IEHP UM Subcommittee Approved Authorization Guidelines

Bariatric Surgery for Morbid Obesity

According to the National Institutes of Health (NIH) Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity, the risk for morbidity and mortality accompanying obesity increases with the degree of overweight. Thus, treatment of clinically severe obesity involves an effort to create a caloric deficit sufficient to result in weight loss and reduction of weight-associated risk factors or co-morbidities. Compared to other interventions available, surgery has produced the longest period of sustained weight loss. Determination of both perioperative risk and long-term complications is important and requires assessing the risk/benefit ratio in each case. Patients whose BMI exceeds 40 kg/m2 are potential candidates for surgery if they strongly desire substantial weight loss, because obesity severely impairs the quality of their lives. Less severe obese patients (BMIs of 36-40 kg/m2) also may be considered for surgery. This group primarily includes those patients with high-risk co-morbid conditions (cardiovascular, sleep apnea, uncontrolled type 2 diabetes) or weight-induced physical problems interfering with performance of daily life activities.

Patients opting for surgical intervention should be followed by a multidisciplinary team (medical, behavioral and nutritional). As for all other interventions for obesity, an integrated program should be in place that will provide guidance concerning the necessary dietary regimen, appropriate physical activity, and behavioral and social support both prior to and after the surgical procedure. The Swedish Obesity Study identifies that even though there may be reduction or resolution of symptoms with diet and exercise, surgery has the longest and best long term outcome for morbidly obese.

Selection Criteria for Bariatric Surgical Procedure(s)

Persistent Morbid Obesity, unresponsive to conservative medical management:

Prospective surgical candidates must:

A. Be overweight according to body habitus, age, sex, and height, and have a BMI greater than 40; or a BMI of 36-40 in conjunction with severe co-morbidities such as:

1. Cardiovascular disease
2. Sleep apnea
3. Uncontrolled type 2 diabetes
4. Hypertension
B. Be able to document the presence of severe obesity that has persisted for at least 5 years, and failed conservative medical management in the form of:

1. A structured, physician-supervised weight loss program, (Lite Weighs type-program), for a minimum of 6 consecutive months within the past two years prior to the request for surgery, or
2. A combination of a physician-supervised weight loss, (Lite Weighs type-program), and exercise program for a minimum of 6 consecutive months within the past two years prior to the request for surgery;
3. MD supervision should be at a minimum, one visit per month.
4. All physician supervised weight loss visits must be completed before Member will be allowed to consult with a surgeon.

C. Demonstrate no evidence of GI pathology, liver, renal disease or other contraindications to the proposed surgery;

D. Provide an attestation, signed by Member and Surgeon, showing that the Member has attended a pre-operative education course covering risks, nutrition, exercise and lifestyle changes;

E. Document their agreement to cooperate with extensive post-operative follow-up plans for medical management by a multi-disciplinary team, including the surgeon, their primary care provider, and a psychologist and/or psychiatrist;

F. Be age 18-64 years;

G. Be documented as free of alcohol and drug dependence;

H. Once all physician supervised weight loss visits are completed the Member must have a documented pre-operative psychological evaluation, performed by a psychologist and/or psychiatrist who is independent of the surgeon. Please submit this request to the UM department at IEHP. The evaluation should include the following:

1. Psychiatric/psychological history
2. Mental status exam
3. Clinical findings from the interview with the Member
4. Psychiatric diagnostic co-morbidities
5. Recommendations regarding Member’s capability of complying with post-surgical behavioral changes in terms of eating, medical follow-up, etc
6. Recommendations regarding the appropriateness of bariatric surgery

I. Demonstrate the psychological capacity to understand the procedure, its long-term complications and its attendant risks, including the possibility of death; and
J. Be motivated to undergo the procedure and have demonstrated full compliance with medical recommendations to include at least one pre-operative psychiatric evaluation.

Note:
A. Super-obese candidates (BMI > 50) often require a modified pre-operative program, including:
   1. Consideration for early surgical intervention by reducing the provider-supervised weight loss program requirement to 3 consecutive months within a 2-year timeframe
   2. MD supervision should be at a minimum, one visit per month

B. Approved procedures include:

**Laparoscopic Adjustable Gastric Banding (LAGB):**

Laparoscopic adjustable gastric banding involves placing a gastric band around the exterior of the stomach. A thin flexible tube attaches the band to a reservoir that is implanted subcutaneously in the rectus sheath so that the band can be adjusted without further surgery. The size of the stomach can be progressively reduced to induce greater weight loss, or expanded if complications such as vomiting develop. Because the stomach is never entered, the surgery and any revision, if necessary, are proposed to be safer than conventional surgical treatments. Additional proposed advantages include reversibility of the procedure and maintenance of gastrointestinal anatomic integrity. However, serious complications may include slippage of the external band or band erosion through the stomach wall. Furthermore, incorrect positioning of the band may result in vomiting as well as ineffective weight loss. Recent improvements in surgical technique have decreased the incidence of such complications in some series, based on preliminary results, with erosions becoming rare and slippage (necessitating re-operation) occurring in about 2–5% of surgeries. Mortality is also generally less than other bariatric surgery procedures, amounting to about 1 in 1,000 to 1 in 2,000 procedures. Currently there is only one device approved by the FDA (in June, 2001) for marketing in the United States, called Lap-Band® (Inamed Health, formerly BioEnterics®).

**Gastric bypass (Roux-en Y):**

The most commonly performed restrictive approach is the Roux Y gastric bypass, which combines gastric restrictive and malabsorptive features. It involves a horizontal or vertical partitioning of the stomach, which results in a 90% restriction. It is followed by a Roux Y procedure in which the small intestine is reconfigured into a Y consisting of two limbs and a common channel. The proximal small bowel remains attached to the stomach and duodenum below the gastric division or partition. This limb is called the pancreatico-biliary conduit (or limb) and it drains bile, digestive enzymes, and gastric secretions. Other limb, sometimes called the Roux limb, is attached to and drains the small proximal gastric pouch, and so carries only food. The Y is created at the point where the pancreatico-biliary conduit and the Roux limb are connected. At this point the digestive
juices and food mix and go on together, passing through the remaining arm of the Y, known as the common channel. Gastric bypass not only prevents the ability to ingest larger volumes at any one meal, but also induces a “dumping syndrome” if the patient ingests too much food or a high-sugar liquid meal. This unpleasant "dumping syndrome" occurs when a large amount of partially digested food is delivered directly to part of the small intestine from the stomach and can cause nausea, weakness, sweating, faintness, abdominal pain and vomiting. The dumping syndrome may further reduce intake particularly among "sweet eaters." Surgical complications include leakage and stomal stricture. Since a major portion of digestion occurs in the stomach – specifically the process of breaking down food into nutrients – the amount of nutrients available for absorption is also reduced. As a result, this procedure requires that individuals take vitamin and mineral supplements. Gastric bypass may be performed using an open or laparoscopic approach.

**Laparoscopic or Open Sleeve Gastrectomy (SG):**

Sleeve Gastrectomy is also known as partial or vertical gastrectomy; it is a restrictive procedure that is now being proposed as a definitive procedure for morbid obesity. The surgery can be an open or laparoscopic procedure and involves the resection of the greater curvature of the stomach with the remainder resembling a tube or sleeve. The resulting decrease in stomach size inhibits distention of the stomach so that early satiety is achieved. Preservation of the pyloric sphincter prevents the dumping syndrome. Other advantages of this procedure include the lack of intestinal anastomosis and no implantation of a foreign body. Major complications associated with SG include staple-line leak and postoperative hemorrhage.

**Repeat or Revision of Previous Gastric Restrictive Surgery:**

Repeat bariatric or revision of a previous bariatric restrictive surgery is medically necessary for members whose initial bariatric surgery was medically necessary (i.e., who met medical necessity criteria for their initial bariatric surgery), and who meet the following medical necessity criteria:

1. The primary bariatric surgery failed due to dilation of the gastric pouch documented on either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD) and the primary procedure was successful in inducing weight loss prior to the pouch dilation. There must be documentation that the member has been enrolled in and compliant with a prescribed nutrition and exercise program following the procedure; or

2. Replacement of an adjustable band due to complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments.

**Elective Cholecystectomy in Conjunction with Bariatric Surgery:**

Elective cholecystectomy in conjunction with surgery for morbid obesity is covered as a preventive measure due to the high incidence (-28%) of gall bladder disease that occurs over time subsequent to these surgical procedures.
Contraindications:

1. Patients with unacceptable operative risk.
2. Active substance abuse and psychiatric disorders (e.g., schizophrenia, borderline personality disorder, active suicidal ideation, or uncontrolled depression).
3. Pre-operative psychological evaluation that determines if the patient is not a suitable candidate for surgery.
4. Desire for pregnancy within near future after gastric bypass.

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Revised:

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Bibliography:

14. IEHP Independent Medical Review, Case Studies and Analysis. 2005
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PRE-OP GASTRIC BYPASS ATTESTATION

INITIALS

__________  I attended a New Patient Education Class.

__________  My doctor explained to me the risks and benefits of Gastric Bypass surgery. I understand these risks and benefits.

__________  My doctor explained to me what can go wrong during the surgery and afterwards. I understand these risks.

__________  I have been counseled how to eat, how to use nutritional supplements after surgery and what my nutritional requirements are.

__________  I have been instructed how to exercise before and after surgery. I understand these instructions and what is expected of me.

__________  I have been instructed how to make lifestyle changes that will help make the surgery more successful. The lifestyle changes that I expect include:

  ▪ Relationships
  ▪ Social support systems
  ▪ Coping with stress
  ▪ Relapse prevention
  ▪ Positive thinking techniques
  ▪ Problem solving techniques

I have received a psychosocial assessment, which included specific evaluation of my clear understanding of the risks and benefits of surgery, an evaluation of my post-surgical expectations, and an evaluation of my ability to follow my post-operative routine.

__________  I understand the lifestyle changes I must make. I understand how I must behave. I will comply fully and take full responsibility for my behaviors and choices.

Print Patient’s Name

__________________________
Signature of Patient or Guardian

__________________________  Date