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Northwest Region Utilization Review

UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial Members

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POLICY AND CRITERIA

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR THE BARIATRIC SURGERY PREPARATION PROGRAM (NOTE: admission into the Program, also known as the Severe Obesity Program, is required prior to consideration of bariatric surgery) FOR COMMERCIAL LINES OF BUSINESS

CRITERIA

Patients will be eligible to participate in the preparation process and may be a candidate for bariatric surgery if:

1. Body Mass Index (BMI) is >35 Kg/m2 with one or more of the following serious co-morbid conditions at the time of initiation of physician-directed therapy for obesity and/or referral to the Severe Obesity Program:

    a. Sleep apnea requiring treatment with Continuous Positive Airway Pressure (CPAP) or inability to use CPAP with an Apnea/Hypopnea Index (AHI) >15 on sleep study *or* inability to use CPAP with an AHI >5 and documentation of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, hypertension, ischemic heart disease, or history of stroke;

    b. Congestive heart failure (CHF) or cardiomyopathy with a NW Permanente Cardiologist recommendation for bariatric surgery;

    c. Obesity hypoventilation and PC02 $\geq$45 and a NW Permanente Pulmonologist recommendation for bariatric surgery;

    d. Diabetes mellitus requiring medical therapy that includes insulin or an insulin sensitizing oral agent *i.e.* metformin or pioglitazone (or documented intolerance to insulin or insulin sensitizing oral agents) or >15 pound weight gain within 2 years of starting insulin therapy or endocrinologist recommendation for bariatric surgery;

    e. Severe hypertriglyceridemia (>1000 mg/dl) requiring medical therapy, which includes fibrate drugs and therapeutic doses of omega-3 fatty acid (6 grams daily), or a NW Permanente Endocrinologist recommendation for bariatric surgery;

    f. Hypertension with blood pressure >140/90 (130/80 in the presence of diabetes or renal disease) documented on two consecutive visits requiring the use of antihypertensive medications, including a diuretic, unless contraindicated;

    g. Extremity edema with ulceration documented by a NW Permanente Primary Care Provider;

h. Gastroesophageal reflux requiring prolonged medical management documented by a NW Permanente Physician;

i. Stress incontinence related to obesity and a NW Permanente Urologist or uro-gynecologist recommendation for bariatric surgery;

j. Pseudotumor cerebri documented by a NW Permanente Neurologist.

OR

2. BMI is ≥40 Kg/m2 with no co-morbid condition at the time of initiation of physician-directed therapy for obesity and/or referral to the Severe Obesity Program;

AND

3. Be ≥18 years old and general health adequate to tolerate surgery;

AND,

4. Members with a history of tobacco products* use must have a documented "quit" date ≥6 months prior to referral for consultation.

   *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

5. Have documentation in the medical record or referral that the member has been previously unsuccessful with medical treatment for obesity. The general expectation is bariatric surgery will not be done until a prior effort to lose weight is made as an adult. Programs attempted prior to adult years do not qualify.

   Practitioner documentation in the medical record of one of the following must occur:

   a. Minimum of 6-month participation (does not need to be continuous or uninterrupted for 6 months) in a recognized commercial behavioral weight management program. For example, 4 months with Weight Watchers and 2 months with Jenny Craig would meet criteria. The treatment program must include hypocaloric diet changes, nutrition education, physical activity, and behavior change strategies. Acceptable programs include but are not limited to: Weight Watchers or similar behavioral-based programs such as Medifast, Nutrisystem, and/or Jenny Craig. Non-commercial, book-based programs, such as Atkins and Dr. Phil, do not qualify.

   b. Minimum of 6-month participation in a Physician, Nurse Practitioner, Physician Assistant, Registered Dietician, or Licensed Behavioral Therapist supervised weight loss program, with or without obesity pharmacotherapy.

   c. Three or more primary care visits over a minimum of 6 months with weight management treatment and follow-up plan in the progress note.

   d. Participation in and completion of all sessions of Kaiser Permanente NW Health Engagement and Wellness Service weight management course.

NOTE: Currently, the bariatric surgical procedures offered are limited to laparoscopic Roux-en-Y Gastric Bypass (RNYGB) and laparoscopic sleeve gastrectomy. The type of surgical procedure performed is up to the clinical discretion of the surgeon.

Roux-en-Y Gastric Bypass (RYGBP) is a procedure that restricts the size of the stomach by stapling shut 90% of the lower stomach and bypassing the nearby intestine.

Laparoscopic Sleeve Gastrectomy is an irreversible surgical removal of a large portion of the stomach along the greater curvature in which the stomach is reduced to about 25% of its original size.

OTHER REQUIREMENTS

After the bariatric surgery referral, but prior to bariatric surgery, the member must complete **all** program requirements. Surgical clearance must be received.

OTHER CONSIDERATIONS

1. Surgical risk determinations: Individuals with BMI >60 and/or age >60 years are at higher surgical risk. Decisions regarding the appropriateness of surgery will be made individually based on rehabilitation potential and the physician and surgeon's judgment regarding surgical risk and likelihood of benefit.

2. Revisional bariatric surgery: Patients who have previously had bariatric surgery requesting re-operation for weight loss or severe reflux will be managed individually but will need to meet BMI and co-morbidity requirements. There is no evidence suggesting that performing more aggressive bariatric procedures is indicated for weight regain after procedures with both restrictive and malabsorptive components or impaired absorption of nutrients, such as roux-en-y gastric bypass.

3. Because the most common reason for surgical failure (weight regain) is inappropriate eating behaviors and lack of physical activity, patients will need to have their current behaviors carefully assessed and surgery will not be recommended unless current behaviors are conducive to post-operative success.

CONTRAINDICATIONS TO BE DETERMINED PRE-OPERATIVELY BY THE SURGEON

1. Current pregnancy or desire for pregnancy in the next 18 months
2. Alcohol or substance abuse within the last year
3. Nicotine use, including *tobacco products and nicotine replacement therapy (NRT) **products within 6 months prior to surgery

   *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

   **NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

4. Uncontrolled major psychiatric disorder. If you suspect the presence of uncontrolled depression, suicidal ideation, paranoid ideation, psychotic disorder, multiple personality disorder or active/untreated eating disorder i.e. bulimia, a NW Permanente Psychiatrist must be consulted pre-referral to ascertain control.

5. Endogenous reasons for obesity i.e. Cushing's disease

6. Clinical cirrhosis or advanced liver disease is a contraindication to bariatric surgery due to excessive operative mortality. Patients with hepatitis C or chronic active hepatitis B, prior jejunoileal bypass, or chronically abnormal liver tests of any cause should be evaluated with further testing including transaminase levels, tests of hepatic synthetic function (albumin and PT/INR), CBC, and abdominal ultrasound with doppler. If significant abnormalities are found (i.e., ascites, hepatofugal blood flow, splenomegaly, thrombocytopenia, albumin < 3, coagulopathy despite vitamin K replacement, referral to gastroenterology is recommended for further evaluation prior to consideration of bariatric surgery. Although fatty infiltration of the liver and NASH (non-alcoholic steatohepatitis) are the most common causes of abnormal transaminase levels in severely obese patients, persistently abnormal liver tests should have serologic evaluation for chronic viral hepatitis as well as other causes of transaminase elevation.
7. Other conditions that the primary care provider, bariatric surgeon, KPNW consultant, or Severe Obesity Team members feel would raise the risk of surgery to unacceptable levels.

SPECIAL GROUP CONSIDERATIONS

Commercial (UR10A): Applies to all commercial groups, including Federal, OEBB and PEBB members
Medicare: See UR 10B Medicare MNC for bariatric surgery
Washington Medicaid: Not covered
Oregon Medicaid: See UR 10C OHP MNC

NOTE

Patients requesting repeat bariatric procedures need to have their prior operative records obtained to define post-surgical anatomy. If this is not possible, an upper GI x-ray may be useful. If metabolic, renal, or hepatic complications are present from prior jejunoileal bypass, general surgery referral is recommended regardless of the BMI status to discuss revision of this operation unless clinical cirrhosis or other conditions are present that would increase operative risk to unacceptable levels.

Patients with mechanical complications stemming from previous bariatric surgeries (i.e. vomiting, obstruction) should be referred to general surgery or gastroenterology for further evaluation.

Patients with intact post bariatric surgical anatomy from previous procedures with both malabsorbtive and restrictive components will not be offered revisional operative procedures (ie stomal narrowing, band over bypass or pouch reductions) because of inadequate weight loss or weight regain. Those whose operative anatomy have broken down (ie gastric-gastric fistulae) will be considered for revisions as indicated by risk/benefit ratios.

RATIONALE

EVIDENCE BASIS

The KP National Guideline Program clinical practice guideline recommendations include a summary of the evidence relevant to selecting patients for bariatric surgery. Brief excerpts from that evidence summary are included here:

“Efficacy:

- Weight loss: In obese adults, bariatric surgery produces greater weight loss and maintenance of lost weight than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight.

- Weight loss at 2 to 3 years following a variety of surgical procedures in adults with presurgical BMI ≥30 varies from a mean of 20% to 35% of initial weight and a mean difference from nonsurgical comparators of 14% to 37% depending on procedure. (SOE: High)
- Mean weight loss at 10 years following a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) is approximately 16% of initial weight, representing a mean weight regain of 7%. (SOE: Low)

- Comorbidities: In obese adults, bariatric surgery generally results in more favorable impact on obesity-related comorbid conditions than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss.
  - Glycemic control
    - At 2 to 3 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve a mean weight loss of 20% to 35%, there is a ↓in FPG, insulin and incidence of T2DM and there is a greater likelihood of diabetes remission among those with T2DM at baseline. Remission was defined variously depending on the study. (SOE: high)
    - At 10 years, incidence and prevalence of T2DM are lower in those who have undergone surgery. However, among those in whom T2DM remits after surgery, diabetes may recur over time. (SOE: low)
  - Blood pressure control
    - At 2 to 3 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, blood pressure or use of blood pressure medication is reduced compared with nonsurgical management. Blood pressure tends to increase over time, and at 10 years post-surgery, there is no difference in mean SBP or the incidence of new cases of hypertension in those who underwent bariatric surgery compared to those who did not undergo surgery. (SOE: low)
    - Among obese adults with baseline hypertension, a greater percentage is in remission at 2 to 3 years and 10 years following bariatric surgery compared with nonsurgical management. (SOE: low)
  - Cholesterol and lipid control
    - At 2 to 3 years and 10 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, serum TG levels are lower, HDL-C levels are higher, TC-to-HDL-C ratio is lower, and changes in TC or LDL-C levels are inconsistent compared with nonsurgical management. (SOE: low)
  - Quality of life
    - Most measures of health-related quality of life (HRQOL) are improved at 2 and 10 years following bariatric surgery. (SOE: moderate)
  - Total mortality
    - Total mortality is decreased compared with nonsurgical management at mean follow-up of 11 years after undergoing a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) in patients with mean BMI >40 who achieve a mean long-term weight loss of 16% (SOE: low)
  - CVD risk
    - There are insufficient data on the efficacy of bariatric surgical procedures for weight loss and maintenance or CVD risk factors 2 or more years post-surgery in patients with a BMI <35.

Complications:
Perioperative (≤30 days) and longer term (>30 days) complications following bariatric surgery vary by procedure and patient-derived risk factors.

- Roux-en-Y Gastric Bypass.
    - When performed by an experienced surgeon, perioperative complications following laparoscopic gastric bypass:
        - Consist of a major adverse outcome in approximately 4% to 5%, including mortality (0.2%), DVT and/or pulmonary embolism (PE) (0.4%), and a requirement for reoperation (3% to 5%). Rates of any complication, major or minor, range from 2% to 18%. (SOE: moderate)
        - Are less frequent for the laparoscopic approach than for open incision. (SOE: moderate)
        - When performed by an experienced surgeon, perioperative complications following open gastric bypass:
            - Consist of a major adverse outcome in approximately 8%, including mortality (2%), DVT/PE (1%), and reoperation (5%). (SOE: low)
        - When performed by an experienced surgeon, perioperative complications following gastric bypass (laparoscopic or open):
            - Are associated with extremely high BMI, inability to walk 200 feet, history of DVT/PE, and history of obstructive sleep apnea. (SOE: low)
- Laparoscopic Sleeve Gastrectomy
    - There is insufficient evidence to establish the incidence of perioperative and longer-term complications."

REFERENCES

1. CMS NCD 100.1 *Bariatric Surgery for Treatment of Morbid Obesity*
2. Maggard MA, Shugarman LR, Suttorp M, et al. Meta-analysis: surgical treatment of obesity. Ann Intern Med 2005;142:547-559
3. Milliman Care Guidelines On-line: http://www.careguidelines.com
4. NIH consensus conference document: http://consensus.nih.gov/1991/1991GISurgeryObesity084html.htm
5. Sjostrom L, Lindroos AK, Peltonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. N Engl J Med 2004;351:2683-2693
6. KP National Guideline Committee. (2022) Management of Overweight and Obesity in Adults Clinical Practice Recommendations. Available at: https://cl.kp.org/natl/cmi/programs/weight_mgmt/guideline/index.html