Medical Policy

Bariatric Surgery

Policy Number: OCA 3.49
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Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ New Hampshire Medicaid</td>
<td>☑ MassHealth</td>
</tr>
<tr>
<td>☑ NH Health Protection Program</td>
<td>☑ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
</tr>
<tr>
<td></td>
<td>☑ Senior Care Options ◊</td>
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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers specific bariatric procedures for the treatment of morbid obesity to be medically necessary when the Plan’s medical criteria are met (as specified in the Medical Policy Statement section). Other procedures for the treatment of morbid obesity are considered experimental and investigational. Prior authorization is required for all bariatric procedures.

It will be determined during the Plan’s prior authorization process if the procedure is considered experimental and investigational for the requested indication. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.
Description of Item or Service

Bariatric Surgery: Surgical procedures that promote weight loss for the treatment of morbid obesity. Bariatric procedures are based on two (2) primary principles to promote weight loss: Gastric restriction (defined below in item A) and intestinal malabsorption (summarized below in item B).

A. **Gastric Restriction:** Gastric restrictive procedures involve reducing the size of the stomach to restrict the amount of food ingested, producing a feeling of fullness. Examples of gastric restrictive procedures include adjustable silicone gastric banding (ASGB) and the vertical banded gastroplasty (VBG).

B. **Intestinal Malabsorption:** Intestinal malabsorption procedures involve the creation of a small stomach pouch to restrict food intake and rerouting or bypassing parts of the small intestine to create malabsorption. Examples of intestinal malabsorption combined with gastric restrictive procedures include the Roux-en-Y gastrojejunostomy or Roux-en-Y gastric bypass (RYGB), and the biliopancreatic diversion (BPD) with or without duodenal switch (DS). Specific examples of bariatric surgery procedures include but are not limited to the following, as specified below in items 1 through 13:

1. **Adjustable Silicone Gastric Banding (ASGB):** A gastric restrictive procedure by which a silicone band is inserted to create a small gastric pouch. Saline is injected into the balloon of the silicone band to adjust the diameter of the stomal opening. Weight loss is promoted by limiting food intake. Complications can include band erosion, gastric perforation, food intolerance, and/or band migration. This procedure is performed using a minimally invasive laparoscope or with an open technique if unable to perform the procedure laparoscopically. (Examples include the Lap-Band® System or the REALIZE™ Adjustable Gastric Band.)

2. **Biliopancreatic Diversion (BPD) or Scopinaro Procedure:** A restrictive and malabsorption procedure where a partial gastrectomy is done to create a small pouch that is connected directly to the final segment of the small intestine, diverting bile and pancreatic juice into the distal ileum. Weight loss is promoted by the malabsorption of fat and protein. Nutritional deficiencies, severe iron deficiency anemia, lactose intolerance, and/or vitamin deficiencies are common. According to the peer reviewed published scientific literature, the evidence is not sufficient to support conclusions on the benefit/risk ratio for BPD compared with gastric bypass. The studies do not distinguish small differences in weight loss between the two (2) procedures, and the data does not support the hypothesis that BPD results in greater weight loss than gastric bypass. Complication rates are poorly reported in these trials. Limited data suggests that long-term nutritional and vitamin deficiencies occur at a high rate following BPD. The rates of nutritional deficiencies and the consequences of these deficiencies require further investigation.
3. **Biliopancreatic Diversion with Duodenal Switch (BPDDS):** This procedure is a variant of the BPD where instead of a partial gastrectomy, a “sleeve” gastrectomy is performed along the vertical axis of the stomach to decrease the volume, and the small intestine is then divided with one end attached to the stomach to create an “alimentary limb.” All the food moves through this segment but not much is absorbed. Weight loss is promoted through the principles of malabsorption and the reduction of the stomach volume. The potential for metabolic complications is less with the BPDDS than with the BPD procedure; however, individuals who undergo BPDDS need life-long supplementation of fat-soluble vitamins, vitamin B12, iron, and calcium.

4. **Fobi-Pouch:** A limiting proximal gastric pouch procedure that involves a small (less than 25 ml) vertical banded pouch, a Silastic ring around the stomach creating a stoma, and a gastroenterostomy to a Roux-en-Y limb.

5. **Jejunoileal Bypass:** Also known as intestinal bypass, the proximal jejunum is joined to the distal ileum, bypassing a large segment of the small bowel.

6. **Loop Gastric Bypass:** A gastric pouch in the shape of a tube created by dividing the stomach at the junction of the body and the antrum, parallel to the lesser curve. A loop of jejunum is then anastomosed to the gastric pouch.

7. **Mini Gastric Bypass:** Using a laparoscopic approach, the stomach is pouchered and a loop of the jejunum is anastomosed directly to the stomach pouch.

8. **ROSE Procedure:** The ROSE procedure is also referred to as revision obesity surgery endoscopic; restorative obesity surgery endoscopic; restorative obesity surgery, endoluminal; and peroral endoscopic surgery. The ROSE procedure involves the application of an endoscope into the esophagus to provide access to the stomach so that the size of the gastric pouch and/or nearby structures can be reduced. This procedure is primarily reserved for when a patient regains weight following gastric bypass surgery.

9. **Roux-en-Y Gastrojejunostomy or Roux-en-Y Gastric Bypass (RYGB):** The gastric bypass or RYGB is considered the gold standard for bariatric surgery and the most common. It is a restrictive and malabsorptive procedure that surgically alters the stomach’s capacity using surgical staples to create a small pouch that restricts food intake. A Y-shaped section of the small intestine is anastomosed to the pouch to allow food to bypass the duodenum and jejunum to limit the body’s ability to digest food. A short limb RYGB is 150 cm or less and a long limb RYGB is greater than 150 cm. Weight loss is promoted by restriction of the amount of food and limitation of the digestion of food. RYGB can cause nutritional deficiencies due to the malabsorption of nutrients; for example, iron deficiency resulting in anemia is common.
Dumping syndrome is a common side effect. Symptoms include nausea, abdominal cramps, diarrhea, rapid heart rate, sweating, weakness, headache, faintness, hunger, shakiness, difficulty concentrating, and/or dizziness. Because the pylorus sphincter is bypassed, food is allowed to pass rapidly into the intestines.

10. **Roux-en-Y Gastric Bypass (RYGB) Combined with Gastric Banding**: This combination is being investigated as a strategy to enhance weight loss and avoid weight regain. The evidence supporting use of this combined procedure is currently limited.

11. **Sleeve Gastrectomy or Vertical Sleeve Gastrectomy**: A variant of the vertical banded gastroplasty involving a subtotal gastric resection for the creation of a long lesser-curve-based gastric conduit. The operation preserves the pyloric sphincter and function of the stomach while drastically reducing stomach volume; the gastric restriction reduces the amount of food that can be eaten. It is postulated that weight loss occurs since the removed section of the stomach produces most of the hormone ghrelin, which is responsible for appetite and hunger. Sleeve gastrectomy procedures may be performed as either laparoscopic or open, but the procedure is most often performed laparoscopically. The sleeve gastrectomy is the first part of the surgical process for BPDDS; however, the sleeve gastrectomy may be all that is needed for the patient to lose a sufficient amount of weight and the BPDDS is not necessary. The sleeve gastrectomy has also been utilized as a first-stage bariatric procedure to reduce surgical risk in high-risk, super-obese patients with a BMI > 50 kg/m². Laparoscopic sleeve gastrectomy may be technically easier and a faster procedure than either open or laparoscopic Roux-en-Y gastric bypass and less complex than BPDDS.

12. **StomaphyX**: The StomaphyX is a sterile, single-use device for use in endoluminal transoral tissue approximation and ligation in the GI tract. It is used for endoscopic plication and revision of the gastric pouch (EPRGP) in patients who underwent gastric bypass surgery.

13. **Vertical Banded Gastroplasty (VBG)**: A gastric restrictive procedure that can be performed either laparoscopically or open whereby a small stomach pouch is created by placing staples in a vertical segment of the stomach. Weight loss is promoted by restriction of the amount of food intake. The most common complication is persistent esophageal reflux disease. This procedure has been largely abandoned because long-term weight loss is not achieved.

**Revisional Bariatric Surgery (RBS)**: A wide assortment of complex abdominal operations performed to treat patients who have experienced complications, insufficient amelioration of comorbid conditions, failure of weight loss, and/or weight regain after bariatric surgery for severe obesity.
Medical Policy Statement

The Plan considers the following open or laparoscopic bariatric procedures to be medically necessary when medical record documentation supports that the applicable Plan criteria have been met, as specified below in item I for all members and item II for age-specific criteria. Applicable criteria must be met in item III ONLY for a revision to a prior bariatric procedure or a reversal.

I. Criteria for All Members (Adults and Adolescents):

ALL of the following criteria must be met for each adult and adolescent member, as specified below in items A through H:

A. Persistent obesity despite previous attempts to lose weight with non-surgical, clinician-supervised weight reduction methods (such as diet, exercise, behavioral modification, exercise, and/or pharmaceutical interventions), and these efforts have been fully appraised by the physician requesting authorization for bariatric surgery; AND

B. Successful completion of a psychological assessment demonstrating readiness for surgery; AND

C. Preoperative nutritional assessment demonstrating motivation and willingness to make necessary changes in eating and drinking habits, both before and after surgery; AND

D. Ability to participate in pre and post-surgical treatment with long-term follow-up; AND

E. Presurgical identification and treatment of all metabolic causes for obesity, such as adrenal or thyroid disorders; AND

F. Strict abstention from pregnancy and breast-feeding from the time of surgery through the postoperative period of rapid weight loss which is expected during the first year after gastric bypass (not applicable for the banding procedure); AND

G. A separate medical evaluation, within the previous six (6) months of the scheduled surgery from a physician other than the requesting surgeon, that includes a risk assessment and recommendations for perioperative management, as indicated; AND

H. Member meets ALL applicable age and procedure-specific clinical criteria specified below in item II and item III; AND

*Bariatric Surgery*
II. Age-Specific Criteria (Adult or Adolescent Members):

ONE (1) of the following sets of age-specific criteria must be met, as specified below in item A for an adult member or item B for an adolescent member.

A. Criteria for Adult Members (Age 18 or Older on the Date of Service):

ALL of the following criteria must be met for an adult member, as specified below in items 1 through 5:

1. ALL criteria must be met in item I, as specified above; AND

2. The surgery is to be performed by an appropriately privileged bariatric surgeon in association with a recognized formal obesity surgery program accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP);∞ AND

∞ Note: Resource to identify MBSAQIP accreditation available at: https://www.facs.org/search/bariatric-surgery-centers?allresults=

3. The bariatric surgeon has notified the Plan of the surgical treatment plan established for the member and meets ONE (1) of the following criteria, as specified below in item a or item b:

   a. The surgery is a single, stand-alone bariatric procedure; OR

   b. The procedure is part of a multi-staged bariatric surgical approach to treatment;** AND

   **Note: Notification of a treatment plan which includes a multi-staged bariatric procedure is required at the time of the first bariatric surgery and before each additional procedure. A separate prior authorization is required before each bariatric procedure.

4. Member must attend support group to learn about bariatric surgery from other patients; AND

5. Criteria are met for a stand-alone procedure or a multi-staged procedure, as specified below in item a or item b:

   a. Single, Stand-Alone Bariatric Procedure for Adults:

      BOTH of the following criteria are met, as specified below in item (1) and item (2):
(1) Bariatric surgery is a single, stand-alone procedure and ONE (1) of the following procedures will be performed, as specified below in items (a) through (d):

(a) Laparoscopic adjustable silicone gastric banding (LASGB);*** OR

***Note: A request for a scheduled, open adjustable silicone gastric banding (ASGB) requires Medical Director review with supporting documentation which specifies why the member is a candidate for an open ASGB rather than a LASGB, as stated in the Limitations section of this policy.

(b) Open or laparoscopic biliopancreatic diversion with duodenal switch (BPDDS); OR

(c) Open or laparoscopic Roux-en-Y gastric bypass; OR

(d) Open or laparoscopic sleeve gastrectomy; AND

(2) Bariatric surgery is a single, stand-alone procedure and ONE (1) of the following criteria is met, as specified in item (a) or item (b) below:

(a) Member has a BMI of 40 kg/m\(^2\) or higher with a strong desire for substantial weight loss for improvement in quality of life; OR

(b) Member has a BMI of 35 kg/m\(^2\) or higher with at least ONE (1) of the following high-risk comorbidities, as specified below in items i through ix:

i. Coronary artery disease; OR

ii. Diabetes mellitus type 2; OR

iii. Hypertension meeting Stage I JNC-7 criteria which require pharmacologic control with at least two (2) antihypertensive medications; OR

iv. Joint disease of weight bearing joints, treatable but for the obesity; OR

v. Obesity-related cardiomyopathy; OR

vi. Obesity-related pulmonary hypertension; OR

vii. Obstructive sleep apnea; OR

viii. Pickwickian syndrome; OR

*Bariatric Surgery

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ix.  Pseudotumor cerebri; OR

b.  **Bariatric Procedure is First in a Planned, Multi-Staged Procedure for Adults:**

The following TWO (2) criteria must be met, as specified below in item (1) and item (2): €

(1)  Member has a BMI of 40 kg/m$^2$ or higher; AND

(2)  The first procedure is a sleeve gastrectomy; OR

€ Note: Notification of a treatment plan which includes a multi-staged bariatric procedure is required at the time of the first bariatric surgery and before each additional procedure. A separate prior authorization is required before each bariatric procedure.

**B. Criteria for Adolescent Members (Under Age 18 on the Date of Service):**

ALL of the following criteria must be met for an adolescent member under the age of 18 on the date of service, as specified below in items 1 through 10:

1.  ALL criteria in Section I above must be met; AND

2.  The surgery is to be performed by an appropriately privileged bariatric surgeon in association with a recognized formal obesity surgery program accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)¥ that has experience treating adolescent patients for bariatric surgery; AND

¥ Note: Resource to identify MBSAQIP accreditation available at: https://www.facs.org/search/bariatric-surgery-centers?allresults=

3.  The bariatric surgeon has notified the Plan of the surgical treatment plan established for the adolescent member and BOTH of the following criteria are met, as specified below in item a and item b:

   a.  The surgery is a single, stand-alone bariatric procedure and is not part of a multi-staged bariatric procedure; AND

   b.  Bariatric surgery is a single, stand-alone procedure† and ONE (1) of the following procedures will be performed, as specified below in item (1) or item (2):

   (1)  Roux-en-Y gastric bypass (open or laparoscopic); OR

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(2) Sleeve gastrectomy (open or laparoscopic); † AND

Notes:

† Notification of a treatment plan which includes a multi-staged bariatric procedure is required at the time of the first bariatric surgery and before each additional procedure. A separate prior authorization is required before each bariatric procedure. Any multi-staged bariatric procedure for an adolescent member, including a Roux-en-Y gastric bypass or sleeve gastrectomy, requires Medical Director review.

‡ American Society for Metabolic and Bariatric Surgery (ASMBS) states that long-term adolescent outcomes data are required for adolescents undergoing sleeve gastrectomy, but the preliminary results from ongoing studies appear to demonstrate excellent weight reduction, reversal of associated co-morbid diseases, and morbidity outcomes similar to those of the adult population. (Source: ASMBS Pediatric Best Practice Guidelines.)

4. The member’s age meets ONE (1) of the following criteria, as specified below in item a or item b:

a. 15 years of age or older on the date of service if the member is a boy (including an adolescent member born with male reproductive organs and/or with typical male karyotype with only one [1] X chromosome, if known); OR

b. 13 years of age or older on the date of service if the member is a girl (including an adolescent member born with female reproductive organs and/or with typical female karyotype with two [2] X chromosomes, if known); AND

5. ONE (1) of the following BMI requirements must be met, as specified below in item a or item b:

a. BMI of 35 kg/m² or higher with at least ONE (1) of the following serious comorbidities, as specified below in items (1) through (6):

   (1) Diabetes mellitus type 2; OR

   (2) Moderate or severe obstructive sleep apnea (apnea hypopnea index [AHI] 15 events/hour); OR

   (3) Nonalcoholic steatohepatitis (NASH); OR

   (4) Pseudotumor cerebri; OR

   (5) Other serious comorbidity as determined by the Medical Director; OR

   (6) Medical condition determined by the Medical Director to be a serious comorbidity.

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(5) Severe or complicated hypertension; OR

(6) Other documented, serious comorbidity related to the member’s obesity; OR

b. BMI of 40 kg/m² or higher with at least ONE (1) of the following obesity-related comorbidities, as specified below in items (1) through (12):

(1) Dyslipidemia; OR

(2) Gastroesophageal reflux; OR

(3) Hypertension; OR

(4) Moderate to severe nonalcoholic fatty liver disease; OR

(5) Obstructive sleep apnea (apnea hypopnea index [AHI] 5 events/hour); OR

(6) Panniculitis; OR

(7) Significant impairment in activities of daily living; OR

(8) Urinary incontinence; OR

(9) Venous stasis disease; OR

(10) Severe psychosocial distress; OR

(11) Significantly impaired quality of life; OR

(12) Weight-related arthropathies

6. Attainment of Tanner sexual maturity stage IV with written documentation provided to the Plan; AND

7. Member is has completed bone growth and is at least 95% of predicted adult height, as estimated by bone age, with written documentation provided to the Plan; AND

8. Support group attendance accompanied by a family member or guardian to learn about surgery from other patients; AND

9. Documentation by a psychologist regarding psychological suitability and willingness to undergo surgery; AND

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10. Documentation by a licensed social worker to determine whether the degree of support available in the home environment appears sufficient for post-operative care and compliance; AND

III. Guidelines for Revisional Bariatric Surgery or Reversals:

The following applicable criteria must be met ONLY when the member is a candidate for either a revision to a prior bariatric procedure (and all criteria in item A must be met) or a reversal (and the criterion specified in item B must be met).

A. Revision to a Prior Bariatric Procedure (Revisional Bariatric Surgery):

ALL of the following criteria must be met, as specified below in items 1 through 4:

1. ALL criteria must be met in item I listed above for all members, and ALL appropriate age-specific criteria listed in item II must be met (i.e., item IIA for adult members or item IIB for adolescent members); AND

2. The prior bariatric procedure has been performed at least one (1) year before the scheduled revision (unless otherwise specified in the Limitations section of this Plan policy); AND

3. Surgical evaluation must have occurred within four (4) months of the planned surgery; AND

4. At least ONE (1) of the following criteria is met, as specified below in item (a), item (b), or item (c):

   (a) Documentation of compliance with the previously prescribed postoperative dietary and exercise program; OR

   (b) Anatomic failure of the prior bariatric surgery with persistent or recurrent obesity; OR

   (c) Secondary complications such as stricture, obstruction, erosion, or band slippage.

B. Reversals:

Reversals for bariatric procedures may be considered medically necessary on a case-by-case basis. See the Plan policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment.
Limitations

A. Open adjustable silicone gastric banding (ASGB) is not considered medically necessary for an adult member unless at least ONE (1) of the following criteria is met, as specified below in item 1 or item 2:

1. A laparoscopic ASGB procedure was unsuccessfully attempted by the attending surgeon and an unscheduled, open ASGB is medically required for the member’s safety; OR

2. A request for a scheduled, open ASGB is reviewed prospectively by a Plan Medical Director and is determined to be medically necessary by the Plan Medical Director based on the member’s medical condition; see Plan medical policy, Medically Necessary (policy number OCA 3.14).

B. The Plan requires Medical Director review to determine the medical necessity of a request for ANY of the following bariatric procedures for adolescent members, as specified below in items 1 through 6 (and all other applicable limitations listed in this section also apply):

1. Adjustable gastric banding for an adolescent member under age 18 on the date of service (since the implanted device is FDA approved for adult patients only); OR

2. Biliopancreatic diversion (BPD) with or without duodenal switch (DS) for an adolescent member under age 18 on the date of service; OR

3. Sleeve gastrectomy for an adolescent member under age 18 on the date of service when Plan medical criteria are NOT met; OR

4. Bariatric surgery for an adolescent boy (including an adolescent boy born with male reproductive organs and/or with typical male karyotype with only one [1] X chromosome, if known) who is less than 15 years of age on the date of service; OR

5. Bariatric surgery for an adolescent girl (including an adolescent member born with female reproductive organs and/or with typical female karyotype with two [2] X chromosomes, if known) who is less than 13 years of age on the date of service; OR

6. Any staged bariatric procedure for an adolescent member under age 18 on the date of service (including the first procedure).

C. The Plan considers ANY of the following procedures experimental and investigational for ALL members, as specified below in items 1 through 10:

1. Biliopancreatic diversion (BPD) without a duodenal switch for all members;*** OR

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****Note: According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), the duodenal switch diminishes the most severe complications of BPD, including dumping syndrome and peptic ulceration of the anastomosis.

2. Fobi-pouch; OR

3. Endoscopic bariatric procedures, gastric plication, and pouch reduction; examples include but are not limited to the ROSE procedure, EndoCinch, and Stomaphyx™; OR

4. Intragastric balloon system; examples include but are not limited to the Orbera System (formerly known as BIB; Apollo Endosurgery Inc.), the Spatz Adjustable Balloon (Spatz FGIA Inc.), the Obalon Balloon (Obalon Therapeutics), the Heliosphere BAG (Santé Actions Group), and the ReShape Duo (ReShape Medical Inc.); OR

5. Jejunoileal bypass; OR

6. Loop gastric bypass; OR

7. Mini-gastric bypass (i.e., gastric bypass using Billroth II type of anastomosis); OR

8. Roux-en-Y gastric bypass combined with simultaneous gastric banding; OR

9. Vertical banded gastroplasty (VBG); OR

10. Other bariatric procedure not specified in this Plan policy.

D. The Plan considers bariatric surgery to be experimental and investigational for all members when used for an indication that does not meet Plan criteria, including but not limited to ANY of the following, as specified below in items 1 through 3:

1. A cure for type 2 diabetes; OR

2. Gastroesophageal reflux disease (GERD); OR

3. Infertility.

E. The Plan considers the bariatric surgery to be experimental and investigational for all members when a device is used for the bariatric procedure that is not FDA approved for the specified indication, for the member’s age, and/or member’s medical condition.

F. Contraindications for bariatric surgery for all members include any ONE (1) of the following (and a member with one of these contraindications requires individual consideration by a Plan

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Medical Director, as specified in the Plan’s *Clinical Criteria* policy, policy number OCA 3.201), as specified below in items 1 through 9:

1. Advanced cancer; OR

2. Current substance abuse; OR

3. End-stage cardiopulmonary disease; OR

4. End-stage liver disease; OR

5. End-stage renal disease; OR

6. Lack of comprehension of the risks–benefits, expected outcomes, alternatives, and lifestyle changes required with bariatric surgery; OR

7. Pregnancy or planned pregnancy during expected weight loss; OR

8. Noncompliance with previous medical care that severely impacted the member’s health and safety; OR


G. The second procedure (and any additional procedure beyond the first procedure) for all members in a multi-staged bariatric procedure requires Medical Director review.

H. The first bariatric surgery in a planned, multi-staged bariatric procedure requires Medical Director review when ANY of the following criteria is met, as specified below in items 1 through 3:

1. The first procedure is not a sleeve gastrectomy for an adult; OR

2. Any staged bariatric procedure for an adolescent (including the first procedure); OR

3. Other Plan criteria are not met.

I. Any revisional bariatric procedure where the prior bariatric procedure was performed less than one (1) year before the scheduled revision requires Plan Medical Director review; this may be due to a complication that may require more immediate surgical intervention.

J. Plan Medical Director review is required for requests for bariatric surgery when applicable Plan criteria are not met, as specified in the Medical Policy Statement section.
**Definitions**

**Apnea Hypopnea Index (AHI):** Criterion used for diagnosis or to determine treatment for obstructive sleep apnea (OSA); the measurement represents the average of the combined number of apnea and hypopnea episodes that occur per hour of sleep. Types include mild OSA (AHI of 5-15 per hour), moderate OSA (AHI of 15-30 per hour), or severe OSA (AHI of more than 30 per hour).

**Body Mass Index (BMI):** Body mass index describes relative weight for height and correlates with total fat content. BMI is calculated as weight (kg)/height squared (m²). The classification of BMI is specified in the table below. To estimate BMI using pounds and inches, use the following formula: Weight (pounds)/height (inches) x 703.

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<th>Description</th>
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**Morbid Obesity (Clinically Severe Obesity):** A disease of excess energy stores in the form of fat. Clinically severe obesity correlates with a body mass index (BMI) of greater than or equal to 40 kg/m² or a BMI of greater than or equal to 35 kg/m² accompanied by comorbid conditions that include but are not limited to: coronary artery disease, clinically refractory hypertension, severe obstructive sleep apnea, type 2 diabetes, Pickwickian syndrome, obesity related cardiomyopathy, and/or pulmonary hypertension.

**Nonalcoholic Steatohepatitis (NASH):** A common and often silent liver disease. It resembles alcoholic liver disease, but occurs in individuals who drink little or no alcohol. The major feature in NASH is fat in the liver, along with inflammation and damage. Most individuals with NASH feel well and are not aware that they have a liver problem. Nevertheless, NASH can be severe and can lead to cirrhosis, in which the liver is permanently damaged and scarred and no longer able to work properly. (Source: National Institute of Diabetes and Digestive and Kidney Disease)
Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>43644</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
</tr>
<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
</tr>
<tr>
<td>43659</td>
<td>Unlisted laparoscopy procedure, stomach</td>
</tr>
<tr>
<td></td>
<td>(Plan note: Use to report removal and replacement of both gastric restrictive device and subcutaneous port components)</td>
</tr>
<tr>
<td>43770</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)</td>
</tr>
<tr>
<td>43771</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43772</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43773</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components</td>
</tr>
</tbody>
</table>
Bariatric Surgery

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<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)</td>
</tr>
<tr>
<td>43843</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty</td>
</tr>
<tr>
<td>43845</td>
<td>Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoejejunostomy and ileejunostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)</td>
</tr>
<tr>
<td>43846</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy</td>
</tr>
<tr>
<td>43847</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption</td>
</tr>
<tr>
<td>43848</td>
<td>Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)</td>
</tr>
<tr>
<td>43886</td>
<td>Gastric restrictive procedure, open; revision of subcutaneous port component only</td>
</tr>
<tr>
<td>43887</td>
<td>Gastric restrictive procedure, open; removal of subcutaneous port component only</td>
</tr>
<tr>
<td>43888</td>
<td>Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only</td>
</tr>
</tbody>
</table>

Clinical Background Information

Obesity is a major health problem in the United States and is increasing to epidemic proportions. It is the second most common preventable cause of morbidity and mortality after smoking. The comorbidities associated with obesity substantially raise the health risk of individuals with obesity. The diseases associated with obesity include hypertension, type 2 diabetes, coronary heart disease, dyslipidemia, gallbladder disease, stroke, osteoarthritis, sleep apnea, and certain cancers. The National Heart Lung Blood Institute (NHLBI) defines overweight as a body mass index (BMI) of 25 to 29.9 kg/m² and obesity as a BMI of 30 kg/m² or higher. Recently, statistics show that over 2% of the United States population has a BMI over 40 kg/m². The goal of weight loss treatment is to improve the comorbidities and decrease the future complications related to obesity. The initial weight loss goal should be to reduce body weight by approximately 10% from baseline.

According to the American Gastroenterological Association, a stepwise approach is recommended for the treatment of obesity based on the National Institutes of Health (NIH) panel on the identification, evaluation, and treatment of overweight and obese adults. The stepwise principles of obesity therapy include interventions in the following order: dietary strategies that promote loss of weight and an increase in physical activity, behavior modification therapy to facilitate changes in eating habits, pharmacotherapy, and finally bariatric surgery. Surgical therapy is recommended in patients with a BMI of 40kg/m² or greater, or those individuals with a BMI 35.0 - 39.9 kg/m² with one or more severe comorbidities.

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17 of 37
obesity-related medical complications (e.g., hypertension, type 2 diabetes, heart failure, or sleep apnea) if they have been unsuccessful in achieving weight loss with conventional therapy based on the stepwise approach. Candidates for surgery must have acceptable operative risks and be able to comply with long-term treatment and follow-up.

The type of surgical procedure depends on the expertise of the surgeon and the individual’s BMI. Gastric bypass is the most common procedure. All gastric restrictive and intestinal malabsorption procedures can be performed with the open or minimally invasive laparoscopic technique. Weight loss is similar with either laparoscopic or open procedure, but the laparoscopic approach is associated with fewer post-operative complications, shorter hospital stay, and earlier return to functional status. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), laparoscopic surgery may be difficult or impossible in patients with giant ventral hernias, severe intra-abdominal adhesions, large liver, high BMI with central obesity or physiological intolerance of pneumoperitoneum. Surgeons performing bariatric surgery should possess the necessary skills to perform open bariatric surgery in the event it becomes necessary to convert to an open procedure.

Malabsorptive procedures should be considered in individuals with a BMI of 50 kg/m² or higher. Complications following gastric restrictive and malabsorption procedures can include: peritonitis secondary to anastomotic leak or perforation, gastric pouch dilatation, band erosion, stricture, reflux esophagitis, anastomatic ulcer, incisional hernia, internal abdominal wall hernias and nutritional deficiencies. Patients who lose a large amount of weight following bariatric surgery often form gallstones or sludge during the first year. Other complications can include deep vein thrombosis (DVT), pulmonary embolism, and/or wound infections. Reversal or revisional surgery may be necessary in some patients.

There are multiple comorbid conditions associated with severe obesity in youths, including metabolic disorders, hypertension, non-alcoholic fatty liver disease, musculoskeletal problems and/or obstructive sleep apnea syndrome. Severely obese youths are much more likely to become severely obese adults with associated health risks and adverse outcomes. Bariatric surgery is appropriate and available for only some adolescents with severe obesity.

Currently, the most common operations being performed in children affected by severe obesity are the Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), and sleeve gastrectomy. There is good evidence that RYGB is reasonably safe and highly effective compared with lifestyle modification for the treatment of severe obesity with adolescents who are skeletally mature. Relatively good safety and efficacy data for LAGB in adolescents have been reported, although a high rate of reoperation and sparse long-term data, along with a lack of FDA approval for the device, hamper recommendations for usage before adulthood. Sleeve gastrectomy has been performed less often in adolescents than the RYGB or the adjustable gastric banding, but has been performed in increasing numbers throughout the past few years. Long-term data is not yet available on sleeve gastrectomy performed on adolescents, but preliminary results from on-going studies of adolescents undergoing the procedure demonstrate excellent weight reduction, reversal of co-morbidities, and complication rates similar to those of the adult population. Advantages of the gastric sleeve for Bariatric Surgery

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adolescents include the following: there is no foreign body left to erode or require removal, no adjustments are needed, malabsorption should be less with a reduction in ghrelin (reducing hunger satiety signals), bowel obstruction later in life is unlikely, the pylorus is preserved, and the biliary tract is not excluded. According to SAGES, laparoscopic sleeve gastrectomy in the pediatric age group is as safe and effective as it is in adults. Pediatric patients had fewer serious complications and were more compliant with follow-up than adults. Nevertheless, long-term results are required to further clarify the safety and efficacy of LSG in pediatric patients.

Specific dietary guidelines follow bariatric surgery. The postoperative diet is started with frequent small servings of water and ice chips for the first few days. The progression of the diet to solid foods begins with liquids and pureed foods to soft textured food and can be advanced slowly over several weeks as tolerated. Generally, the initial gastric capacity is 30 to 60 mL with a progression up to 120 to 150 mL. Individuals should understand that they need to eat for 20 minutes or more to avoid bolus feeding and allow the feeling of fullness to occur. Liquids should be ingested well before meals or at least 30 minutes afterwards. Proteins should be eaten first followed by fats and carbohydrates. Lifelong vitamin B12 injections and daily multivitamin therapy may be necessary in some patients.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) 100.1 includes the following clinical guidelines for bariatric surgery for the treatment of morbid obesity for Medicare beneficiaries and specifies that type 2 diabetes mellitus is an applicable comorbidity: “…Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. These procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center…; or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence.” Verify CMS criteria in the applicable NCD, local coverage determination (LCD), and/or coverage guidelines in in effect on the date of the prior authorization request for bariatric surgery for a Senior Care Options member.

Services related to bariatric surgery may or may not include intensive behavioral therapy for obesity. According to CMS NCD 210.12, CMS covers intensive behavioral therapy for obesity, defined as a body mass index (BMI) ≥ 30 kg/m², for the prevention or early detection of illness or disability. Intensive behavioral therapy for obesity consists of the following: (1) Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed kg/m²); (2) dietary (nutritional) assessment; and (3) intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise. Additional administrative guidelines for covered behavioral therapy for obesity are included in NCD 210.12.

Medical nutrition services (MNT) may or may not also be necessary for individuals who will receive or have had bariatric surgery. CMS NCD 180.1 includes medically necessary indications for MNT for a Bariatric Surgery

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beneficiary with a diagnosis of renal disease and/or diabetes according to CMS established criteria based on duration of treatment, episode of care, date of service, and number of units administered per day. As stated in NCD 180.1, additional treatment may be considered medically necessary and covered if the treating physician determines that there is a change in the beneficiary’s medical condition, diagnosis, and/or treatment regimen that requires a change in MNT and physician orders additional MNT during that episode of care. See the Plan medical policy, Medical Nutrition Therapy in the Outpatient or Office Setting (policy number OCA 3.66), for additional Plan guidelines related to this service.

References


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Bariatric Surgery

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Hayes News - Government. CMS Decision Related to Bariatric Surgical Procedures to Treat Type 2 Diabetes. Winifred Hayes, Inc. February 17, 2009.


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### Original Approval Details

<table>
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<tr>
<th>Regulatory Approval:</th>
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<tbody>
<tr>
<td>Internal Approval:</td>
<td>11/01/14</td>
</tr>
</tbody>
</table>

### Original Effective Date and Version Number

| 01/01/05 Version 1 |

### Policy Owner

Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)

### Approved by

Quality and Clinical Management Committee (Q&CMC)

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### *Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12

### *Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13

### *Effective Date for the Senior Care Options Product(s): 01/01/16

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### Policy Revisions History

<table>
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<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/06/05</td>
<td>Updated clinical coverage criteria.</td>
<td>Version 2</td>
<td>12/06/05: Q&amp;CMC</td>
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<tr>
<td>02/06/07</td>
<td>Updated references, added CMS and other payer coverage information.</td>
<td>Version 3</td>
<td>02/06/07: Q&amp;CMC</td>
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<tr>
<td>06/01/07</td>
<td>Revised template.</td>
<td>Version 4</td>
<td></td>
</tr>
<tr>
<td>01/08/08</td>
<td>Clinical criteria revised, vertical banded gastroplasty and sleeve gastrectomy are considered investigational. Revisions effective 07/01/08.</td>
<td>07/01/08 Version 5</td>
<td>01/08/08: MPCTAC 01/22/08: Utilization Management Committee (UMC) 02/19/08: QIC</td>
</tr>
<tr>
<td>12/01/10</td>
<td>Added criteria for the revision of prior bariatric surgery, the sleeve gastrectomy, BPD procedures and bariatric reversal procedures. Added the StomaphyX and ROSE procedures as investigational. Updated references.</td>
<td>Version 8</td>
<td>12/28/10: MPCTAC 01/26/11: QIC</td>
</tr>
<tr>
<td>12/01/11</td>
<td>Updated definitions, clinical criteria and limitations sections with additional procedures that are considered investigational. Updated the criteria for sleeve gastrectomy.</td>
<td>Version 9</td>
<td>12/12/11: MPCTAC 12/20/11: QIC</td>
</tr>
</tbody>
</table>

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### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision Details</th>
<th>Version</th>
<th>Effective Date</th>
<th>Reviewing Body</th>
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</thead>
<tbody>
<tr>
<td>07/01/12</td>
<td>Off cycle review for Well Sense Health Plan. Revised Summary statement, revised and reformatted Clinical Guideline Statement, revised Limitations, updated code list, deleted reference to MassHealth medical necessity guidelines.</td>
<td>Version 10</td>
<td>08/03/12</td>
<td>MPCTAC 09/05/12</td>
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<tr>
<td>02/01/13</td>
<td>Review for effective date 06/01/13. Revised Summary section, reformatted and revised clinical criteria in Medical Policy Statement section (formerly named the Clinical Guideline Statement section), reformatted and added limitations and contraindications, revised language in Applicable Coding section and updated code list, text added to Clinical Background Information section, and revised and added references.</td>
<td>Version 11</td>
<td>02/20/13</td>
<td>MPCTAC 03/21/13</td>
</tr>
<tr>
<td>11/01/13</td>
<td>Review for effective date 03/01/14. Added CPT code 43842 (for vertical-banded gastroplasty) as an experimental and investigational code.</td>
<td>Version 13</td>
<td>11/20/13</td>
<td>MPCTAC 12/19/13</td>
</tr>
<tr>
<td>02/01/14</td>
<td>Review for effective date 06/01/14. Updated Description of Item or Service, Clinical Background Information, and References section. Updated criteria in the Medical Policy Statement section and Limitation section.</td>
<td>Version 14</td>
<td>02/19/14</td>
<td>MPCTAC 02/26/14</td>
</tr>
<tr>
<td>01/01/15</td>
<td>Review for effective date 06/01/15. Updated Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised medical criteria in the Medical Policy Statement section and Limitations section. Added sleeve gastrectomy as a medically necessary procedure for adolescent members</td>
<td>Version 15</td>
<td>02/18/15</td>
<td>MPCTAC 03/11/15</td>
</tr>
</tbody>
</table>

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Policy Revisions History

07/01/12: Off cycle review for Well Sense Health Plan. Revised Summary statement, revised and reformatted Clinical Guideline Statement, revised Limitations, updated code list, deleted reference to MassHealth medical necessity guidelines.

02/01/13: Review for effective date 06/01/13. Revised Summary section, reformatted and revised clinical criteria in Medical Policy Statement section (formerly named the Clinical Guideline Statement section), reformatted and added limitations and contraindications, revised language in Applicable Coding section and updated code list, text added to Clinical Background Information section, and revised and added references.


11/01/13: Review for effective date 03/01/14. Added CPT code 43842 (for vertical-banded gastroplasty) as an experimental and investigational code.

02/01/14: Review for effective date 06/01/14. Updated Description of Item or Service, Clinical Background Information, and References section. Updated criteria in the Medical Policy Statement section and Limitation section.

01/01/15: Review for effective date 06/01/15. Updated Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised medical criteria in the Medical Policy Statement section and Limitations section. Added sleeve gastrectomy as a medically necessary procedure for adolescent members.

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Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Version</th>
<th>Review Date</th>
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<tr>
<td>11/01/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and corresponding notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/18/15: MPCTAC</td>
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<td>11/25/15: MPCTAC</td>
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<td>12/09/15: QIC</td>
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<tr>
<td>11/25/15</td>
<td>Review for effective date 03/01/16. Revised criteria in the Medical Policy Statement and Limitations sections. Revised the Definitions and References sections.</td>
<td>03/01/16</td>
<td>11/18/15: MPCTAC</td>
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<td>12/09/15: QIC</td>
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<tr>
<td>09/01/16 and 09/28/16</td>
<td>Review for effective date 11/01/16. Updated Description of Item or Service, Clinical Background Information, References, and Reference to Applicable Laws and Regulations. Administrative changes made to clarify language related to gender.</td>
<td>11/01/16</td>
<td>09/21/16: MPCTAC</td>
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Last Review Date

09/28/16

Next Review Date

11/01/16

Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Medical Nutrition Therapy in the Outpatient or Office Setting* (policy number OCA 3.66)
Medical Policy - *Medically Necessary*, policy number OCA 3.14
Reimbursement Policy - *Anesthesia*, policy number 4.103
Reimbursement Policy - *Anesthesia*, policy number SCO 4.103

Bariatric Surgery

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Reimbursement Policy - Anesthesia, policy number WS 4.11
Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number 4.108
Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number SCO 4.108
Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number WS 4.108
Reimbursement Policy - General Billing and Coding Guidelines, policy number 4.31
Reimbursement Policy - General Billing and Coding Guidelines, policy number SCO 4.31
Reimbursement Policy - General Billing and Coding Guidelines, policy number WS 4.31
Reimbursement Policy - Hospital, policy number WS 4.21
Reimbursement Policy - Inpatient Hospital, policy number, policy number 4.110
Reimbursement Policy - Inpatient Hospital, policy number, policy number SCO 4.110
Reimbursement Policy - Outpatient Hospital, policy number 4.17
Reimbursement Policy - Outpatient Hospital, policy number SCO 4.17

Reference to Applicable Laws and Regulations


Disclaimer Information: *

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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