RELEVANCE:
The CPG for Bariatric Surgery has been developed by a multidisciplinary team, who has both experience with, and an interest in the treatment of the morbidly obese patient. Recently there has been an explosion of information regarding the high incidence and near epidemic proportions of Morbid Obesity and associated comorbidities and their relationship to morbidity, mortality and health care spending. Evidence supports Roux en Y gastric bypass (RYGB) and laparoscopic Roux en Y Gastric Bypass (LRYGB) procedures as permanent measures that may be appropriate for a select subset of the obese population. These procedures have a long record of outcomes including weight loss, resolution of comorbidities and short and long term complications. Recent evidence support laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG) as alternative procedures. The evidence is not as long term. The weight loss and resolution of comorbidities occur more slowly and to a lesser degree than either RYGB or LRYGB with LAGB although literature reported morbidity and mortality are lower, however. LSG has weight loss and comorbidity resolution similar to LRYGB, and superior to LAGB. The complication rates of LSG are similar to LAGB and higher than LAGB. The LAGB requires more frequent follow-up for potential adjustments, and is reversible. Studies have shown survival advantage for patients who undergo bariatric surgery and that the overall complication rates of bariatric surgeries performed at centers of excellence are similar to those seen in less complicated abdominal surgeries. By standardizing the teaching, screening and selection process we expect to decrease patient and provider confusion and maximize compliance with life changes required for post-op success. We expect decreased costs to the system as a whole initially, by internalizing the procedure as well as specialty consults. Long term we would expect to decrease morbidity by improving comorbid conditions such as hypertension, diabetes, hyperlipidemia and sleep apnea with a corresponding decrease in the number of pharmaceutical and durable medical equipment needed. We also expect increase in patient’s quality and duration of life as a result of improvement in comorbid conditions associated with obesity.

ENTRY CRITERIA:

A. Weight Loss Attempts:
Previous failed attempts at weight loss will need to be documented. Patients are expected to lose up to 5% of their body weight from the time that they enroll in the program until surgery is performed. Exceptions may be made on an individual case by case basis.

B. BMI Criteria:
Patients with a BMI at time of entry into the program of at least 40 require no comorbidities. Patients with a BMI under 35 are excluded. Patients with a BMI at time of entry into the program of greater than 35 but less than 40 must have at least one of the comorbidities listed below.

C. Approved Comorbidities:

• Diabetes
• Hypertension

• Hyperlipidemia

• Obstructive Sleep Apnea with use of a CPAP mask for at least 2 months before surgery

D. Age:

• Patients must be at least 18 years of age.

EXCLUSION CRITERIA:

A. Psychiatric Disorders
Patients with major psychiatric disorders that limit their ability to achieve the life style changes necessary for success are excluded.

B. Other (contraindications)
Patients who are pregnant or desire pregnancy within two years of starting the program are excluded. Patients with a projected life expectancy from conditions not expected to be improved by the surgery (i.e. malignancy) of less than 3 years are excluded. Documentation must be provided by the provider caring for this condition in this patient. Cigarette smoking must be stopped for at least 3 months prior to surgery. Exogenous estrogen must be stopped for at least 3 months prior to surgery. Tight glycemic control with an HgA1c less than 7.5 is desired. Other conditions that present prohibitive risks for surgery shall be evaluated on an individual basis.

C. BMI Upper Limits of Eligibility
All patients are evaluated individually based upon comorbidities and risks. Patients weighing more than the safe weight limits of the hospital beds and imaging systems (currently 450 lbs) will be considered for referral to a tertiary care center on an individual basis.

D. Physical Activity
Patients with poor potential for physical rehabilitation are excluded. An example would be a patient with end stage pulmonary hypertension with cardiomyopathy.

E. History of Bariatric Surgery
Failed weight loss or weight regain are not indications for secondary (revisional) Bariatric Surgery. There is insufficient evidence to show that additional surgery in these cases is of benefit. These patients are best managed by Behavioral Health and Nutritional Services. A small subset of patients will have surgical complications (staple line disruptions with fistula formation, band slippage, etc.) that warrant surgical intervention. All patients considering secondary Bariatric Surgical procedures will be evaluated to determine the presence of any surgical complications.

PRE-APPROVAL ASSESSMENT AND MANAGEMENT PROGRAMS

A. Multidisciplinary Team
A multidisciplinary team consisting of, but not limited to, the RN Case Manager, Bariatric Surgeons, representatives from Nutrition Services, Behavioral Health, Internal Medicine, and Wound Care shall meet at least once each month. Their function is to review patients prior to surgical consultation, and share concerns that each discipline may have concerning the patient. In addition, issues concerning post-operative patients may also be discussed as needed. They will also review issues concerning the Bariatric Surgery program as they arise, and share educational information concerning Bariatric Surgery and Obesity related issues.

B. Orientation
When a patient is referred to the program, they will receive an orientation concerning the structure of the program by the RN Case Manager. All patients have the option of attending preoperative orientation programs sponsored at Parma Community General Hospital. At the discretion of the RN Case Manager, individual cases will be presented to the Bariatric Surgeon prior to entry into the program in order to insure that they are suitable candidates.

C. Nutrition Assessment
All patients must be involved with the nutrition program for at least 6 visits over at least a 6 month period of time to include assessment of nutritional status, nutritional knowledge, eating patterns and readiness to make behavioral change. They must demonstrate understanding of the dietary changes required for weight loss after surgery.

D. Medical Evaluation
All patients shall have a history and physical performed by their primary care physician with special attention paid to screening for comorbidities and making appropriate specialty referrals. A baseline set of blood work will also be ordered, including CBC, CMP, lipid panel, TSH, and PTH. HgA1c and EKG will be ordered when indicated. Referral into the Bariatric program must be made by the primary care physician.

E. Mental Health Intake Appointment
An Intake assessment is scheduled in BHS after at least 2 visits with the dietitian are completed, unless referred sooner by the bariatric surgery team.

F. Mental Health Intake Assessment
At least 1-2 BHS visits for completion of the assessment which includes:

a. Completing the requirements of a routine Intake assessment with a particular focus on issues related to food and weight management to identify:

i. any major psychiatric disorders that would render surgery contraindicated (i.e. anorexia, bulimia, psychosis, substance abuse, borderline personality disorder),

ii. disorders that require further psychiatric intervention (i.e. major depression, panic disorder), or

iii. Issues that potentially could interfere with a successful surgical outcome (i.e. emotional eating/primarily using food to cope).
b. Assessment of the following areas to determine realistic expectations of the surgery and motivation/readiness for behavioral change:

   i. weight loss history and outcomes,
   ii. impact of obesity on lifestyle and relationships,
   iii. level of knowledge about the surgery,
   iv. reasons for seeking the surgery and expected outcomes including potential barriers to success,
   v. The role of food in their life and their planned substitute post operatively.

c. Identifying evidence of an ability to comply and commit to post operative diet and lifestyle changes i.e., history of follow through and compliance in other life areas such as dietitian visits, diabetes/HTN regime, medical visits etc.

d. An evaluation of the social system to identify the availability of resources to support the patient before and immediately after surgery, and over the post operative course.

e. Communication and collaboration with the bariatric surgery team, especially the dietitian, pre- and postoperatively as necessary, to validate data, determine recommendations, and develop a multidisciplinary treatment plan as indicated.

G. Mental Health Follow-Up
Further follow-up is recommended to the patient if, based on the assessment:

   a. there is significant question related to the appropriateness for surgery and further assessment is needed, or
   b. There are issues identified that if addressed pre-operatively could contribute to a positive post-op outcome.

Should there be a question by the bariatric surgery team regarding the patient’s psychiatric appropriateness for surgery, the team can refer the patient for a 2nd opinion in BHS or consult with a psychologist regarding psychological testing. At the time the surgery date is set, a follow-up visit approximately one month post op is scheduled by the patient to evaluate the post operative adjustment as well as the need for additional psychiatric intervention to maximize surgical success and patient satisfaction.

H. Support Group
A support group for post-operative patients will meet on a regular basis. There will also be group meetings during the pre-operative period with participation by nutrition, BHS, surgery and other specialties as needed.

I. Prevention Screening
Prevention screening for obesity will be a part of well person care throughout the region.

J. Weight Loss
All patients must demonstrate up to 5% weight loss from time of entry into the dietary program until surgery in order to be considered for surgery.

K. Physical Activity
An individualized physical activity plan shall be part of the pre-operative and post-operative care of the patient.

L. Specialty Consultations
Specialty consultations will be obtained based upon the recommendations of the PCP, anesthesiologist or surgeon.

M. Pharmacy Review
Review of medications to ensure that appropriate forms of medications with appropriate doses for a patient with a small stomach size post-op.

N. Laboratory Review
In addition to screening tests for metabolic and nutritional disorders that are a part of the initial medical evaluation and routine preadmission testing lab tests, CBC, BMP, Ferritin, FIBC, B12, 25-OH Vitamin D, Thiamine, red cell folate, and prealbumin shall be ordered at 3, 6, 9, 12, 18, and 24 months post-surgery, and annually thereafter for all patients who have had Bariatric surgery.

FORMAL APPROVAL PROCESS:
Upon successful completion of all evaluations, including the recommendations of the multidisciplinary team, a decision concerning the surgical treatment of the patient will be made by the OPMG Bariatric Surgeon. Patients will also be presented to the multidisciplinary team if they have shown little or no progress after 6 nutritional visits. The team will discuss the case and make a determination regarding the subsequent disposition of the patient. Options include (but are not limited to) referral to the OPMG Bariatric Surgeon, referral to Behavioral Health or changing the nutritionist assigned to the patient. If the recommendation requires an external referral, one will be generated by the OPMG Bariatric Surgeon and reviewed by the OPMG Chief of Surgery and the Medical Management Department. If it is denied, the patient has the right to appeal the decision.

SURGERY:
Open Roux en Y Gastric Bypass (RYGP), laparoscopic Roux en Y Gastric Bypass (LRYGP), Laparoscopic Sleeve Gastrectomy (LSG), and Laparoscopic Adjustable Gastric Bands (LAGB) are the standard procedures that will be performed as primary procedures. The decision concerning which procedure shall be performed will be part of a shared educational discussion involving the patient and surgeon. Patients who satisfy criteria but cannot be handled by our program will be referred to a tertiary center on an individual basis upon the recommendation of the OPMG Bariatric Surgeons and Medical Management.

PERI-OPERATIVE CARE:
All procedures are performed at an accredited Bariatric Surgery Center of Excellence, Parma Community General Hospital (PCGH) by an accredited surgeon. All inpatient and outpatient cases are monitored for length of stay and readmission rates. LAGB may be considered as an outpatient
procedure at the discretion of the operating surgeon based upon quality outcomes. All LAGB patients will have a contrast upper GI series in the immediate postoperative period to document appropriate band placement.

**POST-OPERATIVE CARE:**
Post-operative care shall be provided by the operating surgeon at 10 days, 6 weeks, 3, 6, 9, 12, and 18 months after RYGB, LSG, LRYGB and LAGB. They shall be seen by their PCP within the first month after surgery, as needed in the first two years after surgery, and annually thereafter. For Laparoscopic Adjustable Gastric Bands, the first band fill will occur at the six week visit, and the second at the three month visit. Subsequent fills will be based upon patient symptoms and weight loss, and patients will be seen on an as needed basis by the operating surgeon at any time between the scheduled visits for adjustments based upon symptoms.

There is a Bariatric Surgeon on-call list, managed by physician scheduling, available for all providers to use as needed when urgent or emergent consultation is considered.

At the 6 week post op visit with the surgeon patients are screened for depression using a standardized depression screening tool. If depressed, the patient is referred back to BHS for further evaluation and follow-up. BHS will outreach the patient by telephone to schedule a follow-up appointment.

Nutrition care post operatively will include a telephone follow-up at 10 days post op and office visits at 1, 3, 6, 9, 12, 18 and 24 months then yearly thereafter. Patients will also be encouraged to attend a Kaiser or non-Kaiser support group on a regular basis.

**OUTCOMES:**
Quarterly, the patients screened for depression at the 6 week post op visit and determined to be depressed will be monitored for referral and follow-up in BHS. Outcome data on all patients are being recorded and will be analyzed on at least an annual basis. Patient outcome data will also be entered into the National BOLD Database in order to maintain Center of Excellence status.

**REFERENCES:**
Bariatric Surgery for Morbid Obesity (including LASGB-Gastric Banding); Assessment of Kaiser Permanente Interregional New Technologies Committee, November 14, 2005.
Bariatric Surgery Reduces Obesity-related Disease; Evidence-Based Healthcare & Public Health (2005) 9, 255–256