TITLE: BARIATRIC SURGERY

EFFECTIVE DATE: January 1, 2018

This policy was developed with input from specialists in general and bariatric surgery, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of gastrointestinal surgery for morbid obesity. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. Bariatric surgical preparatory program is a multi-disciplinary approach to preoperative care of the bariatric patient. It encompasses bariatric surgical procedure education; dietary, nutrition, and exercise counseling; management of comorbidities; nursing care; and psychological evaluation and counseling, as warranted.

B. Body Mass Index (BMI) is a formula that uses a person’s body mass (height and weight) to estimate that person’s risk for morbidity and premature mortality. (See Appendix 1 – Body Mass Index [BMI] Conversion Table.) A BMI between 35 and 39 is viewed as a very high health risk, while a BMI of 40 or more is viewed as an extremely high health risk. The BMI associated with the lowest mortality is between 20 and 25. Note: BMI is not to be used with certain groups of people (i.e., athletes, body builders, or pregnant women) who have high BMIs due to muscle mass, fetal tissue, etc.

C. Combined restrictive and malabsorptive surgical procedures restrict meal size and may alter the digestion process, thus causing food to be incompletely absorbed. Examples of combined restrictive and malabsorptive procedures include Roux-en-Y gastric bypass and biliopancreatic diversion with duodenal switch.

D. Estimates of adult height are qualitative indices that assist a caregiver in determining whether a child is growing as expected. One commonly used tool is a growth chart, which records a child’s height, weight, and head size over time. Other methods are the ‘two years times two’ method (i.e., doubling a boys height at age two; doubling a girls height at 18 months) or a mid-parental height adjustment measurement.

E. Morbid obesity is a condition in which excessive body fat compromises organ systems, psychosocial well-being, and overall quality of life. Co-morbidities associated with this condition are often exacerbated by weight gain and improved with sustained weight loss. While there is no uniform consensus on how to operationally define morbid obesity, the current convention is to calculate the person’s Body Mass Index (BMI). Morbid obesity is defined as having a BMI of 40 or more, or having a BMI between 35 and 39.9 with additional co-morbidities. A BMI between 35 and 40 is roughly equivalent to 100 pounds overweight for an average adult, depending on height.

F. Restrictive surgical procedures reduce the size of the stomach and limit the amount of food that can be ingested at one time. Surgical incision and resection of the intestine is not involved. Examples of purely
restrictive operations for morbid obesity include adjustable silicone gastric banding (LapBand), sleeve gastrectomy, and vertical banded gastroplasty.

G. **Skeletal (bone) maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of either the knee or of the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.

H. **Substance use disorder**, as defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is a problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress. The symptoms associated with a substance use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).

I. **Super-obesity** refers to overweight individuals with a BMI of 50-60. Patients with BMI >60 are classified as super-super obese.

J. **Sexual Maturity Rating** (aka, Tanner stage/Tanner scale) is a measure of physical development in children, adolescents, and adults. The scale is named after its originator, James Tanner, a British pediatrician. The scale defines physical measurement of maturity based on external primary and secondary sex characteristics, such as breast or genital size, testicular volume, and development of pubic hair. (See Appendix 2 – Tanner Stages).

K. **Weight loss surgery** encompasses major operations with significant risks of complications. The risks are reduced if the operation and follow-up care are performed by a specialist in bariatric surgery.

II. Common surgical interventions

A. **Purely Restrictive procedures**:

1. **Vertical banded gastroplasty** consists of constructing a small pouch by placing a vertical staple line along the lesser curvature of the stomach. An opening (or stoma) is created at the distal end of the pouch to allow food to pass normally, but more slowly, from the pouch to the stomach and then to the small intestines. The pouch generally holds about one ounce of food. The person feels full quickly and experiences pain, nausea and/or vomiting when overeating. Both open and laparoscopic techniques are performed for this procedure.

2. **Adjustable silicone gastric banding** is similar in intent to the vertical banded gastroplasty except that an inflatable, adjustable silicone band is laparoscopically inserted around the upper stomach to create a small stomach pouch. An injection reservoir is enclosed under the skin's surface. The inflatable inner surface of the band is then injected with saline to a level suitable for food restriction and subsequent weight loss, as well as patient comfort. The degree of inflation can be adjusted by a clinician as needed. By removing the silicone band, the procedure can be reversed with minimal need for stomach reconstruction. Although most commonly inserted laparoscopically, this procedure can also be done using an open incision.

3. **Sleeve gastrectomy** is a restrictive procedure that is accomplished by removing the outer portion (upper curvature) of the stomach. This leaves a small sleeve of stomach, reducing stomach volume as much as 80 percent. The procedure was originally designed as the first step of a restrictive/malabsorption staged procedure, but is recently being suggested as a primary (one stage) procedure.

B. **Combined Restrictive and Malabsorptive procedures**:

1. **Roux-en-Y gastric bypass** and its variants consist of two basic steps: creating a small stomach pouch and re-routing the intestines to connect to the pouch. First, a small gastric pouch is constructed, thereby partitioning the pouch from the remaining stomach. The intestine is cut, and the distal end of the bowel is attached to the pouch where the stoma is created. The remaining intestinal limb is reattached farther down the intestinal tract, thereby creating a Y-shaped limb of varying lengths. Gastric bypass procedures work by restricting food intake and by limiting the absorption of calories and nutrients. A gastric bypass is both a gastric restrictive and a malabsorptive procedure. Both open and laparoscopic techniques are performed for this procedure.

2. **Biliopancreatic diversion with duodenal switch** combines biliopancreatic/intestinal bypass and stomach size reduction. First, a sleeve gastrectomy is done, creating a smaller stomach with both the esophageal connection and the pyloric valve remaining intact. Next, a shorter alimentary limb is created from the pylorus to the duodenum and carries food. A longer biliary limb runs from the pancreas and liver and carries bile and pancreatic secretions. The biliary limb is then connected to the alimentary limb, creating a short common channel where limited fat absorption can occur prior to content entry into the colon. This procedure is primarily malabsorptive, with less restriction than that in the Roux-en-Y gastric bypass. Both open and two-stage laparoscopic techniques are performed for this procedure.
BENEFIT CONSIDERATIONS

1. Prior authorization is **required** for gastrointestinal surgery for morbid obesity for the initial surgical procedure, for a surgical revision, and for a second procedure.

2. Coverage may vary according to the terms of the member's plan document.

3. Gastrointestinal surgical procedures for morbid obesity or surgery for weight loss not specifically mentioned in the Medical Necessity Criteria section are **investigative and therefore not covered**. These include, but are not limited to:
   a. Gastroplasty (gastric stapling without banding)
   b. Open loop gastric bypass ("mini" gastric bypass; omega loop gastric bypass; single-anastomosis gastric bypass)
   c. Unmodified biliopancreatic diversion
   d. Combined vertical banded gastroplasty-gastric bypass
   e. Magenstrasse and Mill Procedure (laparoscopic non banded vertical gastroplasty)
   f. Transected silastic ring vertical gastric bypass (Fobi pouch)
   g. Jejuno-ileal bypass
   h. Endoscopic procedures for morbid obesity including, but not limited to, natural orifice transluminal endoscopic surgery and endoscopic revision following bariatric surgery (all methods including, but not limited to, endoluminal suturing and/or stapling, prosthetic insertion [e.g., intragastric balloon; endoluminal sleeve], or endoscopic sclerosant injection).

4. A second procedure for gastrointestinal surgery for morbid obesity in the absence of complications is **not covered**.

5. A reversal (takedown) of gastrointestinal surgery for morbid obesity in the absence of complications is **not covered**.

6. The following services are **NOT covered**:
   1. Education classes
   2. Liquid protein diet replacements/supplements
   3. Appetite suppressants
   4. Over-the-counter vitamin and/or mineral supplements
   5. Weight loss program fees.

7. Medica network providers who are designated by Medica as a bariatric surgeon of excellence will be eligible for reimbursement for bariatric surgical procedures or revisions considered not investigative by Medica's Medical Technology Assessment Committee when performed at a facility designated as a bariatric center of excellence (COE) by Medica. Coverage may vary according to the terms of the member’s plan document.

8. Medica has entered into separate contracts with designated providers and facilities to provide gastrointestinal surgery for morbid obesity services as described in the member’s plan document. Medica network providers who are **not designated** by Medica as a bariatric surgeon of excellence (COE) may **not be eligible** for reimbursement from Medica when performing gastrointestinal surgery for morbid obesity, dependent on the terms of the member’s plan document.

9. Medica network providers who are designated by Medica as a bariatric surgeon of excellence, but are performing gastrointestinal surgery for morbid obesity at a **facility not designated** by Medica as an inpatient bariatric centers of excellence (COE), **may not be eligible** by Medica for reimbursement for facility charges when performing gastrointestinal surgery for morbid obesity, dependent on the term’s of the member’s plan document.

10. The Medica approved list, **COE Programs for Bariatric Care** (surgeons and hospitals), in the Medica service area is available online at www.medica.com in the Providers” section. This list is subject to change based on the ongoing approval process for the program. This listing is also available by calling Medica’s Provider Literature Request Line at 952-992-2355 or toll-free at 1-800-458-5512, option 1, then option 5, ext. 2-2355.

11. Additional information regarding surgeons or centers of excellence for bariatric care outside the Medica service area can be found on the ASMBS Web site at: http://asmbs.org or the ACS Web site at www.facs.org.

12. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.

13. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.

Effective Date: January 1, 2018
MEDICAL NECESSITY CRITERIA

I. Indications for initial procedure in individuals over 18 years of age

Gastrointestinal surgery for morbid obesity is considered medically necessary when documentation in the medical record indicates all of the following criteria are met:

A. One of the following procedures is being requested:
   1. Open or laparoscopic Roux-en-Y (RNY) gastric bypass
   2. Laparoscopic adjustable silicone gastric banding
   3. Open or laparoscopic sleeve gastrectomy
   4. Open or laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS)
   5. Vertical banded gastroplasty (VBG)

B. Psychiatric/psychological evaluation has been conducted by a licensed psychologist or psychiatrist, or other licensed mental health professional who has an appropriate working knowledge of the psychosocial issues involved in obesity and bariatric surgery, and all of the following are documented:
   1. Evaluation has been completed within the past 12 months.
   2. Confirmation of the individual’s ability to understand the risks and goals of the surgical procedure.
   3. Absence of unmanageable acute psychiatric illness and/or psychological distress, including but not limited to depression or substance use disorder.
   4. Confirmation of individual’s understanding of need to comply with long-term aftercare and with the behavioral changes expected after surgery.

D. The initial pre-surgical consultation with the bariatric surgical preparatory team has occurred at least one month prior to the date of surgery.

E. One of the following is documented:
   1. A BMI equal to or greater than 40, and all of the following are documented:
      a. BMI recorded at least one-month preceding surgery.
      b. Participation in a diet, nutrition, and exercise counseling regimen as recommended and documented by the bariatric surgical preparatory team.
   2. A BMI between 35 and 39.9, and all of the following are documented:
      a. BMI recorded at least one month preceding surgery.
      b. One of the following comorbidities documented in the medical record:
         i. Diabetes mellitus requiring medication (insulin or oral hypoglycemic) or a documented glycosylated hemoglobin (HgbA1c) level at or above 8 documented within the 12 months prior to surgical intervention.
         ii. Clinically significant hyperlipemia or dyslipidemia requiring medical management or a documented LDL level greater than 130 milligrams per deciliter.
         iii. Hypertension requiring medical management or blood pressure equal to or greater than 140 mmHg systolic and/or 90 mmHg diastolic documented on more than one occasion.
         iv. Obstructive sleep apnea requiring CPAP or other related sleep apnea treatment.
         v. Significant gastroesophageal reflux disease (GERD) (e.g., esophagitis with open reflux/transient lower esophageal sphincter relaxation when Nissen fundoplication has been previously determined not appropriate.)
      c. Participation in a diet, nutrition, and exercise counseling regimen as recommended and documented by the bariatric surgical preparatory team.

II. Indications for initial procedure in individuals less than or equal to 18 years of age

Gastrointestinal surgery for morbid obesity is considered medically necessary when documentation in the medical record indicates all of the following criteria are met:

A. The individual meets criteria I.A.-E., above.

B. Greater than 95% of estimated adult height has been achieved based on previously documented individual growth pattern (e.g., two years times two measurement, mid-parental measurement, growth chart tracking)

C. A minimum Tanner stage of IV. (See Appendix 2.)

III. Indications for surgical revisions

Surgical revision following previous gastrointestinal surgery for morbid obesity is considered medically necessary when documentation in the medical record indicates that all of the following criteria are met:

A. One of the following procedures is being requested:
   1. Open or laparoscopic Roux-en-Y (RNY) gastric bypass
   2. Open or laparoscopic sleeve gastrectomy
   3. Open or laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS)
   4. Removal of adjustable gastric band and/or port
   5. Vertical banded gastroplasty (VBG).
B. Documentation in the medical record that the BMI prior to the initial procedure was equal to or greater than 35.
C. Documentation in medical record of a surgical complication following the primary procedure and related medical confirmation (e.g., imaging results, endoscopic reports).

NOTE: Examples of complications include, but are not limited to:
1. Stoma ulcer or dilation
2. Mechanical obstruction
3. Significant malnutrition
4. Stenosis
5. Leakage (e.g., from staple line breakdown, distal stricture, band, port, tubing)
6. Esophageal or pouch dilation
7. Uncontrollable gastroesophageal reflux (with or without hiatal hernia), esophagitis, and/or vomiting
8. Gastric band erosion or slippage of gastric band or port
9. Infection around hardware (e.g., port used for band adjustments, staple line)
10. New or recurrent hiatal hernia
11. Gastric hemorrhage
12. Hardware failure/malfunction of a mechanical device

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
1. For Medicare members, refer to the following, as applicable, available at: http://www.cms.hhs.gov/mcd/search.asp?

DOCUMENT HISTORY

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<thead>
<tr>
<th>Original MPC Effective Date</th>
<th>November 2005</th>
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<tbody>
<tr>
<td>Administrative Updates</td>
<td>05/01/2017</td>
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References:

Pre 04/2016 Medical Policy Committee (MPC):


35. ECRI Institute. *ECRI Health Technology Forecast: Metabolic (Bariatric) Surgery for Treating Type 2 Diabetes Mellitus in Patients with BMI <35 kg/m2.* April 2013. Plymouth Meeting, PA.


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04/2016 MPC:


06/2017 MPC:


10/2017 MPC:


The BMI describes relative weight for height. It is calculated as weight (in kilograms) / height (in meters) squared. The National Heart, Lung, and Blood Institute (NHLBI) guidelines classify overweight as a BMI of 25 through 29.9 kg/meter squared, obesity as a BMI equal to or greater than 30 kg/meter squared, and extreme obesity as a BMI equal to or greater than 40 kg/meter squared.

APPENDIX 2 – Tanner Stages

Because the onset and progression of puberty are so variable, Tanner has proposed a scale, now uniformly accepted, to describe the onset and progression of pubertal changes. Boys and girls are rated on a 5 point scale. Boys are rated for genital development and pubic hair growth, and girls are rated for breast development and pubic hair growth.

Pubic hair growth in females is staged as follows:
- **Stage I (Preadolescent)** - Vellos hair develops over the pubes in a manner not greater than that over the anterior wall. There is no sexual hair.
- **Stage II** - Sparse, long, pigmented, downy hair, which is straight or only slightly curled, appears. These hairs are seen mainly along the labia. This stage is difficult to quantitate on black and white photographs, particularly when pictures are of fair-haired subjects.
- **Stage III** - Considerably darker, coarser, and curlier sexual hair appears. The hair has now spread sparsely over the junction of the pubes.
- **Stage IV** - The hair distribution is adult in type but decreased in total quantity. There is no spread to the medial surface of the thighs.
- **Stage V** - Hair is adult in quantity and type and appears to have an inverse triangle of the classically feminine type. There is spread to the medial surface of the thighs but not above the base of the inverse triangle.

The stages in male pubic hair development are as follows:
- **Stage I (Preadolescent)** - Vellos hair appears over the pubes with a degree of development similar to that over the abdominal wall. There is no androgen-sensitive pubic hair.
- **Stage II** - There is sparse development of long pigmented downy hair, which is only slightly curled or straight. The hair is seen chiefly at the base of penis. This stage may be difficult to evaluate on a photograph, especially if the subject has fair hair.
- **Stage III** - The pubic hair is considerably darker, coarser, and curlier. The distribution is now spread over the junction of the pubes, and at this point that hair may be recognized easily on black and white photographs.
- **Stage IV** - The hair distribution is now adult in type but still is considerably less that seen in adults. There is no spread to the medial surface of the thighs.
- **Stage V** - Hair distribution is adult in quantity and type and is described in the inverse triangle. There can be spread to the medial surface of the thighs.

In young women, the Tanner stages for breast development are as follows:
- **Stage I (Preadolescent)** - Only the papilla is elevated above the level of the chest wall.
- **Stage II (Breast Budding)** - Elevation of the breasts and papillae may occur as small mounds along with some increased diameter of the areolae.
- **Stage III** - The breasts and areolae continue to enlarge, although they show no separation of contour.
- **Stage IV** - The areolae and papillae elevate above the level of the breasts and form secondary mounds with further development of the overall breast tissue.
- **Stage V** - Mature female breasts have developed. The papillae may extend slightly above the contour of the breasts as the result of the recession of the areolae.

The stages for male genitalia development are as follows:
- **Stage I (Preadolescent)** - The testes, scrotal sac, and penis have a size and proportion similar to those seen in early childhood.
- **Stage II** - There is enlargement of the scrotum and testes and a change in the texture of the scrotal skin. The scrotal skin may also be reddened, a finding not obvious when viewed on a black and white photograph.
- **Stage III** - Further growth of the penis has occurred, initially in length, although with some increase in circumference. There also is increased growth of the testes and scrotum.
- **Stage IV** - The penis is significantly enlarged in length and circumference, with further development of the glans penis. The testes and scrotum continue to enlarge, and there is distinct darkening of the scrotal skin. This is difficult to evaluate on a black-and-white photograph.
- **Stage V** - The genitalia are adult with regard to size and shape.