curative

TITLE:	BARIATRIC SURGERY POLICY AND PROCEDURE
POLICY #:	MM-PNP-005
VERSION #:	02
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	06/24/2022
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1. PURPOSE

This policy addresses the medical necessity review of bariatric surgery options and pre-operative requirements.

2. SCOPE

Medical UM Department

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Provides guidelines for medical necessity review of weight loss/bariatric procedures and associated requirements that must be completed before surgical intervention will be approved. **The following procedures may be considered medically necessary when performed by surgeons who are adequately trained and experienced in the specific techniques used and when the surgery is part of a comprehensive bariatric surgery program performed at a Bariatric Accredited Center.**

Medical Necessity

Roux-en-Y Gastric Bypass (RYGB), Laparoscopic Adjustable Silicone Gastric Banding (LASGB), Sleeve Gastrectomy, Biliopancreatic Diversion (BPD), Duodenal Switch (DS) Procedures, Single Anastomosis Duodenal-Ileal Switch (SADI-S), and Sleeve Gastrectomy with Single Anastomosis Duodeno-Ileal Bypass (SIPS)

Open or laparoscopic short or long-limb Roux-en-Y gastric bypass (RYGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD) with or without duodenal switch (DS), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic single anastomosis duodenal-ileal switch (SADI-S), OR, open or laparoscopic sleeve gastrectomy with single anastomosis duodeno-ileal bypass (SIPS) is considered medically necessary when the selection criteria listed below are met:

Must meet requirements below for adults or adolescents*:*

- **Adults:**
  - For adults aged 18 years or older, presence of persistent severe obesity, documented in contemporaneous clinical records, defined as ***any*** of the following:
    - Body mass index exceeding 40 (or exceeding 37.5 for persons of Asian ancestry) measured prior to preoperative preparatory program with documented failure of weight loss by medical management; ***or***
    - BMI greater than 35 (or exceeding 32.5 for persons of Asian ancestry) measured prior to preoperative preparatory program **in conjunction with *any*** of the following severe co-morbidities:
      - Clinically significant obstructive sleep apnea ***or***
      - Coronary heart disease, with objective documentation (by exercise stress test, radionuclide stress test, pharmacologic stress test, stress echocardiography, CT angiography, coronary angiography, heart failure or prior myocardial infarction); ***or***
      - Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and/or 90 mmHg diastolic despite concurrent use of 3 anti-hypertensive agents of different classes); ***or***
      - Insulin Resistance or Type 2 diabetes mellitus; ***or***
      - Nonalcoholic steatohepatitis (NASH); ***or***
      - Idiopathic intracranial hypertension (pseudotumor cerebri) **AND**

    The individual must also meet the following criteria:

      - One year use of Munjaro, unless there is a documented intolerance to or member has a contraindication to Mounjaro use, ***and***
      - Member has participated in an 6-12 month intensive multicomponent behavioral intervention designed to help participants achieve or maintain weight loss through a combination of dietary changes and increased physical activity. This intensive multicomponent behavioral intervention must meet includes ***all*** of the following:
        - Monthly documented detailed weight history with 5% weight loss, ***and***
        - Dietary modification program with documented changes, ***and***
        - Physical activity modification program (documented); ***and***
      - Psychosocial-behavioral evaluation and sign-off by an individual who is professionally recognized as part of a behavioral health discipline to provide screening and identification of risk factors or potential postoperative challenges that maycontribute to a poor postoperative outcome, ***or***

- Participation in a 6 month multidisciplinary surgical preparatory regimen

Note: **Member's participation in an intensive multicomponent behavioral intervention must be documented in the medical record.** Records must document compliance with the program requirements listed above. For members who participate in an intensive multicomponent behavioral intervention (e.g., Noom, Jenny Craig, MediFast, Minute Clinic/Health Hubs, OptiFast, Weight Watchers, etc), program records documenting the member's participation and progress may substitute for medical records. Program must be intensive (12 or more sessions on separate dates over any duration of time) and occur within 2 years prior to surgery.

- **Adolescents:**
  - For adolescents who have completed bone growth (generally age of 13 in girls and age of 15 in boys), the bariatric surgical procedures identified are proven and medically necessary for treating obesity when **all** of the following criteria are met:
    - One of the following:
      - Class III obesity; ***or***
      - Class II obesity in the presence of one or more of the following co-morbidities:
    - Insulin resistance or Type 2 diabetes; ***or***
    - Poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90mm Hg or greater, despite pharmacotherapy)]; ***or***
    - Obstructive Sleep Apnea confirmed on polysomnography with an AHI or RDI of > 30; ***or***
    - Evidence of Nonalcoholic Fatty Liver Disease (NAFLD), ***or***
    - Idiopathic intracranial hypertension (pseudotumor cerebri) **AND**

    The individual must also receive an evaluation at, or in consultation with, a Multidisciplinary center focused on the surgical treatment of severe childhood obesity. This may include Adolescent centers that have received accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) or can demonstrate similar programmatic components

    Note: NASH determination may include either a liver biopsy or the presence of advanced hepatic fibrosis identified by FibroScan, FibroTest-ActiTest, magnetic resonance elastography, or Enhanced Liver Fibrosis (ELF) test.

    The individual must also meet the following criteria:

    - One year use of Munjaro, unless there is a documented intolerance to or member has a contraindication to Mounjaro use, and
    - Member has participated in an 6-12 month intensive multicomponent behavioral intervention designed to help participants achieve or maintain weight loss through

a combination of dietary changes and increased physical activity. This intensive multicomponent behavioral intervention must meet includes all of the following:

- Monthly documented detailed weight history with 5% weight loss, ***and***
- Dietary modification program with documented changes, ***and***
- Physical activity modification program (documented); ***and***

- Psychosocial-behavioral evaluation and sign-off by an individual who is professionally recognized as part of a behavioral healthdiscipline to provide screening and identification of risk factors or potential postoperative challenges that maycontribute to a poor postoperative outcome, ***or***

- Participation in a 6 month multidisciplinary surgical preparatory regimen

Note: **Member's participation in an intensive multicomponent behavioral intervention must be documented in the medical record.** Records must document compliance with the program requirements listed above. For members who participate in an intensive multicomponent behavioral intervention (e.g., Noom, Jenny Craig, MediFast, Minute Clinic/Health Hubs, OptiFast, Weight Watchers, etc), program records documenting the member's participation and progress may substitute for medical records. Program must be intensive (12 or more sessions on separate dates over any duration of time) and occur within 2 years prior to surgery.

Note: Programs may extend beyond two years if the final session occurred within two years prior to surgery; ***and***

- Intensive multicomponent behavioral intervention may be in-person or remote, and may be group or individual-based; ***and***

- The intensive multicomponent behavioral intervention program must have components focusing on nutrition, physical activity, and behavioral modification (e.g., self-monitoring, identifying barriers, and problem solving). The multicomponent behavioral intervention program may be supervised by behavioral therapists, psychologists, registered dietitians, exercise physiologists, lifestyle coaches or other staff; ***and***

- Screening for obstructive sleep apnea (OSA), using a validated screening questionnaire (including the ESS, STOP Questionnaire (Snoring, Tiredness, Observed Apnea, High Blood Pressure), STOP-Bang Questionnaire (STOP Questionnaire plus BMI, Age, Neck Circumference, and Gender), Berlin Questionnaire, Wisconsin Sleep Questionnaire, or the Multivariable Apnea Prediction (MVAP) tool). The medical records should document that OSA screening has been performed, although the results of such screening do not need to be forwarded to Curative for review. **Note**: Screening is not required for persons already diagnosed with OSA; ***and***

- For members who have an active substance abuse disorder, or have a history of eating disorder (in addition to obesity) or severe psychiatric disturbance (schizophrenia, borderline personality disorder, suicidal ideation, severe depression) or who are currently under the care of a psychologist/psychiatrist, pre-operative psychological clearance is necessary in order to exclude members who are unable to provide informed consent or who are unable to comply with the pre- and post-operative regimen.

Note: The presence of depression due to obesity is not normally considered a contraindication to obesity surgery.

Vertical Banded Gastroplasty (VBG)

Open or laparoscopic vertical banded gastroplasty (VBG) is considered medically necessary for members who meet the selection criteria above for obesity surgery and who are at increased risk of adverse consequences of a RYGB due to the presence of *any* of the following co-morbid medical conditions:

- Demonstrated complications from extensive adhesions involving the intestines from prior major abdominal surgery, multiple minor surgeries, or major trauma; ***or***
- Hepatic cirrhosis with elevated liver function tests; ***or***
- Inflammatory bowel disease (Crohn's disease or ulcerative colitis); ***or***
- Poorly controlled systemic disease (American Society of Anesthesiology (ASA) Class IV) (see Appendix); ***or***
- Radiation enteritis.

Curative considers VBG experimental and investigational when medical necessity criteria are not met.

A planned two-stage procedure is proven and medically necessary when all of the following criteria are met:

- Initial BMI ≥ 50 kg/m2 prior to first stage bariatric procedure; and
- Second stage occurs within 2 years following the primary bariatric surgery procedure; and
- Individual has been compliant with nutrition and exercise; and
- Individual meets medical necessity criteria listed above at time of second stage procedure

Bariatric Surgery Complications

The following are considered medically necessary:

- Removal of a gastric band when recommended by the member's physician;

- Surgery to correct complications from bariatric surgery, such as obstruction, stricture, erosion, or band slippage;
- Surgery for Candy cane syndrome (Roux syndrome) when member is symptomatic (abdominal pain, nausea, and emesis) and diagnosis is confirmed by endoscopy or upper gastrointestinal contrast studies;
- Replacement of an adjustable band is considered medically necessary if there are complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments;
- Conversion of sleeve gastrectomy to Roux-en-Y gastric bypass is considered medically necessary for the treatment of symptomatic gastroesophageal reflux disease (GERD) meeting the following criteria:
    - Reflux is documented by abnormal 24-hour pH monitoring or endoscopically proven esophagitis performed after the sleeve gastrectomy; and
    - Symptoms persist despite optimal medical therapy, including behavioral modification and at least one month of maximum proton pump inhibitor (PPI) therapy.

    Note: When performed primarily for the purpose of treating reflux meeting these criteria, conversion of sleeve gastrectomy to Roux-en-Y gastric bypass is not considered repeat bariatric surgery;
- Repeat bariatric surgery for members whose initial bariatric surgery was medically necessary (i.e., who met medical necessity criteria for their initial bariatric surgery), and who meet *any* of the following medical necessity criteria:
    - Conversion to a sleeve gastrectomy, RYGB or BPD/DS is considered medically necessary for members who have not had adequate success (defined as sustained loss of more than 50 % of excess body weight) 2 years following the primary bariatric surgery procedure and the member has been compliant with a prescribed nutrition and exercise program following the procedure; *or*
    - Revision of a primary bariatric surgery procedure that has failed due to dilation of the gastric pouch, dilated gastrojejunal stoma, or dilation of the gastrojejunostomy anastomosis is considered medically necessary if the primary procedure was successful in inducing weight loss prior to the dilation of the pouch or GJ anastomosis, and the member has been compliant with a prescribed nutrition and exercise program following the procedure; *or*
    - Conversion from an adjustable band to a sleeve gastrectomy, RYGB or BPD/DS is considered medically necessary for members who have been compliant with a prescribed nutrition and exercise program following the band procedure, and there are complications that cannot be corrected with band manipulation, adjustments or replacement.

Cholecystectomy

As a high incidence of gallbladder disease (28%) has been documented after surgery for morbid obesity, Curative considers routine cholecystectomy medically necessary when performed in concert with elective bariatric procedures.

Liver Biopsy

Curative considers routine liver biopsy during bariatric surgery to be **not** medically necessary in the absence of signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged liver).

Experimental and Investigational

The following procedures are considered experimental and investigational because the peer-reviewed medical literature shows them to be either unsafe or inadequately studied:

- Adjunctive omentectomy to bariatric surgery
- AspireAssist aspiration therapy
- "Band over bypass" or LASGB revision of prior Roux-en-Y gastric bypass (i.e., placement of a gastric band for the management of weight regain after Roux-en-Y gastric bypass)
- "Band over sleeve" or LASGB revision of prior sleeve gastrectomy
- Bariatric surgery as a treatment for idiopathic intracranial hypertension in persons not meeting medical necessity criteria for obesity surgery above
- Bariatric surgery as a treatment for infertility in persons not meeting medical necessity criteria for obesity surgery above
- Bariatric surgery as a treatment for type-2 diabetes in persons with a BMI less than 35
- Conversion of a sleeve gastrectomy to a Roux-en-Y gastric bypass for the treatment of bile reflux
- Conversion to sleeve gastrectomy for hypoglycemia post-RYGB
- Duodenal ileal switch for the treatment of gastroparesis
- Gastric bypass as a treatment for gastroparesis in persons not meeting medical necessity criteria for obesity surgery above
- Gastroplasty, more commonly known as "stomach stapling" (see below for clarification from vertical band gastroplasty)
- Laparoscopic gastric diversion with gastro-jejunal reconstruction for the treatment of GERD with esophagitis
- Laparoscopic gastric plication (also known as laparoscopic greater curvature plication [LGCP]), with or without gastric banding
- Laparoscopic single-anastomosis duodeno-ileal bypass with gastric plication
- LASGB, RYGB, and BPD/DS procedures not meeting the medical necessity criteria above
- Liposuction (suction-assisted lipectomy; ultrasonic assisted liposuction)

- Loop gastric bypass
- Mini gastric bypass
- Natural orifice transoral endoscopic surgery (NOTES) techniques for bariatric surgery including, but may not be limited to, the following:
    - Endoscopic outlet reduction (transoral outlet reduction (TORe)) for treatment of weight gain after Roux-en-Y gastric bypass; ***or***
    - Gastrointestinal liners (endoscopic duodenal-jejunal bypass, endoscopic gastrointestinal bypass devices; e.g., EndoBarrier and the ValenTx Endo Bypass System); *or*
    - Intragastric balloon (e.g., the Obalon Balloon System, and the ReShape Integrated Dual Balloon System); ***or***
    - Mini sleeve gastrectomy; ***or***
    - Restorative obesity surgery, endoluminal (ROSE) procedure for the treatment of weight regain after gastric bypass surgery; ***or***
    - Transoral gastroplasty (TG) (vertical sutured gastroplasty; endoluminal vertical gastroplasty; endoscopic sleeve gastroplasty); ***or***
    - Use of any endoscopic closure device (Over the Scope clip [OTSC] system set, Apollo OverStitch endoscopic suturing system, StomaphyX endoluminal fastener and delivery system) in conjunction with NOTES;
- Open adjustable gastric banding
- Prophylactic mesh placement for prevention of incisional hernia after open bariatric surgery
- Prophylactic pyloroplasty via botulinum toxin injection following laparoscopic sleeve gastrectomy
- Roux-en-Y gastric bypass as a treatment for gastroesophageal reflux in persons not meeting medical necessity criteria for obesity surgery
- Roux-en-Y gastrojejunostomy for the treatment of persistent gastro-esophageal reflux disease following antireflux surgery in persons not meeting medical necessity criteria for obesity surgery above
- Sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery
- Silastic ring vertical gastric bypass (Fobi pouch)
- Use of a coated stent for gastro-jejunal fistula following bariatric surgery
- Vagus nerve blocking (e.g., the VBLOC device, also known as the Maestro Implant or the Maestro Rechargeable System)
- VBG, except in limited circumstances noted above.
- Measurement of serum C-reactive protein as a predictor for complications following bariatric surgery because the effectiveness of this approach has not been established

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical UM Associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

N/A

12. DOCUMENT CONTROL

APPROVED BY:		
Charles,Brandon	3/25/2024	DocuSigned by: Charles,Brandon DE2813BF834C49A...
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

N/A