Policy: MP065
Section: Medical Benefit Policy
Subject: Obesity Surgery

I. Policy: Obesity Surgery

II. Purpose/Objective:
   To provide a policy of coverage regarding Obesity Surgery

III. Responsibility:
   A. Medical Directors
   B. Medical Management

IV. Required Definitions
   1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
   2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
   3. Devised – the date the policy was implemented.
   4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
   5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

   a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
   c. in accordance with current standards of good medical treatment practiced by the general medical community.
   d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
   e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Morbid obesity is a condition of persistent and uncontrollable weight gain that constitutes a present or potential threat to life. Obesity is most often defined by the body mass index, a mathematical formula that is used to quantitatively evaluate body fat by reflecting the presence of excess adipose tissue. Body mass index is weight in kilograms divided by height in meters squared (kg/m²). Morbid obesity is characterized by a weight which is at least 100 pounds or 100% over the ideal body weight.

INDICATIONS: Requires Prior Medical Director or Designee Authorization All Criteria Must Be Met
The surgical treatment of morbid obesity (i.e. open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic biliopancreatic diversion, open or laparoscopic sleeve gastrectomy, and/or adjustable laparoscopic band gastroplasty*) has been medically proven to improve health outcomes and is therefore medically necessary for selected patients. Patients must meet all of the following criteria:

1. Medical documentation of a diagnosis of morbid obesity that has persisted for a minimum of three years (two years for Medicaid business segment), which is supported by a minimum of semi-annual physician office acquired weights per year and
   a) Documented evidence of Class 3* obesity with a body mass index (BMI)** of forty (40) or greater with no co-morbidities (not applicable to Medicare. Surgical treatment for primary obesity is not a covered Medicare service); or
   b) Documented evidence of Class 2** obesity with a BMI of thirty-five (35) or greater with a diagnosis of at least one of the following comorbidities:
      • diabetes mellitus; or
      • obstructive sleep apnea diagnosed by polysomnography and requiring positive airway pressure (CPAP/BIPAP); or
      • biopsy proven non-alcoholic steatohepatitis (NASH); or
      • Coronary artery disease with documentation of previous myocardial infarction or angioplasty with stenting; or
      • Uncontrolled hypertension refractory to maximized doses of at least three (3) anti-hypertensive medications
      • Hyperlipidemia refractory to diet and maximum doses of lipid lowering medications (applicable to Medicare and Medicaid only)
      • Severe arthropathy of spine and/or weight-bearing joints (when obesity prohibits appropriate surgical management of joint dysfunction) (applicable to Medicare and Medicaid only)
      • Obesity-induced cardiomyopathy (applicable to Medicare and Medicaid only)
      • Hepatic steatosis without prior evidence of active inflammation (applicable to Medicare and Medicaid only)
      • Pseudotumor cerebri (documented idiopathic intracerebral hypertension). (applicable to Medicare and Medicaid only)

In 2016 the Center for Disease Control (CD) classified adult body mass index (BMI) for obesity as:
   Class 1 obesity is BMI 30 to 34.9
   ** Class 2 obesity is BMI 35 to 39.9
   *Class 3 obesity is BMI greater than or equal to 40

Note: BMI is calculated by Kg/M²  [(Body weight in kilograms) divided by (height in meters)² ].

And

2. Member has failed† at least one physician-supervised‡ weight loss program lasting at least 4 months.

† failed= not losing and maintaining at least 20% reduction of highest weight
physician-supervised programs may include:

- Physician visits addressing obesity or related co-morbidities
- LA Weight Loss™
- Physician’s Weight Loss®
- Weight Watchers®
- Other – upon review of program

And

3. The planned surgical intervention is one that is approved by the Plan based on evidence-based data regarding safety and outcomes. These include:
   - Roux-en-Y gastric bypass (open or laparoscopic)
   - Sleeve Gastrectomy (open or laparoscopic)
   - Biliopancreatic diversion with duodenal switch (BPD/DS)

*Note: Requests for adjustable laparoscopic banded gastroplasty will be evaluated on a "per case" basis

4. Pre-Surgical Program:

   Members considering surgery must participate in at least a 6 month comprehensive program (consisting of at least a minimum of 6 visits over the 6 month timeframe within 12 months prior to surgery) in a facility designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (NBSQIP) https://www.facs.org/quality-programs/mbsaqip. Facility participation in the Geisinger Bariatrics Proven Care® program will be considered in lieu of the designation as a Center of Excellence (COE) by NBSQIP. This program must be physician-supervised and consist of dietary management, physical activity, psychiatric evaluation, medical management, behavior modification as well as social support.

   For more information, please view the following links:

   http://www.cms.hhs.gov/MedicareApprovedFacilities/BSF/list.asp

   http://www.asbs.org/html/about/membersearch2.html

   And

5. The member’s diagnostic history does not display evidence of substance abuse, psychosis, eating disorders or uncontrolled depression within the past twenty-four (24) months, and

6. The member has stopped smoking for a minimum of two months (if applicable) prior to the requested surgery; and

7. Members who are prospective surgical candidates must have achieved full growth (18 years of age) before surgical intervention is considered; and

8. Surgery for morbid obesity must be performed in an institution designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (NBSQIP) https://www.facs.org/quality-programs/mbsaqip. Facility participation in the Geisinger Bariatrics Proven Care® program will be considered in lieu of the designation as a COE by NBSQIP. (Not Applicable to Medicare and Medicaid business segments eff. Sept 25, 2013 ) per http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Bariatric-Surgery.html

LIMITATIONS:
Revision of bariatric surgery: Bariatric surgery revision requires prior authorization
Coverage is limited to one bariatric surgery per lifetime regardless of insurance carrier at the time of surgery with the following exception:

- Bariatric surgery revision will be considered for coverage only when requested as treatment for an associated medical complication such as, but not limited to obstruction, fistula or stricture for which no other treatment option is available, bowel perforation, band erosion or migration, or band failure. The revision must occur within a maximum of 16 weeks of the precipitating complication.
Inadequate weight loss due to individual noncompliance with postoperative nutrition and exercise recommendations is not a medically necessary indication for revision or conversion surgery and is not covered by the Plan.

Laparoscopic adjustable silicone gastric banding (LASGB) requests will be reviewed on a per-case basis and considered for coverage only by exception.

For Medicare and Medicaid lines of Business:
Original Medicare limits coverage of bariatric surgical interventions to procedures such as but not limited to, open and laparoscopic Roux-en-Y gastric bypass, Biliopancreatic Diversion with Duodenal Switch, open or laparoscopic sleeve gastrectomy, and laparoscopic adjustable gastric banding. Original Medicare considers open adjustable gastric banding; or open and laparoscopic vertical banded gastroplasty to be non-covered procedures. Therefore, these procedures will not be eligible for coverage for insured individuals enrolled in that line of business.

EXCLUSIONS:
The following surgical interventions are considered investigational and are NOT COVERED.

- **Jejunoileal bypass** as a treatment for morbid obesity is considered *investigational*.
- **Gastric wrapping** as a treatment of morbid obesity is considered *investigational*.
- **Gastric balloon** is considered *investigational* since the long-term safety and efficacy of the device in the treatment of morbid obesity has not been established.
- **Open and laparoscopic vertical banded gastroplasty** as a treatment of morbid obesity is considered *investigational*.
  *NOTE: Vertical-banded gastroplasty is eligible for coverage for Medicaid Business segment*
- **Endoscopic Sleeve Gastroplasty** is considered investigational since the long-term safety and efficacy of the device in the treatment of morbid obesity has not been established.
- **Natural Orifice Transluminal Endoscopic Surgery™ (NOTES™) (e.g., StomaphyX™)/endoscopic oral assisted procedures sleeve gastrectomy (SG)** as a treatment for morbid obesity is considered investigational.

Revision of gastric bypass surgery, when performed solely due to the failure to lose weight or failure to maintain weight loss due to dilation of the gastric pouch *is NOT COVERED.*

**Note:** May be reviewed on a “per-case” basis through the Program Exception process for Medicaid

Revision of laparoscopic band gastroplasty to surgical gastric restrictive or malabsorptive procedures, when performed solely due to the failure to lose weight or failure to maintain weight loss *are NOT COVERED.*

**Note:** May be reviewed on a “per-case” basis through the Program Exception process for Medicaid

Revision associated medical complication such as, but not limited to obstruction, fistula or stricture for which no other treatment option is available beyond a maximum of 16 weeks of the precipitating complication will be considered a second surgery unrelated to the first episode, and therefore *NOT COVERED*

**Note:** May be reviewed on a “per-case” basis through the Program Exception process for Medicaid

Evidence of non-compliance while enrolled in a weight loss program managed by a licensed physician or registered dietician provider will result in a denial of request for surgical intervention for the treatment of morbid obesity.

The AspireAssist device or any pumping device for the mechanical removal of stomach contents for the purpose of weight loss is considered Unproven and *NOT COVERED.*

There is insufficient evidence in the published, peer-reviewed medical literature to support the use of bariatric surgery as a treatment for the primary diagnosis of gastroparesis, infertility, gastroesophageal reflux, or diabetes members with a BMI of less than 35. Use of bariatric procedures as treatment of these conditions is considered *experimental, investigational or unproven,* and therefore, *NOT COVERED.*

There is insufficient evidence in the published, peer-reviewed medical literature to support the use of space-occupying balloon inserts as a treatment for obesity. Use of this bariatric procedure is considered experimental, investigational or unproven, and therefore, *NOT COVERED.*
Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Obesity Surgery
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

HMO, TPA:

S2083 Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline
43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-y gastroenterostomy (roux limb 150 cm or less)
43645 with gastric bypass and small intestine reconstruction to limit absorption
43846 Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (less than 100 cm) Roux-en-y gastroenterostomy
43659 (Unlisted laparoscopy procedure, stomach)
43773 LAPAROSCOPY, SURGICAL, GASTR RESTR PROC, REMOVAL AND REPLACE GASTRIC BAND
43774 LAPAROSCOPY, SURGICAL, GASTR RESTR PROC, REMOVAL OF ADJ GAST BAND AND PORT
43843 Gastric restrictive procedure, without gastric bypass, for morbid obesity, other than vertical-banded gastroplasty (Coding used for Laparoscopic Band gastroplasty)
43845 Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch
43848 Revision of gastric restrictive procedure for morbid obesity (separate procedure)
43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)
43771 Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable band component only
43772 Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable band component only
43775 Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)

GOLD members may be eligible for the following procedures:

43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-y gastroenterostomy (roux limb 150 cm or less)
43645 with gastric bypass and small intestine reconstruction to limit absorption
43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)
43771 Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable band component only
43772 Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable band component only
43773 LAPAROSCOPY, SURGICAL, GASTR RESTR PROC, REMOVAL AND REPLACE GASTRIC BAND
43774 LAPAROSCOPY, SURGICAL, GASTR RESTR PROC, REMOVAL OF ADJ GAST BAND AND PORT
43775 Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)

43845 Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch
43846 gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (less than 100cm) Roux-en-y gastroenterostomy
43847 with small bowel reconstruction to limit absorption
43848 Revision of gastric restrictive procedure for morbid obesity (separate procedure)
43886 GASTR RESTR PROC, REVISION OF SUBCUTANEOUS PORT COMPONENT ONLY
43887 GASTR RESTR PROC, REMOVAL OF SUBCUTANEOUS PORT COMPONENT ONLY
43888 GASTR RESTR PROC, REMOVE AND REPLACE SUBCUTANEOUS PORT
Non-Covered procedures for GOLD (Not applicable to Medicaid)
43842 Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty


For members enrolled in the Gold product, please refer to the current version of Novitas Policy L35022 for additional ICD-10 coding.

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


CMS Manual Publication 100-3, Chapter 1, Section 100.1 http://www.cms.hhs.gov/transmittals/downloads/R54NCD.pdf


Jolly K et al. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. BMJ 2011 Nov 3; 343


National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Morbid Obesity (100.1) http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&bc=AgAAgAAAAAAA&ncdver=3


This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/98

Revised: 12/99, 03/02, 11/02, 12/03; 7/05 (revised criteria); 4/06 (revised criteria); 9/08; 9/09 (revised criteria & exclusion); 2/11 (revised approved procedure); 6/11 (formatting), 8/11, 2/13 (revised Medicare coverage); 10/13 (revised Medicare/Medicaid criteria); 2/15 (add comorbidities, exclude lap band); 2/16 (clarify facility accreditation); 2/17 (added approved procedure, indications, exclusion), 4/18 (added vertical banded gastroplasty as covered for Medicaid; noted exceptions for PA MA) 4/19 (revised indications, exclusions, and conditions for revision)

Reviewed: 9/07, 8/12, 2/14