 (six) weeks prior to surgery
- Psychological/psychiatric condition
 - Schizophrenia, borderline personality disorder, suicidal ideation, severe or recurrent depression, or bipolar affective disorders with difficult-to-control manifestations (e.g., history of recurrent lapses in control or recurrent failure to comply with management regimen)
 - Intellectual disability that prevents personally provided informed consent or the ability to understand and comply with a reasonable pre- and post-operative regimen
 - Any other psychological/psychiatric disorder that, in the opinion of a psychologist/psychiatrist, imparts a significant risk of psychological/psychiatric decompensation or interference with long-term postoperative management.
- History of significant eating disorders, including anorexia nervosa, bulimia, and pica (ingesting sand, clay, or other abnormal substances)
- Hepatic disease with prior documented inflammation, portal hypertension, or ascites (fluid accumulation in the peritoneal cavity)
- Severe hiatal hernia/gastroesophageal reflux (for purely restrictive procedures such as laparoscopic adjustable gastric banding)
- Autoimmune and rheumatological disorders (including inflammatory bowel diseases and vasculitides) that will be exacerbated by the presence of intra-abdominal foreign bodies (for the laparoscopic adjustable gastric banding procedure)
- Current drug and/or alcohol abuse
- Non-compliance with medical treatment of obesity or treatment of other chronic medical conditions

6. Post-payment Audit Statement

The medical record should include documentation that reflects the medical necessity criteria and is subject to audit by Highmark WholecareSM at any time pursuant to the terms of your provider agreement.

7. Place of Service

Bariatric surgery may be performed as either an inpatient or outpatient basis depending upon the individual patient's condition or comorbidities. The following procedures are typically considered inpatient procedures:

- Biliopancreatic Diversion with Duodenal Switch
- Roux-en-Y Gastric Bypass
- Sleeve Gastrectomy
- Bariatric Revisional Surgery

Governing Bodies Approval

In 2001, the U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND® System and the REALIZE™ indicates they are for use only in the severely obese adult patients. Devices that are used for laparoscopic adjustable gastric banding do not have FDA approval in the U.S. for individuals younger than age 18 years.

StomaphyX®, an endoscopically guided system, received FDA approval in 2007 and is indicated for use in endoluminal transoral tissue approximation, ligation in the GI tract.

Transoral gastroplasty (TOGA) is not currently FDA-approved.

Gastrointestinal liners (e.g., EndoBarrier) have not received FDA approval.

The ASPIREAssist® system was FDA-approved in June 2016 with the intent to assist in weight reduction in obese patients. An endoscopic surgical procedure is used to place a tube into the stomach and is connected to a port valve, which lies outside on the skin. Twenty to thirty minutes after each meal, the patient is to connect a drainage tube to the port and empty the stomach contents. Approximately 30 percent of the calories consumed are removed. The system is approved for use in adults aged 22 and older with a BMI of 35.0 to 55.0 kg/m² who have failed to achieve and maintain weight loss with non-surgical weight loss modalities.

There are two FDA-approved intragastric balloon systems, the ORBERA and the ReShape Integrated Dual Balloon System. The ORBERA was approved in August 2015 and the ReShape received approval in July 2015. Both devices are intended for use in obese adults who have failed weight reduction with diet and exercise and have no contraindications. The devices are placed endoscopically, inflated with saline, with a maximum placement time of 6 months. There is no research on the comparison of the ASPIREAssist versus other bariatric surgical procedures.

CMS

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)
- Local Coverage Determination (LCD) Bariatric Surgical Management of Morbid Obesity (L35022)
- Local Coverage Article (LCA) Billing and Coding: Bariatric Surgical Management of Morbid Obesity (A56422)

Summary of Literature

Obesity is an officially recognized global disease and continues to be a risk factor for chronic medical conditions such as cardiovascular diseases, diabetes, chronic kidney disease, nonalcoholic fatty liver disease, metabolic syndrome, and many cancers. Obesity is now included among the global non-communicable disease targets identified by the World Health Organization (WHO). In 2015, a total of 107.7 million children and 603.7 million adults had obesity worldwide. The prevalence of obesity in the United States is among the highest in the world. According to the National Health and Nutrition Examination Survey 2013–2016 data set, 38.9% of U.S. adults and 18.5% of youth aged 2 to 19 years had obesity. This translates into 93.3 million adults and 13.7 million children and youth, respectively. More women (40.8%) than men (36.5%) were obese, with non-Hispanic black women (55.9%) showing the

highest prevalence. Although the prevalence of obesity has been steady among adults since 2011 to 2012, prevalence in certain subpopulations continue to rise, particularly for those with severe (class III, body mass index [BMI] 40 kg/m²) obesity, among whom overall age-adjusted rates of prevalence are 5.5% and 9.8% for men and women, respectively, and 16.8% for non-Hispanic women (ASMBS, 2020).

Surgical treatment of obesity involves reducing functional gastric capacity and modifying intestinal anatomy to restrict caloric intake and/or induce malabsorption. Various surgical procedures that are intended for the treatment of morbid obesity have been developed, including combined restrictive and malabsorptive bariatric surgery (gastric bypass), gastric restrictive surgery, and gastric malabsorption (biliopancreatic diversion) surgery. In addition to the individualizing of an appropriate bariatric procedure to a specific patient, the method of the procedure must be chosen. Laparoscopic procedures are preferred over open procedures due to the postoperative morbidity and mortality (ASMBS, 2020).

The bariatric surgery patient needs to be well-informed, motivated, willing to participate in long-term care, change dietary patterns, and embrace a revised lifestyle. The patient should be evaluated and subsequently cared for by a team approach involving the surgeon, a nurse practitioner or nurse, a dedicated dietician, and other specialists when needed. In addition to a preoperative history, physical, a preoperative discussion that provides information on postoperative recovery, dietary changes, activity, and clinical outcomes, by the dietician, the bariatric nurse, and the bariatric surgeon, is critical. Availability of a support group is recommended, as is distribution of literature describing procedures, postoperative diets, and exercise (ASMBS, 2020).

Informed consent plays a major role in the preoperative discussions. The risks, benefits, procedural options, choices of surgeon and institution, and the need for long-term follow up and vitamin supplementation should be discussed with the patient before the procedure. Patients must also be provided with educational materials that are culturally and educationally appropriate and access to similar preoperative educational sessions at prospective bariatric surgery centers (ASMBS, 2020).

Pre-procedure weight loss is encouraged and has been shown to reduce liver volume which may help improve the technical aspects of surgery in patients with an enlarged or fatty liver. Pre-procedure weight loss or nutritional therapy may be recommended to patients to improve co-morbidities, such as pre-procedure glycemic targets (ASMBS, 2020).

Tobacco use must be avoided at all times by all patients. In particular, patients who smoke cigarettes should stop as soon as possible, preferably 1 year but at the very least 6 weeks before bariatric procedure. In addition, tobacco use must be avoided after bariatric procedures given the increased risk of poor wound healing, anastomotic ulcer, and overall impaired health. Structured intensive cessation programs are preferable to general advice and should be implemented (ASMBS, 2020).

Nutrition and Exercise Programs

- Patient participation in a physician-supervised nutrition and exercise program must be documented in the medical record by an attending physician who supervised the patient's participation.
- The nutrition and exercise program may be administered as part of the surgical preparative regimen, and participation in the nutrition and exercise program may be supervised by the surgeon who will perform the surgery or by another physician.
- A physician's summary letter is not sufficient documentation. Documentation should include medical records of physician's contemporaneous assessment of the patient's progress throughout the course of the nutrition and exercise program.

- For patients who participate in the physician-administered nutrition and exercise program (e.g., MediFast, OptiFast), program records documenting the patient’s participation and progress may substitute for the physician medical record.
- The nutrition and exercise program must be supervised and monitored by a physician working in cooperation with dietitians and/or nutritionists, with a substantial face-to-face component (must not be entirely remote).
- The nutrition and exercise program must be a cumulative time period (determined by performing surgeon), a cumulative total of 6 (six) months prior to surgery indicating the patient’s commitment to lifestyle changes necessary post-bariatric surgery.

According to ASMBS, the two most common bariatric surgical procedures currently performed in the United States are sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB). Both procedures have been shown to have an excellent safety profile, particularly when performed in accredited centers. Moreover, both procedures provide meaningful and relatively similar weight loss and remission of obesity-associated comorbidities, at levels that are far superior to those of nonsurgical therapy. Both procedures are also associated with significant reductions in premature deaths from cardiovascular diseases, deaths related to type 2 diabetes, and deaths associated with multiple cancers. (ASMBS, 2021).

Vertical banded gastroplasty (VBG), or stomach stapling, is a surgical procedure for obesity that is outdated and rarely performed because it is among the oldest surgical weight loss procedures (Ferreira, 2013). Additionally, there is a high rate of reoperations, and the reversal operation to the VBG procedure is very complex and intense (Dielen, 2005). The biliopancreatic diversion bypass (BPD) without the duodenal switch has little evidence-based case series reported in the U.S. a procedure developed by Nicola Scopinaro (. The BPD procedure may be associated with several serious postoperative complications, such as protein-calorie malabsorption, steatorrhea, diarrhea, foul-smelling stools, severe bone pain, a variety of nutrient deficiencies and other metabolic derangements, and life-long dependency on supplemental vitamins and minerals. Additionally, there have been case reports of liver damage, resulting either in death or liver transplant (ASMBS, 2020). Modifications were made to the BPD procedure to create the biliopancreatic diversion bypass with duodenal switch (BPD/DS), which has significantly diminished the more severe complications of BPD (Sudan, 2011).

The degree of weight loss following bariatric surgery remains variable based on the surgical procedure performed. The biliopancreatic diversion (BPD) has been shown in clinical studies to provide the greatest weight loss. However, the BPD is also noted to have one of the highest complication rates. Both the RYGBP and the SG procedures have been found to produce similar results with rapid weight loss over the first several months followed by slower weight loss for approximately a year to a year and a half. The AGB results in slower weight loss until stabilization is attained by year 2. It has been noted that with the AGB procedure, patients do well initially, but many do not sustain the weight loss. This has resulted in the decrease utilization of ABG in bariatric surgery.

The intragastric balloon (IGB) was developed for use as a temporary aid for obese people who have not had satisfactory results in conservative weight loss treatment for obesity. There are two FDA-approved intragastric balloon devices, the term ‘pediatric’ in reference to a person under the age of 18.

In 2017, ASMBS revised its guidelines on sleeve gastrectomy (SG) as a bariatric procedure. The guidelines stated that substantial long-term outcome data published in the peer reviewed literature, including studies comparing outcomes of various surgical procedures, confirm that SG provides significant and durable weight loss, improvements in medical co-morbidities, improved quality of life, and low complication and mortality rates for obesity treatment. In terms of initial early weight loss and

improvement of most weight-related co-morbid conditions, SG and RYGB appear similar. The effect of SG on GERD, however, is less clear, because GERD improvement is less predictable and GERD may worsen or develop de novo. Preoperative counseling specific to GERD-related outcomes is recommended for all patients undergoing SG.

The ASMBS recognizes SG as an acceptable option for a primary bariatric procedure or as a first-stage procedure in high-risk patients as part of a planned, staged approach. As with any bariatric procedure, long-term weight regain can occur after SG and may require one or more of a variety of reinterventions. Informed consent for SG as a primary procedure should be consistent with the consent provided for other bariatric procedures and, as such, should include the risk of long-term weight regain. In addition, as with all currently recognized bariatric procedures, surgeons performing SG are encouraged to prospectively collect, analyze, and report their outcome data in peer-reviewed scientific forums.

Two-Stage Bariatric Surgery Procedures

Due to the complexity, risks and complications associated with weight loss surgery, there is a subset of patients that may be considered to be very high-risk. The higher the BMI, the greater the risk. A higher BMI is associated with increased number of pre-existing medical conditions which increase surgical risk. Therefore, patients who are considered super morbidly obese are deemed as the riskiest patients.

Staged bariatric procedures have been proposed as a treatment option primarily for the ‘super-obese’ patient, defined as having a BMI greater than 50 kg/m². Staged bariatric procedure refers to a bariatric surgical procedure that is divided into two procedures. The first procedure is considered less of a surgical risk and is a gastric-restrictive procedure which will initiate the weight loss process. This procedure is followed by a malabsorptive surgical procedure once an acceptable weight loss is achieved by the restrictive procedure.

The laparoscopic sleeve gastrectomy was originally utilized as the initial stage of the laparoscopic biliopancreatic diversion with a duodenal switch in super morbidly obese or high-risk patients (Madura and DiBaise, 2012). However, it was observed that several patients who underwent the surgery did not require a second malabsorptive surgery due to significant weight loss.

Rationale

Windover (2013) states that tobacco use persists as the leading cause of preventable death worldwide and is prevalent among bariatric surgical candidates. Based on the author’s research, it is recommended that bariatric surgery centers establish a standard protocol that includes assessment of tobacco use and referrals for tobacco use treatment and intervention for individuals identified as at-risk future tobacco users. Finks et al. (2011) reported that there is an association between tobacco use and respiratory complications following bariatric surgery. Patients who smoked cigarettes within one year of having bariatric surgery were at increased risk for developing pneumonia. There is an increased incidence of developing marginal ulcers (AOR 30.6, 95% CI, 6.4-146, $p < 0.001$) and wound dehiscence (OR 20.9, 95% CI, 1.1-411, $p < 0.046$) postoperatively (Wilson et al. 2006). The latest evidence-based bariatric surgery guidelines recommend advising tobacco users to quit tobacco at least six weeks prior to bariatric surgery (Blackburn et al., 2009).

Significant advances have been made in recent years with the growing role of bariatric surgery in the treatment of patients with type-2 diabetes (T2D). A large body of evidence from 12 RCTs showed that bariatric/metabolic surgery achieves far greater improvements in patients with T2D, when compared to various medical and lifestyle interventions. The improvements can be linked to both weight loss-dependent and independent effects. According to guidelines published by the 2015 Second Diabetes

Surgery Summit Consensus Conference, metabolic surgery should be considered in patients with T2D and obesity (BMI > 35.0 kg/m²) when hyperglycemia is inadequately controlled with lifestyle and optimal medical therapy (ASMBS, 2020).

From a review of 36 studies and 2,570 patients, it was determined that sleeve gastrectomy can be performed safely as a first stage or primary procedure (Brethauer et al. 2009). In 2012, a study reported on the success of the laparoscopic sleeve gastrectomy (LSG) for the super obese patients. The study reported on the longest follow-up LSG (2002-2004) stating the results prove that the procedure is effective, safe, and durable. The mean BMI decreased from 66 kg/m² to 46 kg/m² at 73 months (Eid, et al., 2012).

Bariatric Surgery in Adolescents

The ASMBS Pediatric Committee published its best-practice guidelines for treatment of obesity in adolescents. The guidance provides that children who suffer from obesity are at a significant disadvantage if they are denied metabolic and bariatric surgery (MBS). MBS is clearly one of the main obesity treatment modalities with the best-sustained weight loss and control of obesity-related co-morbidities. Data support the use of MBS in adolescents with severe obesity; either the vertical sleeve gastrectomy (VSG) or the RYGB should be considered for adolescents with a BMI >35 or >120% of the 95th percentile and a co-morbidity or with a BMI >40 or >140% of the 95th percentile. Prior weight loss attempts, Tanner stage, and bone age should not be barriers to definitive treatment. Vitamin levels should be monitored before and after MBS with all attempts to maximize adherence with vitamin supplements long term. Multidisciplinary teams should stabilize and treat preexisting eating disorders, assure stable social support, assess and assist with nutrition and activity knowledge, and consider the addition of medications when appropriate. It is the responsibility of the adolescent MBS program to have a transition plan in place for adolescents to transition to an adult MBS program for lifelong care (ASMBS, 2018).

In 2013, Black et al. reported on a systematic review of the current state of peer-reviewed literature on the safety and effectiveness of bariatric surgery in obese adolescents. It was reported that while there were significant decreases in one-year follow-up BMI, the risk of complications has not been well defined and that long-term studies are needed to establish the harms and benefits of bariatric surgery in this patient population. Hofman (2013) reported that the evidence for bariatric surgery in children and adolescents is scarce and of poor quality. There are moral issues regarding performance of bariatric surgery in young individuals such as: too young to consent, lack of maturity, treatment endpoints, and hidden interests of patients, parents, professionals, industry, and society. More evidence is needed to be able to balance benefits and risks, provide information for a valid consent or assent, and to advise minors and parents. According to Nobili et al. (2015), weight loss surgery should be the last resort in the pediatric population due to lack of consensus on appropriate bariatric surgical intervention selection criteria.

The American Academy of Pediatrics (AAP) published a document regarding pediatric metabolic and bariatric surgery. The document contains information on the evidence, barriers, and best practices related to pediatric and adolescent bariatric surgery. The policy statement uses the term 'pediatric' in reference to a person under 18 years of age. Adolescent refers to a person from age 13 years to 18 years. Several reports are identified in the article including observational cohort studies, case-control series, retrospective case reports, and expert opinion. It is noted that there is a low prevalence of bariatric surgery in adolescents, and the practical and ethical barriers to randomization are known limitations. Current longitudinal studies evaluating safety and efficacy endpoints do not apply specific age limits for the timing of surgery; thus, there is no evidence to support the application of age-based eligibility limits (AAP, 2019).

Research to date has not adequately addressed important issues specific for children and adolescents who may receive bariatric surgery. These issues would include the rate of complications, compliance with therapy, and the potential limitations in the lifespan of surgical interventions and the associated long-term metabolic consequences. Additional research is necessary to address these issues as well as subpopulations of adolescents who might particularly benefit from bariatric surgery.

Bariatric Surgery & Fertility

In a 2017 statement endorsed by the American College of Obstetricians and Gynecologists (ACOG), the ASMBS published a position statement on the impact of obesity and obesity treatment on fertility and fertility therapy. The recommendations noted there is a very high prevalence of obesity among women of childbearing age. Obesity in women is associated with an increased risk of infertility and an increased rate of complications during every stage of pregnancy. The statement provides that bariatric surgery is effective in achieving significant and sustained weight loss in morbidly obese women and has been shown in case-control studies to improve fertility. Pregnancy is not recommended during the rapid weight loss phase after bariatric surgery. Counseling and follow-up regarding contraception during this period is important. The specific impact of either medical weight-loss treatments or bariatric surgery on the responsiveness to subsequent treatments for infertility in both men and women is not clearly understood at this time (ASMBS/ACOG, 2017).

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- Comparative Effectiveness Review Of Bariatric Surgeries For Treatment Of Obesity In Adolescents
 - **C Rating** – For use of vertical sleeve gastrectomy (VSG) in adolescents with severe obesity who have failed to respond to nonsurgical weight loss interventions.
 - **C Rating** - For use of vertical sleeve gastrectomy (VSG) in adolescents with severe obesity who have failed to respond to nonsurgical weight loss interventions.
 - **D1 Rating** - For use of adjustable gastric band (AGB) in adolescents with severe obesity who have failed to respond to nonsurgical weight loss interventions.
 - Consistent, low-quality evidence suggests that bariatric surgery can lead to significant weight loss and improvements in certain obesity-associated comorbidities in carefully selected adolescents with severe obesity over short- to intermediate-term follow-up (typically < 5 years). While bariatric surgery in adolescents is associated with a very low risk of operative complications, a low to moderate risk of postoperative complications and nutritional deficiencies has been reported. The evidence for bariatric surgery in adolescents with severe obesity is limited by the lack of large, well-designed clinical trials that provide data on long-term efficacy and safety of these surgeries.

- Intra-gastric Balloons For Treatment Of Obesity
 - **D2 Rating** - For use of intra-gastric balloons (IGBs), as an adjunct to lifestyle interventions (i.e., diet and exercise), for treatment of obesity in patients unable to lose sufficient weight by conservative means.
 - **D2 Rating** - For use of gas-filled IGBs versus saline-filled IGBs, as an adjunct to lifestyle interventions (i.e., diet and exercise), for treatment of obesity in patients unable to lose sufficient weight by conservative means.
 - **D2 Rating** - For use of IGBs versus hyaluronic acid (HA) injections for treatment of obesity in patients - unable to lose sufficient weight by conservative means.
 - The available low-quality evidence suggests that IGBs have mixed results with regard to weight loss over the short term when used as an adjunct to diet and exercise. IGBs may improve patient-reported QOL but do not appear to have any effect on satiety compared with restricted diet and exercise. These devices are consistently associated with high rates

of gastrointestinal adverse events that are of mild-to-moderate severity, and infrequently associated with more serious events. Minimal evidence suggests that IGBs may support improved dietary restraint. All of the studies lacked long-term follow-up, so that the durability of the effects of IGBs on maintaining weight loss and any safety concerns after their removal is unclear.

- Impact Of Preoperative Supervised Weight Loss Programs On Bariatric Surgery Outcomes
 - **D2 Rating** - For use of preoperative supervised weight loss programs in obese adults who meet other eligibility requirements for bariatric surgery. The evidence suggests that supervised preoperative weight loss programs are not associated with greater weight loss prior to or following bariatric surgery. The effects of these programs on morbidity and mortality are unknown since the studies did not address whether use of these programs affects these outcomes; however, no deaths were reported during the studies.

Coding Requirements

Procedure Codes

CPT Code 43843 should not be reported if there is a more specific bariatric surgery code within the code range listed below.

CPT/HCPCS Code	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 (eg, 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)
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 (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
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Diagnosis Codes

ICD-10 Code	Description
E66.01	Morbid (severe) obesity due to excess calories
Z68.35	Body mass index [BMI] 35.0-35.9, adult
Z68.36	Body mass index [BMI] 36.0-36.9, adult
Z68.37	Body mass index [BMI] 37.0-37.9, adult
Z68.38	Body mass index [BMI] 38.0-38.9, adult
Z68.39	Body mass index [BMI] 39.0-39.9, adult
Z68.41	Body mass index [BMI] 40.0-44.9, adult
Z68.42	Body mass index [BMI] 45.0-49.9, adult
Z68.43	Body mass index [BMI] 50.0-59.9, adult
Z68.44	Body mass index [BMI] 60.0-69.9, adult
Z68.45	Body mass index [BMI] 70 or greater, adult

Non-covered Diagnosis Codes

ICD-10 Code	Description
E66.1	Drug-induced obesity
E66.3	Overweight
E66.8	Other obesity
E66.9	Obesity, unspecified
E66.09	Other obesity due to excess calories
K21.00*	Gastro-esophageal reflux disease with esophagitis, without bleeding
K21.01*	Gastro-esophageal reflux disease with esophagitis, with bleeding

*ICD-10 codes K21.00 and K21.01 are not covered for CPT code 43770.

Informational

The following BMI tables were adapted from the clinical guidelines for the identification, evaluation, and treatment of overweight and obese adults and were prepared by the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute.

Body Mass Index (BMI) chart for up to 287 pounds

To use this table, find the appropriate height in the left-hand column. Move across the row to a given weight. The number at the top of the column is the BMI for the selected height and weight. Pounds have been rounded off.

BMI

Height (inches)	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287
	Body Weight (pounds)																

Body Mass Index chart for up to 443 pounds

To use this table, find the appropriate height in the left-hand column. Move across the row to a given weight. The number at the top of the column is the BMI for the selected height and weight. Pounds have been rounded off.

BMI

Height (inches)	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
58	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386

72	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443
Body Weight (pounds)																			

Classification of Overweight and Obesity by BMI in Adults

	BMI	Obesity Class
Underweight	<18.5 kg/m ²	
Normal weight	18.5 – 24.9 kg/m ²	
Overweight	25.0 – 29.9 kg/m ²	
Obese	30.0 – 34.9 kg/m ²	I
Obese	35.0 – 39.9 kg/m ²	II
Extremely obese	40.0 and higher kg/m ²	III

Classification of Obesity in Adolescents

Class II Obesity	120% of the 95 th percentile height, or an absolute BMI of 35 – 39.9 kg/m ² , whichever is lower
Class III Obesity	140% of the 95 th percentile height, or an absolute BMI of ≥40 kg/m ² , whichever is lower

The American Society of Metabolic and Bariatric Surgeons, 2018

Reimbursement

Participating facilities will be reimbursed per their Highmark WholecareSM contract.

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