

Illinois Department of Healthcare and Family Services Bariatric Surgery Criteria

Program Rationale

Obesity in the United States is increasing affecting 30-36% of the adult population and 17% of youth. [1,2] Obesity increases with advancing age for both sexes in the United States. [1] Racial and ethnic differences are more strongly seen in women than in men. [2,3] Among non-Hispanic black and Mexican-American men, those with higher incomes are more likely to be obese than those with low incomes. On the other hand higher income women are less likely to be obese than low income women. Among men there is no significant relationship between obesity and education. The converse is true for women in that those with college degrees are less likely to be obese compared to less educated women. Obesity overall is increasing at all income and education levels. The incidence of type 2 diabetes mellitus is increasing in the United States. Among new cases of diabetes 81% are obese (BMI>30) and 49% have class II or III obesity (BMI>35). [4] Obesity related conditions such as stroke, heart disease, type 2 diabetes, and certain types of cancer (esophagus, breast -postmenopausal, endometrium, colon and rectum, kidney, pancreas, thyroid, and gallbladder) contribute to the estimated annual medical cost of treatment of obesity in the United States in 2008 of \$147 billion. [3,5]

Initial requirements for preoperative evaluation and management including:

- 1. Six consecutive months of participation in a medically supervised weight loss program within the setting of a pre-surgical multidisciplinary evaluation must be completed within one year before the prior approval request for the bariatric surgery. There is a demonstration of participant responsibility. [6] Patients must demonstrate motivation to comply with proposed post operative treatment, dietary modifications, and participation in long-term follow-up.
- Documentation of nutritional assessment and counseling at each visit with at least one visit with a registered dietitian or nutritionist. Dietary history, eating disorder, pre-surgical caloric reduction, dietary behavior modification, and lifelong need for dietary changes must be completed. An opinion for candidacy for the proposed procedure must be offered.
- 3. Psychosocial-behavioral evaluation must be completed within 12 months of prior approval request by a licensed psychologist, psychiatrist, clinical social worker, and/or advanced practice nurse in collaboration with co-signing psychiatrist. This evaluation must include:
 - mental health history, diagnoses, and current treatments/status

- eating behaviors
- substance abuse evaluation
- stress management
- cognitive abilities
- social functioning including support system
- self esteem and personality factors
- readiness to change and adhere to lifestyle modifications
- opinion must be offered regarding the patient's candidacy for the proposed procedure
- commitment not to become pregnant before surgery and within 18 months following surgery
- 4. Comprehensive medical history and physical examination within 6 months of prior approval request that documents:
 - Previous attempts to lose weight with results over the past 2 years;
 - Elaboration of comorbidities and interventions:
 - Previous noncompliance with medical treatments;
 - Medication list;
 - Blood pressure using appropriately sized cuff, height, and weight;
 - Appropriate laboratory testing to identify underlying potentially treatable conditions such as an endocrine disorder including at a minimum thyroid function panel along with thyroid stimulating hormone;
 - Negative pregnancy test before surgery;
 - Opinion must be offered regarding the patient's candidacy for the proposed procedure.
- 5. The medical record must clearly indicate that any comorbidity is not a contraindication for the proposed surgery.
- 6. Education regarding risks and benefits of bariatric surgery and procedural options. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient's lack of proficiency in the English language, an interpreter is required.
- 7. Optimization of glycemic control.
- 8. Treatment of dyslipidemia.
- 9. Discontinuing estrogen therapy, if applicable.
- 10. Cardiology consultation and beta-adrenergic blockade, if indicated.
- 11. Preoperative weight loss should be considered in patients whom reduction of liver volume is expected to improve the technical aspects of surgery.
- 12. Chest radiograph anterior posterior and lateral.

- 13. Pulmonary evaluation, including arterial blood gas measurement and polysomnography, if indicated.
- 14. Smoking cessation; addiction to alcohol and drugs must be addressed.
- 15. Diagnostic evaluation for deep venous thrombosis and vena cava filter, if indicated.
- 16. Abdominal ultrasonography and viral hepatitis screen.
- 17. Institution of CPAP or BiPAP as indicated for obstructive sleep apnea (OSA), obesity-hypoventilation syndrome (OHS), or Pickwickian syndrome. [7]

Age Specific Requirements

- Adults (18 years of age and older) with body mass index (BMI) of 40 or greater must meet initial requirements
- Adults with BMI 35-39.9 who meet the initial requirements must have one or more of the following severe comorbidities related to obesity:

1. Cardiovascular problems

- Coronary artery disease documented by stress testing, previous need for angioplasty, or coronary bypass.
- Peripheral arterial disease documented by arteriography or Doppler ultrasound of brachial and ankle pressures before and after exercise.
- · Cardiomyopathy documented by echocardiogram or MRI.
- Pulmonary hypertension by echocardiogram.
- Carotid artery disease documented by ultrasound with greater than 70% blockage at least unilaterally.
- Aortic disease documented by CT or MRI.
- Severe valvular disease documented by echocardiogram.
- Medically refractory hypertension defined as a systolic pressure greater than or equal to 140 and/or a diastolic greater than or equal to 90 obtained by appropriately sized cuff despite treatment with at least 2 antihypertensive medications at maximum tolerable dosages.

2. Respiratory problems

- OSA of at least moderate severity documented by sleep study.
- OHS documented by sleep study.
- Pickwickian syndrome (combination of OSA and OHS) documented by sleep study.
- Respiratory insufficiency, such as

- hypercapnia as evidenced by pCO2 greater than 50 mm Hg by arterial blood gas;
- hypoxemia at rest as evidenced by pO2 less than or equal to 55 mmHg on room air by arterial blood gas;
- FEV1/FVC less than 65%;
- DLCO less than 60% of predicted normal;
- 3. Nonalcoholic fatty liver disease (NAFLD) / nonalcoholic steatohepatitis (NASH) with submission of liver function panel.
- 4. Dyslipidemia as defined by hypercholesterolemia greater than 240 mg/dl, hypertriglyceridemia greater than 400 mg/dl, low density lipoprotein greater than 160 mg/dl, or high density lipoprotein less than 40 mg/dl despite therapy with at least one lipid lowering agent at maximum dosage.
- 5. Pseudotumor cerebri.
- 6. Gastroesophageal reflux (GERD).
- 7. Asthma with severity at least of mild persistent.
- 8. Lower extremity venous/lymphatic obstructive stasis disease.
- 9. Severe urinary incontinence.
- 10. Degenerative osteoarthritis documented radiographically in any weight bearing joint or lumbosacral spine affecting performance of activities of daily living.
- 11. Uncontrolled type 2 diabetes mellitus.
- 12. Metabolic syndrome.

Adolescence – must satisfy all of the following [8]

- 1. Meet initial requirements
- 2. Must be at least 15 years old and females must be menstruating
- 3. Must have reached Tanner stage IV plus 95% of projected adult height based upon bone age obtained by wrist radiograph
- 4. BMI of 40 or more with at least one of the comorbidities identified above for adults with BMI's between 35-39.9
- Inclusion of a statement detailing at least one custodial parent or legal guardian's commitment to support and facilitate the adolescent patient's loss of weight, willingness to support, and facilitate permanent life style changes.

Revisions/repeat bariatric surgery

1. Revisions are necessary when there is documentation of a failure or secondary to a surgical complication including but not limited to one of the following: fistula formation, obstruction, stricture, esophagitis unresponsive to nonsurgical treatment, disruption/leakage due to failure of a suture or staple line, band herniation, hemorrhage, hematoma formation, excessive bilious vomiting, stomal dilatation documented by endoscopy, or weight loss of 20% or more below the ideal body weight.

- 2. Revision surgery for replacement of an adjustable gastric band will be deemed necessary due to complications such as slippage or port leakage not remediable with band manipulation or adjustments.
- 3. Revision bariatric surgery is warranted with gastric pouch dilatation, dilatation of the gastrojejunal stoma, or dilatation of gastrojejunostomy anastomosis documented by upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD) producing a weight gain of 20% or more above the stable nadir with the following documentation:
 - Original surgery successfully induced weight loss prior to the pouch dilatation as documented by submission of BMI prior to surgery, BMI at lowest stable nadir, and most recent BMI
 - Pouch dilatation is due to a technical failure or vomiting and not due to stretching from overeating
 - The patient has been compliant with the prescribed nutrition and exercise program per surgeon's statement and as evidenced by submission of post operative follow-up records
- 4. Repeat procedures for revision or conversion to another surgical procedure is considered medically necessary when there is documentation of inadequate weight loss unrelated to a prior surgical complication when all of the following applies:
 - patient continues to meet the initial requirements
 - at least 2 years have lapsed since the original bariatric surgery with weight loss that is less than 50% of the pre-operative excess body weight and weight remains at least 30% over ideal body weight referencing standard tables for adult weight and height by the National Heart, Lung, and Blood Institute [9] or for adolescents by age and sex through growth charts for stature and weight percentiles, BMI index percentiles, and data tables of weight at the Centers For Disease Control and Prevention [10]
 - the patient has been compliant with the prescribed nutrition and exercise program per surgeon's statement and as evidenced by submission of post operative follow-up records

Footnotes:

- 1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity in the United States 2009-2010. NCHS Data Brief. 2012;82:1-8.
- Ogden CL, Carroll MD, McDowell MA, Flegal KM. Obesity among adults in the United States – no statistically significant change since 2003-2004. NCHS Data Brief. 2007;1:1-8.

- 3. Centers for Disease Control and Prevention. Obesity and Overweight for Professionals: Data and Statistics: Adult Obesity. Available at http://www.cdc.gov/obesity/data/adult.html. Last accessed 3-19-14.
- Gregg EW, Cheng YJ, Narayan KM, Thompson TJ, Williamson DF. The relative contributions of different levels of overweight and obesity to the increased prevalence of diabetes in the United States: 1976–2004. *Prev Med*. 2007;45(5):348-352.
- National Cancer Institute at the National Institutes of Health. National Cancer Institute Fact Sheet: Obesity and Cancer Risk. Available at http://www.cancer.gov/cancertopics/factsheet/Risk/obesity. Last accessed 3-18-14.
- 6. SMART Act (SB 2840)
- 7. U.S. Department of Health and Human Services. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery Medical Guidelines For Clinical Practice For the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient. Available at http://www.guideline.gov/content.aspx?id=47785.
- 8. Michalsky M, Reichard K, Inge T, Pratt J, Lenders C. American Society for Metabolic and Bariatric Surgery Pediatric Committee Best Practice Guidelines. Surgery for Obesity and Related Diseases xx (2011) xx accepted 9-16-11.
- 9. Body mass index table. National Heart, Lung, and Blood Institute. Available at http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm . Last accessed 3-27-14.
- 10. Growth charts for stature and weight percentiles, BMI index percentiles, and data tables of weight for age and sex. Centers For Disease Control and Prevention. Available at

http://www.cdc.gov/growthcharts/clinical_charts.htm#Set1. Last accessed 3-27-14.