Geisinger Health Plan Policies and Procedure Manual

Policy: MP065

Section: Medical Benefit Policy

Subject: Obesity Surgery

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

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.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

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, single anastomosis Roux-en-Y, single anastomosis duodenal ileostomy (SADI), open or laparoscopic biliopancreatic diversion with or without duodenal switch, 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:

ADULT CRITERIA (Roux-en-Y gastric bypass (open or laparoscopic), Sleeve Gastrectomy (open or laparoscopic), Biliopancreatic diversion with duodenal switch (BPD/DS)

For Endoscopic Sleeve Gastroplasty – see specific section below

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 2* obesity with a body mass index (BMI)** of thirty-five (35) or greater regardless of presence, absence, or severity of comorbidities **(not applicable to Medicare. Surgical treatment for primary obesity is not a covered Medicare service); or**
    b) Documented evidence of Class 1** obesity with a BMI of 30-34. with a diagnosis of at least one of the following comorbidities associated with metabolic disease:
        - 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
- Uncontrolled gastroesophageal reflux disease GERD **(NOT applicable to Medicare/Medicaid)**
- 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[1] at least one physician-supervised[2] weight loss program lasting at least 4 months.

   [1] failed= not losing and maintaining at least 20% reduction of highest weight

   [2] physician-supervised programs may include but are not limited to :
   - 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, laparoscopic,(**NOTE**: For endoscopic see specific criteria below)
   - 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 program (consisting of at least a minimum of 6 visits over the 6 month timeframe within 12 months prior to surgery) in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (NBSQP) Facility participation in the Geisinger Bariatrics Proven Care® program will be considered in lieu of the designation as a Center of Excellence (COE) by NBSQP. 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.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/vaping nicotine for a minimum of two months (if applicable) prior to the requested surgery; **and**
7. Surgery for morbid obesity must be performed in an institution designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) 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 MBSAQIP. **(Not Applicable to Medicare and Medicaid business segments eff. Sept 25, 2013**

Endoscopic Sleeve Gastroplasty (ESG) – Requires Prior Authorization on a per-case basis when the following criteria are met:

- The member requires weight reduction bridge therapy as recommended by Transplant Medicine, Orthopedics, Pulmonary Medicine or Endocrinology; and
- The member is enrolled in the ESG ProvenCare program; and
- The member has completed an accelerated 3-month comprehensive care plan offering an evaluation with an advanced endoscopy provider, nutrition specialist, dietician, exercise physiologist, adult psychologist, nutrition education class, behavioral education class, bariatric medical evaluation, and an addiction medicine evaluation.
- Procedure for morbid obesity must be performed in an institution designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) 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 MBSAQIP. **(Not Applicable to Medicare and Medicaid business segments eff. Sept 25, 2013**

ADOLESCENT CRITERIA

The surgical treatment of morbid obesity (i.e. open or laparoscopic Roux-en-Y gastric bypass, or open or laparoscopic sleeve gastrectomy) may be considered medically necessary when all of the following criteria are met:

a) Medical documentation of a diagnosis of morbid obesity defined as:
   i. Class 3 obesity (BMI of 40 kg/m^2) or greater; OR greater than 140 percent of the 95th BMI percentile for age with ANY obesity-related comorbidity;

   or

   ii. Class 2 obesity (BMI of 35 - 39 kg/m^2) OR greater than 120 percent of the 95th BMI percentile for age with at least one of the following comorbidities:
      - type 2 diabetes
      - obstructive sleep apnea diagnosed by polysomnography
      - pseudotumor cerebri
      - Poorly controlled hypertension despite pharmacotherapy (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater)
      - hyperlipidemia
      - non-alcoholic steatohepatitis

   and

b) One of the following surgical interventions is planned:
   - open or laparoscopic Roux-en-Y gastric bypass
   - open or laparoscopic sleeve gastrectomy

   and

c) The member is 12 years of age or older; and
d) Documentation of previous failure of physician-supervised weight loss attempt; and
e) Pre-Surgical Program
   - Adolescent members considering surgery must participate in a comprehensive program with documentation of the following:
     - the member has been evaluated by the multidisciplinary pediatric team and is determined to be physically and emotionally mature enough to participate in the program
     - the member demonstrates the ability to adhere to the principles of healthy dietary and activity habits
     - the member has adequate support system and resources to achieve weight loss goals
f) Surgery for morbid obesity must be performed in an institution designated by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) and accredited. Facility participation in the Geisinger Bariatrics Proven Care® program will be considered in lieu of the designation as a COE by MBSAQIP. **(Not Applicable to Medicare and Medicaid)**

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 exceptions:

- 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.
- Conversion from sleeve gastrectomy to Roex-en-Y will be considered for coverage for the treatment of refractory gastroesophageal reflux when less invasive treatments and therapies have proven to be contraindicated or have resulted in therapeutic failure.

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.

Incidental cholecystectomy is considered 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.

Medicare Business Segment:

See: National Coverage Determination. Bariatric Surgery for Treatment of Morbid Obesity 100.1
See: Bariatric Surgery for the Treatment of Morbid Obesity CAG-00250R

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.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, will be evaluated as a Program Exception on a case by case basis.

EXCLUSIONS:
The following surgical interventions are considered investigational, unproven or unsafe and are **NOT COVERED.**

- Jejunoileal bypass
- Gastric wrapping
- Gastric balloon is considered unproven 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 unproven

*** NOTE: Vertical-banded gastroplasty is eligible for coverage for Medicaid Business segment**

- Natural Orifice Transluminal Endoscopic Surgery™ (NOTES™) (e.g., StomaphyX™)/endoscopic oral assisted procedures sleeve gastrectomy (SG) as a treatment for morbid obesity is considered unproven
- There is insufficient evidence in the published, peer-reviewed medical literature to support the use of space-occupying ingestible hydrogel capsules (e.g., Plenity) as a treatment for obesity. Use of this bariatric procedure is considered to be 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 unproven, and therefore, **NOT COVERED**

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

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.

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 any of the following conditions: gastroparesis; infertility; Use of bariatric procedures as treatment of these conditions is considered **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 **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 duodenoilestomy 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)
C9784 Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785 Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

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 duodenoilestomy 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
C9784 Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785 Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

Non-Covered procedures for GOLD (Not applicable to Medicaid)

43842 Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
0813T Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon

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:

Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, National Institutes of Health Evidence Report, No. 98-4083, Sept 1998, pp.86-91

Balsiger BM, Lugue-de Leon E, Sarr MG, “Surgical Treatment of Obesity: Who is an Appropriate Candidate”, *Mayo Clinic Proceedings*, 72(6):551-558, June 1997.

Benotti PN, Forse RA, “The Role of Gastric Surgery in the Multidisciplinary Management of Severe Obesity”, *The American Journal of Surgery*,169(3):361-367, March 1995.

Gastrointestinal Surgery for Severe Obesity, NIH Consensus Statement Online 1991 March 25-27;9(1):1-20.

Allen J, "Surgical Internet at a Glance: Bariatric Surgery", *The American Journal of Surgery*, 179(1):33, Jan 2000.

Hall JC, Watts JM, O'Brien PE, Dunstan RE, Walsh JF, Slavotinek AH, Elmslie RG, "Gastric Surgery for Morbid Obesity. The Adelaide Study", *Annals of Surgery*, 211(4(:419-427, April 1990.

Higa KD, Boone KB, Ho T, Davies OG, "Laparoscopic Roux-en-Y Gastric Bypass for Morbid Obesity: Technique and Preliminary Results of Our First 400 Patients", *Archives of Surgery*, 135(9):1029-1033, Sept. 2000.

O'Boyle CJ, Walters D, Watson DI, Game PA, "Twelve-year Experience With Gastric Bypass and Vertical Banded Gastroplasty for Morbid Obesity", *British Journal of Surgery* – Supplement, 88(Suppliment 1):24, May 2001.

Capella JF, Capella RF, "The Weight Reduction Operation of Choice: Vertical Banded Gastroplasty or Gastric Bypass?", *American Journal of Surgery*, 171(1):74-79, Jan 1996.

Rationale for the Surgical Treatment of Morbid Obesity, American Society for Bariatric Surgery, April 1998, http://www.asbs.org

"Vertical Banded Gastroplasty", Geisinger Technology Assessment Committee, 14 Oct. 1998.

"Lap-Band Surgery for Bariatric Cases", Geisinger Clinic Technology Assessment Committee, 9 Oct. 2002.

National Heart Lung and Blood Institute, Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. NIH Publication No. 98-4083. http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm

ECRI, 12th Annual Conference on Using Evidence in Practice and in Public and Private Policymaking. Preventing and Treating Overweight and Obesity. Oct. 2004.

ECRI, HTAIS, Technology Assessment Report. Bariatric Surgery for Obesity. Sept. 2004.

Buchwald H, Avidor Y, Braunwald E, et. al., Bariatric Surgery: A systematic review and meta-analysis. JAMA Oct. 13, 2004;292(14):1724-1737.

Guardiano SA, Scott JA, Ware JC, Schechner SA. The long-term results of gastric bypass on indexes of sleep apnea. Chest Oct. 2003;124(4):1615-1619.

Sjöström L, Lindroos AK, Peltonen M, et. al. Lifestyle, diabetes and cardiovascular risk factors 10 years after bariatric surgery. NEJM Dec. 23, 2004; 351(26):2683-2693.

Sjöström CD, Peltonen M, Wedel H, Sjöström L. Differentiated long-term effects of intentional weight loss on diabetes and hypertension. Hypertension 2000;36:20-25.

Banasiak RS, Gallagher SF, Lipska A, et. al. Gastric bypass is an effective treatment for obstructive sleep apnea in patients with clinically significant obesity. Obesity Surgery 2003 Feb;13(1):58-61.

Valencia-Flores M, Orea A, Herrera M, et. al. Effect of bariatric surgery on obstructive sleep apnea and hypopnea syndrome, electrocardiogram, and pulmonary arterial pressure. Obesity Surgery 2004 Jun-Jul;14(6):755-762.

Gonzalez R, Gallagher SF, Haines K, Murr MM. Operative technique for converting a failed vertical banded gastroplasty to Rouz-en-Y gastric bypass. J Am Coll Surg 2005;201:366-374.

Wilson JA, Romagnuolo J, Bryne TK, Morgan K, Wilson FA. Predictors of endoscopic findings after roux-en-Y gastric bypass. Am J Gastroenterol 2006;101:2194-2199.

Haines KL, Nelson LG, Gonzalez R, Torrella T, Martin T, Kandil A, Dragotti R, Anderson WM, Gallagher SF, Murr MM. Objective evidence that bariatric surgery improves obesity-related obstructive sleep apnea. Surgery 2007;141:354-8.

Weller WE, Rosati C, Hannan EL. Relationship between surgeon and hospital volume and readmission after bariatric operation. J Am Coll Surg;204:383-391.

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

Snyder B, Scarborough T, Yu S, Wilson E. Failure of adjustable gastric banding: starting BMI of 46 mg/m is a fulcrum of success and failure. Surgery for Obesity and Related Diseases. 2009;5:310-316.

Fogel R, De Fogel J, Bonilla Y, De La Fuente R. Clinical experience of transoral suturing for an endoluminal vertical gastroplasty: 1-year follow-up in 64 patients. Gastrointest Endosc 2008 Jul;68(1):51-8.

Moreno C, Closset J, Dugardeyn S, Barea M, Mehdi A, Collignon L, Zalcman M, Baurain M, Le Moine O, Deviere J. Transoral gastroplasty is safe, feasible, and induces significant weight loss in morbidly obese patients: results of the second human pilot study. Endoscopy 2008 May;40(5):406-13.

Nguyen NT, Hinojosa MW, Smith BR, Reavis KM, Wilson SE. Advances in Circular Stapling Technique for Gastric Bypass: Transoral Placement of the Anvil. Obes Surg 2008 Mar 28;:[Epub ahead of print].

Overcash WT. Natural Orifice Surgery (NOS) Using StomaphyXtrade mark for Repair of Gastric Leaks after Bariatric Revisions. Obes Surg 2008 Jul;18(7):882-5.

Mikami D, Needleman B, Narula V, Durant J, Melvin WS. Natural orifice surgery: initial US experience utilizing the StomaphyX™ device to reduce gastric pouches after Roux-en-Y gastric bypass. Surg Endo 2009;;[Epub ahead of print]

Deviere J, Valdes GO, Herrera LC, Closset J, Le Moine Q, Eisendrath P, Moreno C, Dugardeyn S, Barea M, la de Torre R, Edmundowicz S, Scott S. Safety, feasibility and weight loss after transoral gastroplasty: First human multicenter study. Surg Endo 2008:22;589-598.

Sleeve Gastrectomy. Geisinger Technology Assessment Committee. 12 January 2011.

Himpens J, Dapri G Cadiere GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy: Results after 1 and 3 years. Obes Surg 2006;16:1450-1456.

Brethauer SA, et al. Systematic review of sleeve gastrectomy as staging and primary bariatric procedure. Surg Obesity and Rel Dis.2009;5:469-475.

Bohdjalian A, Langer F, et al. Sleeve gastrectomy as sole and definitive bariatric procedure: 5 year results for weight loss and ghrelin. Obes Surg 2010.

Rubin M, Yehoshua RT, et al. Laparoscopic sleeve gastrectomy with minimal morbidity. Early results in 120 morbidly obese patients. Obes Surg 2008;18:1567-1570.

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

Yermilov I, McGory ML, Shekelle PW, Ko CY, Maggard MA. Appropriateness criteria for bariatric surgery: beyond the NIH guidelines. Obesity (Silver Spring). 2009 Aug;17(8):1521-7.

CMS MLN Matters 8028. https://www.novitas-solutions.com/bulletins/mln/index.html

Brethauer SA, Kothari S, Sudan R, et al. Systematic review on reoperative bariatric surgery: American Society for Metabolic and Bariatric Surgery Revision Task Force. Surg Obes Relat Dis. 2014.

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

Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014; 129(25 Suppl 2):S102-138

Puzziferri N, Roshek TB 3rd, Mayo HG, et al. Long-term follow-up after bariatric surgery: a systematic review. JAMA. 2014; 312(9):934-942.

American College of Cardiology/American Heart Association (ACC/AHA) and the Obesity Society (OS). Executive summary: Guidelines (2013) for the management of overweight and obesity in adults: a report of the ACC/AHA Task

Force on Practice Guidelines and the OS. Based on a systematic review from the Obesity Expert Panel, 2013. Obesity (Silver Spring). 2014; 22 Suppl 2:S5-39

Novitas Solutions, Inc. Local Coverage Determination (LCD): Bariatric Surgical Management of Morbid Obesity (L35022) https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35022&ContrId=323

Thompson CC, Abu BK, et al. The AspireAssist Is an Effective Tool in the Treatment of Class II and Class III Obesity: Results of a One-Year Clinical Trial. Gastroenterology 2016;150(4): Suppl 1, pS86

Forssell H, Norén E. A novel endoscopic weight loss therapy using gastric aspiration: results after 6 months. Endoscopy 2015; 47(01): 68-71

Sullivan S, Stein R, et al. Aspiration Therapy Leads to Weight Loss in Obese Subjects: A Pilot Study. Gastroenterology 2013;145(6): 1245–1252.e5

Winifred S. Hayes, Inc. Medical Technology Directory. (2017, July). Comparative effectiveness of roux-en-y gastric bypass and sleeve gastrectomy for treatment of type II diabetes: a review of reviews.

Wijngaarden LH, Jonker FHW, van den Berg JW, et al. Impact of initial response of laparoscopic adjustable gastric banding on outcomes of revisional laparoscopic Roux-en-Y gastric bypass for morbid obesity. Surg Obes Relat Dis. 2017 Apr;13(4):594-599

Topart P, Becouarn G, Delarue J. Weight loss and nutritional outcomes 10 years after biliopancreatic diversion with duodenal switch. Obes Surg. 2017 Jul;27(7):1645-1650.

Osland E, Yunus RM, Khan S, et al. Diabetes improvement and resolution following laparoscopic vertical sleeve gastrectomy (LVSG) versus laparoscopic Roux-en-Y gastric bypass (LRYGB) procedures: a systematic review of randomized controlled trials. Surg Endosc. 2017a Apr;31(4):1952-1963.

Osland E, Yunus RM, Khan S, et al. Changes in non-diabetic comorbid disease status following laparoscopic vertical sleeve gastrectomy (LVSG) versus laparoscopic Roux-En-Y Gastric Bypass (LRYGB) procedures: a systematic review of randomized controlled trials. Obes Surg. 2017b May;27(5):1208-1221.

Pinto-Bastos A, Conceição EM, Machado PPP. Reoperative bariatric surgery: a systematic review of the reasons for surgery, medical and weight loss outcomes, relevant behavioral factors. Obes Surg. 2017 Oct;27(10):2707-2715.

Qiu J, Lundberg PW, Javier Birriel T, et al. Revisional bariatric surgery for weight regain and refractory complications in a single MBSAQIP accredited center: what are we dealing with? Obes Surg. 2018 Apr 20.

Shoar S, Saber AA. Long-term and midterm outcomes of laparoscopic sleeve gastrectomy versus Roux-en-Y gastric bypass: a systematic review and meta-analysis of comparative studies. Surg Obes Relat Dis. 2017 Feb;13(2):170-180.

Salminen P, Helmiö M, Ovaska J, et al. Effect of laparoscopic sleeve gastrectomy vs laparoscopic Roux-en-Y gastric bypass on weight loss at 5 years among patients with morbid obesity: The SLEEVEPASS randomized clinical trial. JAMA. 2018 Jan 16;319(3):241-254.

Clapp B, Wynn M, Martyn C, et al. Long term (7 or more years) outcomes of the sleeve gastrectomy: a meta-analysis. Surg Obes Relat Dis. 2018 Mar 6.

Abu Dayyeh B, Acosta A, Camilleri M et al. Endoscopic Sleeve Gastroplasty Alters Gastric Physiology and Induces Loss of Body Weight in Obese Individuals. Clinical Gastroenterology and Hepatology 2017;15:37–43

Sharaiha RZ, Kumta NA, et al. Endoscopic Sleeve Gastroplasty Significantly Reduces Body Mass Index and Metabolic Complications in Obese Patients. Clinical Gastroenterology and Hepatology 2017;15:504–510

Sharaiha RZ, Kumta NA, et al. Endoscopic Sleeve Gastroplasty Significantly Reduces Body Mass Index and Metabolic Complicationsin Obese Patients, Clinical Gastroenterology and Hepatology 2017.

Lopez-Nava, G, Bautista-Castaino I, et al. Endoscopic sleeve gastroplasty with 1-year follow-up: factors predictive of success. Endoscopy International Open 2016; 04: E222–E227

Pratt JSA, Browne A, Browne NT, et al. ASMBS pediatric metabolic and bariatric surgery guidelines, 2018 Surgery for Obesity and Related Diseases 2018;14: 882–901

Qi L, Guo Y, Liu CQ, et al. Effects of bariatric surgery on glycemic and lipid metabolism, surgical complication and quality of life in adolescents with obesity: a systematic review and meta-analysis. Surg Obes Relat Dis. Dec 2017;13(12):2037-2055

Graus Morales J, Crespo Pérez L, Marques A, et al. Modified endoscopic gastroplasty for the treatment of obesity. Surg Endosc. 2018;32(9):3936-3942

Hayes, Inc. Comparative Effectiveness Review of Bariatric Surgeries for Treatment of Obesity in Adolescents. Hayes Comparative Effectiveness Review. January 13, 2019

Lee WJ, Almalki O. Gastro Esophageal Reflux Disease after Sleeve Gastrectomy: A Real Issue and Future Perspectives. Am J General GI Surg. 2018; 1(1): 1001

Carandina S, Soprani A, et al. Conversion of sleeve gastrectomy to Roux-en-Y gastric bypass in patients with gastroesophageal reflux disease: results of a multicenter study. Surg Obes Relat Dis. 2020 Jun;16(6):732-737

Lim CH, Lee PC, et al. Resolution of Erosive Esophagitis After Conversion from Vertical Sleeve Gastrectomy to Roux-en-Y Gastric Bypass. Obesity Surgery 2020; 30: 4751–4759

Yashkov Y, Bordan N, Torres A, et al. SADI-S 250 vs Roux-en-Y duodenal switch (RY-DS): Results of 5-year observational study. Obes Surg. 2021;31(2):570-579.

Aminian A, Al-Kurd A, Wilson R, et al. Association of Bariatric Surgery With Major Adverse Liver and Cardiovascular Outcomes in Patients With Biopsy-Proven Nonalcoholic Steatohepatitis. JAMA. 2021 Nov 11.

Greenway FL, Aronne LJ, Raben A, et al. A randomized, double-blind, placebo-controlled study of Gelesis100: a novel nonsystemic oral hydrogel for weight loss. Obesity. 2019;27(2):205–216.

Mechanick JI, Apovian C, et al. Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures –2019 update: cosponsored by American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic & Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists. Surgery for Obesity and Related Diseases 2020;16:175–247

Sewell K, Semenya AM. Cellulose and Citric Acid (Plenity) for Weight Management in Overweight and Obese Adults. Am Fam Physician. 2022;105(3):309-310

Eisenberg D, Shikora SA, Aarts E, et al. 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): Indications for Metabolic and Bariatric Surgery. Surgery for Obesity and Related Diseases 2022;18:1345–1356

Dang JT, Vaughan T, Mocanu V, et al. Conversion of Sleeve Gastrectomy to Roux-en-Y Gastric Bypass: Indications, Prevalence, and Safety. Obes Surg. May 2023; 33(5): 1486-1493

Gudur AR, Geng CX, Kshatri S, et al. Comparison of endoscopic sleeve gastroplasty versus surgical sleeve gastrectomy: a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database analysis. Gastrointest Endosc. 2023 Jan;97(1):11-21

Li X, Hu X, Fu C, et al. Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity: a meta-analysis and systematic review. Obes Surg. 2023 Feb;33(2):611-622

Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. Jan 09 2023

Hedjoudji A, Dayyeh BKA, et al. Efficacy and safety of endoscopic sleeve gastroplasty: a systematic review and meta-analysis. Clin Gastroenterol Hepatol, 2020;18(5):1043-1053

Sharaiha RZ, Hajifathalian K, et al. Five-Year Outcomes of Endoscopic Sleeve Gastroplasty for the Treatment of Obesity. Clinical Gastroenterology and Hepatology 2021;19(5):1051-1057

Thomas V, Suvvari TK, et al. Safety and efficacy of endoscopic sleeve gastroplasty and laparoscopic sleeve gastrectomy in obese type 2 diabetes patients. Surgery Open Digestive Advance 2023(11):100098

Algahtani AR, Elahmedi M, et al. Endoscopic gastroplasty versus laparoscopic sleeve gastrectomy: a noninferiority propensity score–matched comparative study. Gastrointestinal Endoscopy 2022;96(1):44-50

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); 9/20 (add adolescent criteria); 1/21 (add bariatric revision indication), 2/22, 2/23 (add hydrogel capsule exclusion, revise indications); 8/23 (revise verbiage for weight management program requirement); 8/24 (revise AAP guidance criteria for adolescents);10/24 (add ESG criteria)

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

CMS UM Oversight Committee Approval: 12/23; 12/24