Coverage Summary

Obesity: Treatment of Obesity, Non-Surgical and Surgical (Bariatric Surgery)

Policy Number: B-005  Products: UnitedHealthcare Medicare Advantage Plans  Original Approval Date: 04/15/2014
Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 04/18/2017
Related Medicare Advantage Policy Guideline: Bariatric Surgery for Treatment of Morbid Obesity (NCD 100.1)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

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I. COVERAGE

Coverage Statement: Treatment of obesity (surgical and non-surgical may be covered when Medicare criteria are met.

Guidelines/Notes:
1. Non-Surgical Services
   a. Physician prescribed supplemented fasting with monitoring on a case-by-case basis when weight loss is necessary prior to a surgical procedure to minimize any possible complications and the member's obesity co-exists with a high-risk condition, such as cardiac diseases, respiratory diseases, diabetes or hypertension. See the NCD for Treatment of Obesity (40.5). (Accessed April 6, 2017)
b. Physician prescribed supplemental fasting with monitoring on a case by case basis when weight loss is part of a medically necessary treatment plan for hypothyroidism, Cushing's disease or hypothalamic disease. See the NCD for Treatment of Obesity (NCD 40.5) (Accessed April 6, 2017)

c. Intensive Behavioral Therapy for Obesity; see the Coverage Summary for Preventive Health Services and Procedures.

Note: For supplemental fasting, reimbursement for the supplement itself is not covered because food supplements are not considered a drug for Medicare payment purposes.

2. Surgical Treatment - Bariatric Surgery

a. Covered Services and Criteria

Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), or Gastric Reduction Duodenal Switch (BPD/GRDS) and stand-alone laparoscopic sleeve gastrectomy (LSG) are considered reasonable and necessary when all of the following criteria are met:

1) Member has a Body Mass Index (BMI) ≥ 35
2) Member has at least one co-morbidity related to obesity

Note: Effective for services performed on or after February 12, 2009, CMS determined that Type 2 diabetes mellitus is a co-morbidity for the purposes of the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1).

3) Member has previously undergone unsuccessful medical treatment of obesity.

Notes:

- The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or noncovered, for MA members who have a body-mass index ≥ 35, have at least one comorbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local Medicare Administrative Contractor or MA Plan.

- Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient is eligible for coverage on a case-by-case basis or pursuant to a local coverage determination. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

See the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1).

Also see the NCD for Surgery for Diabetes (100.14). (Accessed April 6, 2017)

IMPORTANT NOTES (Facility Requirements):

Effective for dates of service on and after February 21, 2006, bariatric procedures are only covered when performed at facilities that meet one of the following requirements:

1. Certified by the American College of Surgeons (ACS) as a Level 1 Bariatric
Surgery Center (program standards and requirements in effect on February 15, 2006); or
2. Certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

See the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1). (Accessed April 6, 2017)

Effective for dates of service on and after September 24, 2013, facilities are no longer required to be certified. Refer to the CMS Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement (CAG-00250R3). (Accessed April 6, 2017)

For services provided up to and including date of service September 23, 2013: The facilities that have met the CMS’ minimum facility standards for bariatric surgery and have been certified by ACS and/or ASBS are listed and maintained at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Bariatric-Surgery.html. (Accessed April 6, 2017)

b. Utilization Guidelines

- The Medicare NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1) does not provide Utilization Guidelines for Bariatric Surgery.
- Local Coverage Determinations (LCDs) with utilization guidelines for bariatric surgery exist. Compliance with these LCDs is required where applicable. Refer to the LCD Availability Grid (Attachment A) for the state-specific LCDs.
- For states with no LCDs, refer to the Coverage Summary Guidelines below; based on the LCDs for Bariatric Surgical Management of Morbid Obesity (L35022).

  (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)

- Committee approval date: April 18, 2017
- Accessed August 8, 2017

Coverage Summary Guidelines for states with no LCDs:

Comorbid Conditions

Severe obesity is known to aggravate numerous medical conditions. Comorbid conditions for which bariatric surgery is covered include the following:

- Type II diabetes mellitus (by American Diabetes Association diagnostic criteria).
- Refractory hypertension (defined as blood pressure of 140 mmHg systolic and/or 90 mmHg diastolic despite medical treatment with maximal doses of three antihypertensive medications).
- Refractory hyperlipidemia (acceptable levels of lipids unachievable with diet and maximum doses of lipid lowering medications).
- Obesity-induced cardiomyopathy.
- Clinically significant obstructive sleep apnea.
- Obesity-related hypoventilation.
- Pseudotumor cerebri (documented idiopathic intracerebral hypertension).
- Severe arthropathy of spine and/or weight-bearing joints (when obesity prohibits appropriate surgical management of joint dysfunction treatable but for the obesity).
• Hepatic steatosis without prior evidence of active inflammation.

Though the conditions listed above need not be immediately life-threatening for Medicare to cover bariatric surgery, the condition must not be trivial or easily controlled with non-invasive means (such as medication) and must be of sufficient severity as to pose considerable short- or long-term risk to function and/or survival. Consideration of the risk-benefit for each individual patient must be used to determine that surgery for obesity is the best option for treatment for that patient and no contraindications to bariatric surgery may exist.

**Previous Unsuccessful Medical Treatment for Obesity**

With or without bariatric surgery, successful obesity management requires adoption and lifelong practice of healthy eating and physical exercise (i.e. lifestyle modification) by the obese patient. Without adequate patient motivation and/or skills needed to make such lifestyle modifications, the benefit of bariatric surgical procedures is severely jeopardized and not medically reasonable or necessary. Patients considering bariatric surgical options must have been provided with knowledge and tools needed to achieve such lifelong lifestyle changes and must be capable and willing to undergo the changes.

For the purposes of this LCD, a patient will be deemed to have been unsuccessful with medical treatment of obesity if all of the following minimal requirements are met per documentation in the medical record:

• The patient meets BMI requirements stated in national policy (at the time of surgery).
• The patient has been provided with knowledge and tools needed to achieve such lifelong lifestyle changes, exhibits understanding of the needed changes and is demonstrated to clinicians involved in his or her care to be capable and willing to undergo the changes.
• The patient has made a diligent effort to achieve healthy body weight with such efforts described in the medical record and certified by the operating surgeon.
• The patient has failed to maintain a healthy weight despite adequate participation in a structured dietary program overseen by one of the following:
  o Physician (MD or DO)
  o Registered dietician (RD)
  o Board certified specialist in pediatric nutrition (CSP)
  o Board certified specialist in renal nutrition (CSR)
  o Fellow of the American Dietetic Association (FADA)

**Preoperative Psychological/Psychiatric Evaluation**

An objective examination by a mental health professional (psychiatrist or psychologist) experienced in the evaluation and management of bariatric surgery candidates to exclude patients who are unable to personally provide informed consent, who are unable to comply with a reasonable pre- and postoperative regimen, or who have a significant risk of postoperative decompensation is recommended. Such evaluation is a Medicare-covered service. A diagnostic session is appropriate, and treatment sessions are appropriate if the patient has a diagnosable disorder that is likely to respond to psychotherapy. The mental health professional, the surgeon and the patient should be in agreement that the patient is an appropriate candidate for the surgery.

Patients who have a history of psychiatric or psychological disorder or are currently under the care of a psychologist/psychiatrist, or are on psychotropic medications, must undergo
preoperative psychological evaluation and clearance and the patient’s record must include
documentation of the evaluation and assessment.

**Other Preoperative Evaluation**
A patient undergoing bariatric surgical procedures should undergo preoperative evaluation
that is medically reasonable and necessary based upon his comorbid medical conditions
and medical/surgical history. All underlying medical conditions that will likely impact or
complicate the patient’s surgical and postoperative course must be adequately controlled
before surgery. Routine preoperative testing (including upper gastrointestinal endoscopy)
in the absence of signs/symptoms or personal history of a disease that could be negatively
impacted by anesthesia or surgery is excluded from Medicare coverage by law.

**Postoperative Care**
Appropriate postoperative care for the bariatric surgery patient is required for Medicare
coverage of bariatric surgical procedures. Follow-up must include but not be limited to:

- Postoperative care by the operating surgeon immediately following surgery and
  throughout the global period for the surgery.
- At least three follow-up visits with the bariatric surgery team within the first year.
- Lifetime postoperative care for dietary issues (including vitamin, mineral and
  nutritional supplementation), exercise and lifestyle changes reinforced by
  counseling and/or support groups supervised by a physician knowledgeable in the
  long-term care of such patients.

**Contraindications to Bariatric Surgery**
Surgery for severe obesity is a major surgical intervention with a risk of significant early
and late morbidity and perioperative mortality. Surgery for severe obesity is not covered in
the presence of absolute contraindications, including the following:

- Prohibitive perioperative risk of cardiac complications due to cardiac ischemia or
  myocardial dysfunction.
- Severe chronic obstructive airway disease or respiratory dysfunction.
- Non-compliance with medical treatment of obesity or treatment of other chronic
  medical condition.
- Failure to cease tobacco use.
- Psychological/psychiatric conditions:
  - 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).
  - Mental retardation that prevents personally provided informed consent or the ability
    to understand and comply with a reasonable pre- and postoperative 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 the long-term postoperative management.

**Note:** A history of or presence of mild, uncomplicated and adequately treated
depression due to obesity is not normally considered a contraindication to obesity
surgery.

- History of significant eating disorders, including anorexia nervosa, bulimia and pica
  (sand, clay or other abnormal substance).
- Severe hiatal hernia/gastroesophageal reflux (for purely restrictive procedures such as LAGB).
- Autoimmune and rheumatological disorders (including inflammatory bowel diseases and vasculitides) that will be exacerbated by the presence of intra-abdominal foreign bodies (for LAGB procedure).
- Hepatic disease with prior documented inflammation, portal hypertension or ascites.

**Incidental Cholecystectomy**

Incidental cholecystectomy is covered in the presence of signs and/or symptoms of gallbladder disease, finding of a grossly diseased gallbladder at the time of operation or a history of metabolic derangements that will result in symptomatic gallbladder disease following bariatric procedures.

*Note: The above guidelines apply to both primary and revision surgery for obesity.*

3. **Second Bariatric Surgeries**

For coverage information regarding second bariatric surgeries. Refer to the UnitedHealthcare Medical Policy for Bariatric Surgery.

4. **Examples of services that are not covered:**

   a. Treatment of obesity when criteria are not met
   b. Treatment for obesity alone; *see the NCD for Treatment of Obesity (NCD 40.5)* (Accessed April 6, 2017)
   c. Supplemented fasting as a general treatment for obesity, except as indicated above. *See the NCD for Treatment of Obesity (NCD 40.5)* (Accessed April 6, 2017)
   d. Intestinal bypass surgery (e.g., jejunoileal bypass); *see the NCD for Intestinal Bypass Surgery (100.8)* (Accessed April 6, 2017)
   e. Gastric balloon for the treatment of obesity; *see the NCD for Gastric Balloon for Treatment of Obesity (100.11)* (Accessed April 6, 2017)
   f. Open and Laparoscopic vertical banded gastroplasty(VGB); *see the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1)* (Accessed April 6, 2017)
   
   *Note: VGB procedures are essentially no longer performed.*
   g. Open sleeve gastrectomy; *see the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1)* (Accessed April 6, 2017)
   h. Laparoscopic sleeve gastrectomy (prior to June 27, 2012); *see the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1)* (Accessed April 6, 2017)
   
   *Note: Effective for services performed on and after June 27, 2012, UnitedHealthcare may cover stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare Advantage members only when the conditions specified about in Guidelines 2.a above are met.*
   i. Open adjustable gastric banding; *see the NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1)* (Accessed April 6, 2017)

II. **DEFINITIONS**
Adjustable Gastric Banding: Achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc’s encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient’s weight loss. AGB procedures are laparoscopic only. NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1) (Accessed April 6, 2017)

Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS): BPD achieves weight loss by gastric restriction and malabsorption. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. The partial BPD/DS or BPD/GRDS is a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastamosis and a lower ileo-ileal anastamosis. BPD/DS or BPD/GRDS procedures can be open or laparoscopic. NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1) (Accessed April 6, 2017)

Body Mass Index (BMI): BMI is a number calculated from a person's weight and height. BMI is calculated as weight in kilograms per height in meters squared (kg/m²). Centers for Disease Control and Prevention; available at http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html#Definition. (Accessed April 6, 2017)

Gastric balloon: A medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety. NCD for Gastric Balloon for Treatment of Obesity (100.11) (Accessed April 6, 2017)

Roux-en-Y Gastric Bypass (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. NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1) (Accessed April 6, 2017)

Sleeve Gastrectomy: A 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. In the past, sleeve gastrectomy was the first step in a two-stage procedure when performing RYGBP, but more recently has been offered as a stand-alone surgery. Sleeve gastrectomy procedures can be open or laparoscopic. NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1) (Accessed April 6, 2017)

Supplemented Fasting: A type of very low calorie weight reduction regimen used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins and minerals. NCD for Treatment of Obesity (40.5) (Accessed April 6, 2017)

Vertical Banded Gastroplasty (VGB): Achieves weight loss by gastric restriction only. The upper
part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with
the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an
attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense
of fullness after eating small meals. Weight loss from this procedure results entirely from eating less.
VGB procedures are essentially no longer performed. NCD for Bariatric Surgery for Treatment of
Morbid Obesity (100.1) (Accessed April 6, 2017)

III. REFERENCES

See above

IV. REVISION HISTORY

04/18/2017 Annual review with the following update:
Guideline 2 (Surgical Treatment – Bariatric Surgery) – deleted language as same
language is already addressed in the NCD reference, i.e., NCD for Bariatric Surgery
for Treatment of Morbid Obesity (100.1)

04/19/2016 Annual review with the following recommended updates:
Guideline 4 – added specific reference links to the applicable Medicare references to
each example.
Updated all reference links of the applicable LCDs to reflect the condensed link.

04/21/2015 Annual review; without updates

03/24/2015 Guideline #2 (Surgical Treatment-Bariatric Surgery)
• Updated with current CMS language
• Deleted statement “Repeat bariatric surgery is generally not reasonable and
necessary”
Guideline # 3 (Second Bariatric Surgery) - added new section with reference link to
the UnitedHealthcare Medical Policy for Bariatric Surgery.

04/15/2014 New Policy; replaced 2 Coverage Summaries: (1) Obesity Nonsurgical Treatment of
Obesity; and (2) Bariatric Surgery, with additional updates:
• Guideline #2.a (Covered Services and Criteria) – Added “or Gastric Reduction
Duodenal Switch (BPD/GRDS)”
• Guideline #3 (Examples of services that are not covered) – Removed; no CMS
reference: Nutritional liquid supplement; Weight reduction medications, including
diet pills; and Prescription drugs to treat obesity
• Definitions - Morbid Obesity (removed; no CMS reference)

V. ATTACHMENT(S)

Attachment A - LCD Availability Grid
Bariatric Surgical Management of Morbid Obesity
CMS website accessed August 8, 2017

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<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
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</table>

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.
## Attachment A - LCD Availability Grid

**Bariatric Surgical Management of Morbid Obesity**

CMS website accessed August 8, 2017

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

<table>
<thead>
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<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
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<td>A and B MAC</td>
<td>Novitas Solutions, Inc</td>
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<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
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End of Attachment A