

Obesity Surgery Workgroup

SURGICAL MANAGEMENT
OF OBESITY

CONSENSUS GUIDELINE

Obesity Surgery Workgroup Members

Susan Beane, M.D.
Medical Director
Affinity Health Plan

David Finley, M.D.
Medical Director
Oxford Health Plan

Edward Anselm, M.D.
Senior Medical Director
HIP Health Plan of NY

John Collins, M.D.
Executive VP, Medical Affairs
Capital District Physicians' Health Plan

Herbert Segal, M.D.
Medical Director
Fidelis Care New York

Carolyn Leihbacher, M.D.
Associate Medical Director
Hudson Health Plan

Steven Arnold, M.D.
Senior Medical Director
AmeriChoice

Margaret Leonard, R.N. FNP
VP of Clinical Services
Hudson Health Plan

Anthony Mangiapone, M.D.
Medical Director
MVP Health Care

Joseph Chiarella, M.D.
Medical Director
Health Net

Pamela J. Scanlon, R.N.
Project Manager
MVP Health Care

Collin E. M. Brathwaite, M.D.
St. Catherine of Siena Medical Center
Department of Surgery
Stony Brook University Hospital

Christine J. Ren, M.D.
Assistant Professor of Surgery
NYU School of Medicine

Oscar C. Lirio, M.D.
General and Bariatric Surgery

Marina Kurian, M.D.
Lenox Hill Hospital

Mitchell Roslin, M.D.
Lenox Hill Hospital

David Merkel, M.D.
Adirondack Medical Center

Edward Hixson, M.D.
Adirondack Medical Center

L.D. George Angus, M.D., MPH
Nassau University Medical Center
Associate Professor of Surgery
SUNY Stony Brook

John D. Halverson, M.D.
SUNY Upstate Medical University

William O'Malley, M.D.
Assistant Professor of Clinical Surgery
Highland Hospital

Marc Bessler, M.D.
New York Presbyterian Hospital

Elliot R. Goodman, M.D.
Department of Surgery
Beth Israel Medical Center

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OBESITY SURGERY PROJECT

Background

The origin of the Obesity Surgery Project effort was a simple question raised at a meeting of health plan medical directors, “Is there a rise in the number of bariatric surgeries performed in New York State and, if so, is this a phenomenon about which New York Health Plan Association (NYHPA) medical directors should be concerned?” Medical directors responded with a resounding “yes” to the question and set out to learn more about the field of bariatrics and surgical management of obesity. In October of 2001, medical directors decided to collaborate on the development of a consensus guideline, which would assist health plans, their members, policy makers and general practitioners by identifying best practices. The medical directors who came together to study bariatric surgery initially discovered that the field was rapidly evolving with considerable variation in operative techniques, operator skill and experience, as well as varying degrees of institutional commitment to quality outcomes. Working together, these medical directors fashioned a draft consensus guideline for review and endorsement by the NYHPA medical directors in early 2002. In the spring of 2002, the New York State Department of Health announced the availability of Managed Care Quality Improvement grant funding for projects that would further ensure access to high quality care and improve the care provided to New Yorkers.

In response, an Obesity Surgery Project proposal to build on the work done was developed, submitted and approved for funding. The grant proposal identified a collaborative effort that would involve medical directors from participating health plans and a geographically diverse group of high volume bariatric surgeons. The collaborative Obesity Surgery Project was funded to achieve and publish a set of best practice guidelines for bariatric surgery, that reflect a consensus among health plans, leading surgeons and other stakeholders. The Obesity Surgery Project workgroup is charged with:

- ▶▶ Publishing a consensus guideline that defines best practices in all aspects of bariatric surgery including patient selection, surgeon qualifications and training, and equipment needs for facilities offering bariatric surgery.
- ▶▶ Publishing aggregate data on surgical outcomes for selected patients in New York State who underwent bariatric surgery during the study period.
- ▶▶ Publishing aggregate data on medical outcomes for participating health plan’s members who underwent bariatric surgery during the study period.

This collaborative effort builds upon the health plan medical directors and bariatric surgeons commitment to explore, develop and disseminate a set of obesity surgery best practice guidelines to ensure that the highest quality of care is provided to bariatric patients in New York State.

OBESITY: FRAMING THE ISSUE

Problem Statement

The increasing prevalence of obesity and its resulting clinical and economic burden, together with the poor results of medical weight loss therapy, has focused attention on surgical treatment options. Bariatric, or obesity surgery, is one element of a coherent approach to weight management for those with extreme obesity. The purpose of this guideline is to aid in the consideration of surgical treatment for patients with obesity.

Body Mass Index

The Body Mass Index (BMI) has become the standard measure used to assess and define overweight and obesity, chiefly because it is easy to use. The BMI is a weight for height index and is calculated by dividing weight in kilograms by height in meters squared (weight [kg]/height squared [m^2]) or by taking weight in pounds and multiplying by 703; this number is then divided by height in inches squared (weight [lbs] x 703/height squared [$inches^2$]). For example a person who is 66 inches tall and weights 155 lbs has a BMI of 25.

Classification of Weight Status using BMI

Extreme obesity is defined as weight in excess of 100 pounds over the ideal calculated weight or somewhat less than 100 pounds if there is a serious associated medical condition. The BMI is the primary measure used to screen for overweight and obese individuals. The classification of weight status is the same for men and women.

Category	BMI
Underweight	<18.5
Normal	18.5 - 24.9
Overweight	25.0 - 29.9
Obesity Class I	30.0 - 34.9
Obesity Class II	35.0 - 39.9
Extreme Obesity Class III	\geq 40.0

Source: The National Institutes of Health Publication No. 98-4083
September 1998

SURGICAL MANAGEMENT OF OBESITY

Guideline Introduction

It is the recommendation of this collaborative that the contemplation of bariatric surgery for the treatment of Obesity Class II with co-morbidities and Obesity Class III include prudent evaluation of:

- ▶▶ Appropriateness of patient selection.
- ▶▶ Appropriateness of the type of procedure for the patient's needs.
- ▶▶ Consideration of the surgeon's qualifications to perform the chosen procedure.
- ▶▶ Consideration of the facility's ability to support the comprehensive management of the pre and post operative needs of the patient.

Each case should be assessed for relative surgical risk. In other words, the benefits from the surgery must outweigh the risk to the patient from the surgery.

Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI ≥ 40 or ≥ 35 with co morbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality.

EVIDENCE.CATEGORY B: Evidence is from endpoints of intervention studies that include only a limited number of (Randomized Control Trials) RCTs, post hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.

Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report NIH Publication No. 98-4083 September 1998.

CRITERIA FOR PATIENT SELECTION

Surgical intervention is the only proven treatment for patients with severe obesity. Patients can expect to lose approximately 65-75 percent of excess body weight over 12 to 18 months after surgery. As many as 20 percent of patients will lose less than their desired amount of weight or will regain a good deal of weight. Carefully selected patients can achieve rapid and substantial weight reduction within 1 year postoperatively. The patient proposed for obesity surgery should be considered when the following criteria are met:

▶▶ Absolute:

- 1) The patient has a body mass index (BMI) = or > 40 or;
- 2) Has a BMI =or > 35 with a life-threatening or disabling co-morbid condition, such as diabetes mellitus, hypertension, dyslipidemia, other serious cardiopulmonary condition, or severe sleep apnea, and;

▶▶ Other Considerations:

- 1) Has no history of substance abuse or been documented to be substance abuse free for >1 year or is in a controlled treatment program and is stabilized.
- 2) Routine psychological counseling is not always necessary prior to surgery. However, if a patient who is being considered for bariatric surgery has received, in the past 12 months, any intervention (counseling or drug therapy) for behavioral health issues, then the mental health provider should indicate that the issue of surgery has been discussed with the patient, and that there are no identified contraindications to the proposed surgery from the viewpoint of the patient's mental health.
- 3) Is not using any tobacco products and has been tobacco free for six weeks prior to surgery.
- 4) Has no absolute contraindication to major abdominal surgery.
- 5) Has obesity of long standing.
- 6) Has made reasonable attempts to lose weight in a structured and documented program.
- 7) Has demonstrated an understanding of the need for post-surgical attention to lifestyle and dietary changes, and has signed a compliance statement acknowledging same, and is agreeable to life-long follow-up.
- 8) Has been fully counseled on the risks and benefits of the procedure.
- 9) Is preferably between the ages of 18 and 65 years.
- 10) If under 18 or over 65 years of age, review must be conducted by a multi-disciplinary team.

MINIMUM REQUIREMENTS FOR BARIATRIC SURGEONS

- 1) Is a fully trained, Board Certified, or Board Eligible general surgeon.
- 2) Has completed a fellowship or preceptorship in bariatric surgery, including patient education, support groups, operative techniques and post-operative follow-up. During this training, the surgeon must have performed at least 25 bariatric procedures.
- 3) The surgeon must perform a minimum of 25 bariatric surgical cases per year to maintain proficiency in bariatric surgery.
- 4) Evidence strongly suggests that operative experience is important in reducing mortality and morbidity in the surgical management of obesity. Surgeons who have mastered the basic procedures and technology in bariatric surgery are those who have performed at least 100 open bariatric cases (if the surgeon is performing open cases) or 100 laparoscopic bariatric procedures (if the surgeon is performing laparoscopic surgery) following fellowship.
- 5) Maintain a well-informed, up-to-date knowledge of bariatric surgery and the associated literature as evidenced by 25 CME credits in bariatric surgery every two years.
- 6) Perform bariatric surgery in institutions that meet criteria for bariatric care.
- 7) Are knowledgeable in the field of obesity, including patient education and selection and in preoperative and long-term care, including detection and handling of complications.
- 8) Use a multidisciplinary approach and work with a well-trained operating team familiar with the equipment, instruments, and techniques used in bariatric surgery.
- 9) Are personally committed to and have the infrastructure available to strongly encourage the necessary education and life-long follow-up of his/her bariatric surgery patients.
- 10) Have a structured follow-up program in place.

MINIMUM REQUIREMENTS FOR FACILITIES

- 1) Has a bariatric surgery team led by a surgeon meeting minimum requirements for bariatric surgeons.
- 2) Has a team of people who are experienced with and committed to treating bariatric patients.
- 3) Has a specially equipped operating room for bariatric surgery, which includes tables and ancillary equipment available, which can accommodate the morbidly obese and super obese. Appropriate bariatric retractors, staplers, long instruments and other special supplies unique to this type of procedure are available.
- 4) Provides anesthesia for bariatric surgical procedures performed by individuals experienced in this area and who are regularly assigned to bariatric procedures as part of the bariatric surgery team.
- 5) Has a recovery room and intensive care unit capable of providing critical care for obese patients.
- 6) Has hospital beds, adjustable air pressure mattresses, commodes, stretchers, wheelchairs, and gowns to accommodate morbidly obese patients. The facility should have wider doorframes to accommodate larger sized equipment and should provide modified bathroom facilities.
- 7) Has radiology and other diagnostic modalities capable of handling morbidly obese patients.
- 8) Can provide perioperative care including rehabilitation, psychiatric care, nutritional counseling and nursing care for the bariatric patient.
- 9) Institutional commitment to maintain and upgrade facilities, equipment and services necessary to continue to support a bariatric surgical program.

BARIATRIC CENTERS OF EXCELLENCE

While bariatric surgery can be performed successfully in a variety of settings, it is the opinion of this consensus group that there are surgical programs and centers demonstrating more than minimal adherence to the guideline for patient selection, surgeon and facility qualifications. Further, these programs document an ongoing commitment to improving surgical performance and outcomes for patients with obesity. The term "Specialty Center," "Center dedicated to Excellence," or similar term, should be considered when the surgical program adopts a multidisciplinary approach to the care of patients with obesity, including the following elements:

- 1) A bariatric surgeon who spends at least 75 percent of his/her professional efforts in the field and who has qualified coverage and support for patient care.
- 2) Designated nurses or physician extenders dedicated to serving bariatric surgical patients and who are involved in continuing medical education in the bariatric field.
- 3) A full complement of the various consultative services and equipment required for the care of the bariatric surgical patient including furniture, wheelchairs, operating room tables, beds, radiologic facilities, surgical instruments, etc. suitable for the morbidly obese and superobese.
- 4) Availability of organized and supervised support groups for all patients who have undergone bariatric surgery at that institution.
- 5) Performance of > 200 cases per year, with morbidity and mortality outcomes commensurate with accepted national standards.
- 6) A medical director for bariatric surgery who participates in the relevant decision-making administrative meetings of the institution.
- 7) Academic productivity with publication of peer-reviewed articles, participation in national leadership positions in bariatric surgery or active involvement in teaching, training or lecturing in the field of bariatric surgery.
- 8) Documentation of a programmatic dedication to a goal of long-term patient follow up including maintenance of a patient database and results reporting.

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For more information about the Obesity Surgery Project
or to request a copy of the guideline contact:

NY Health Plan Association
90 State Street, Suite 825
Albany, New York 12207
518-462-2293
518-462-2150