

The Physical and Fiscal Impact of the Obesity Epidemic: The Impact of Comorbid Conditions on Patients and Payers

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Summary

The current obesity epidemic in the United States has significant physical and financial impacts on patients and payers. Although it is only one of a number of ways to manage obesity, weight loss surgery is a proven option for the severely obese patient. The cost of the actual surgery is high but is balanced by the benefits of significant weight loss, reduced comorbidity, reduced medications, and reduced weight related mortality.

Key Points

- The prevalence of obesity in the United States has risen to epidemic proportions.
- Obesity affects essentially every organ system in the body.
- Obesity contributes substantially to the cost of many disease processes.
- Surgery is a valid, proven alternative in the management of obesity, especially in the management of severe obesity.
- The two major surgeries in the United States are gastric banding and gastric bypass.
- Each type of surgery has advantages and disadvantages.
- Three to five years is required to break even from a cost perspective.

OBESITY IS TRULY AN EPIDEMIC IN THE United States. There is a disproportionate share of health care dollars going toward treatment of obesity and its consequences. The prevalence of obesity in the United States has risen to epidemic proportions (Exhibit 1).¹ Not only are more people becoming overweight, but the prevalence of severe obesity is rising disproportionately compared to other levels of obesity.

At a BMI greater than 30, a person is defined as having mild obesity. At a BMI of 35, the patient has moderate obesity, and at 40, severe obesity (Exhibit 2). It is no longer unusual for surgeons to be operating on a patient with a body mass index (BMI) of 70.

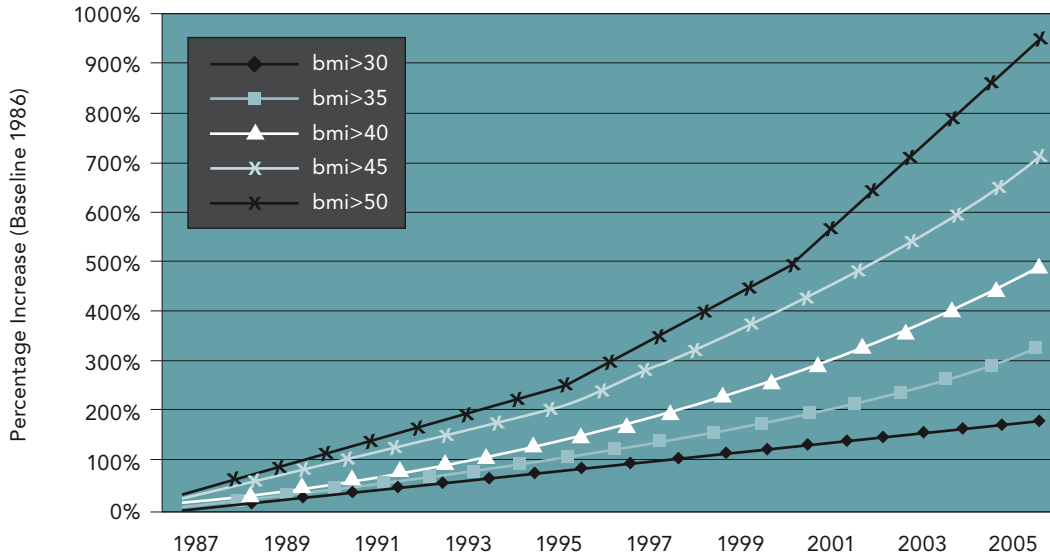
Obesity affects essentially every organ system in the body (Exhibit 3). In addition, quality of life is significantly decreased by increasing weight and improved by losing weight.² Obesity also affects mortality. The relative risk of death and disease goes up disproportionately as weight increases. Being severely overweight increases the relative risk of several diseases (Exhibit 4). The risk for type 2 diabetes, dyslipidemia, nonalcoholic steatohepatitis, and other conditions is increased five fold.

Not surprisingly, obesity contributes substantially to the cost of many disease processes. Almost half the costs of type 2 diabetes are attributable to excess weight.³ In data from a General Motors PPO (177,971 employees, retirees, and adult dependents), people with obesity had a relative cost increase of 1.69 in the cost of care compared with non-obese people.⁴ Exhibit 5 illustrates the health problems and annual costs associated with overweight and obesity in 4.3 million Tricare Prime beneficiaries under age 65.⁵

In the obesity treatment pyramid, treatments offered to patients should be a function of how much extra weight they have (Exhibit 6).⁶ In general, lifestyle changes are recommended to lower BMIs in the 25 to 27 kg/m² range and weight loss medications are indicated for BMIs of 27 to 30. Surgery is indicated for people with BMIs greater than 30 if comorbidities are present or 35 without comorbidities. Surgery is not an alternative to lifestyle therapy or medications and is not a quick fix. Surgery or medication has to be combined with lifestyle changes to be successful.

There are lots of diets that have been shown in the short term to help people lose weight. The key to

Exhibit 1: Increasing Prevalence of Extreme Obesity



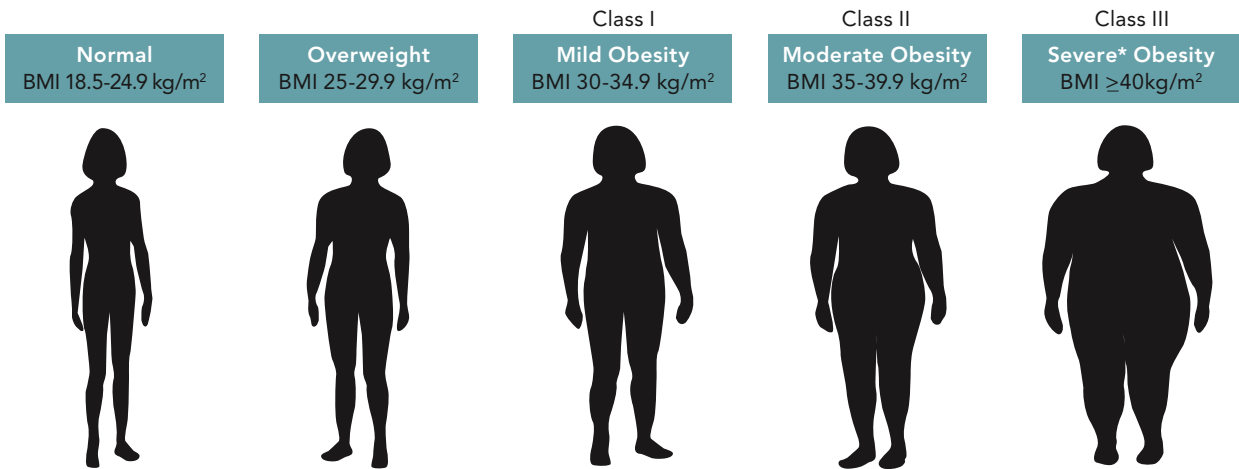
Reference: 1

long-term success is follow-up. Exercise is useful in helping patients to maintain weight loss. Behavior modification is an extremely important intervention. High-intensity, well-designed behavioral treatments can achieve a weight loss of approximately 8 percent to 10 percent of body mass. Gradual weight regain does tend to occur. For moderate obesity, pharmacotherapy (sibutramine and orlistat) results in very modest weight loss. For medications to be effective, they must be combined with lifestyle changes and behavior modification. On these medications, patients will lose a mean of 10 to 15 pounds.

Twelve to 15 percent of patients will lose 10 percent of their body weight on pharmacotherapy. Weight regain typically occurs once the medication is stopped, and some regain occurs after about one year, even if the medication is continued. Unfortunately, pharmacotherapy and lifestyle changes will not result in enough weight loss to significantly help most severely obese patients.

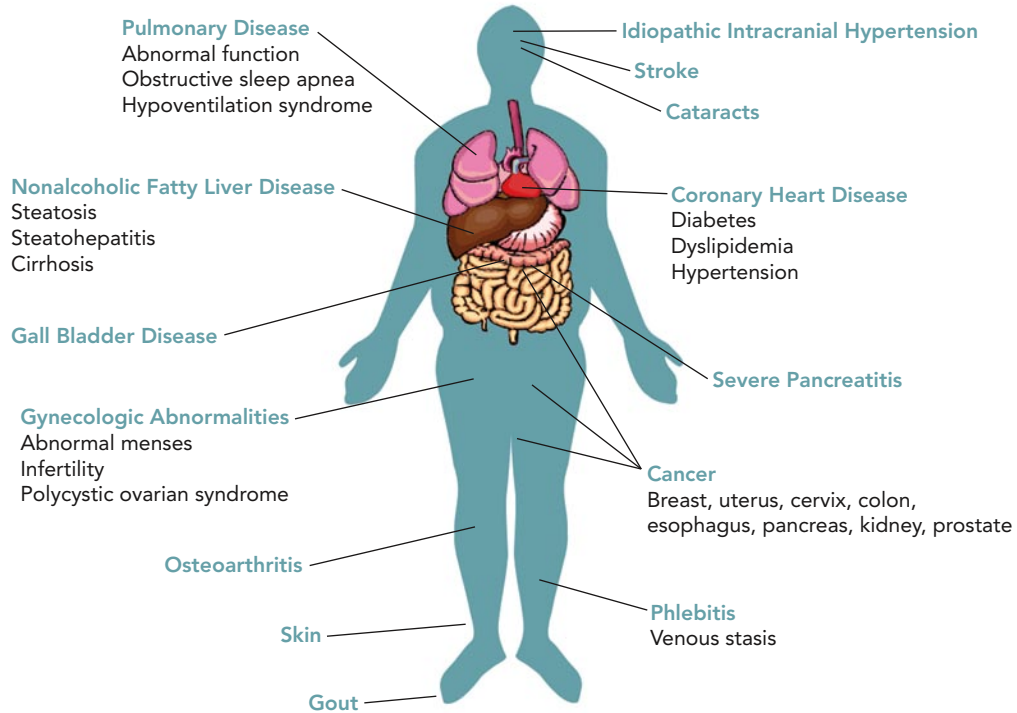
Surgery is a valid, proven alternative in the management of obesity, especially in the management of severe obesity. In the Swedish Obesity Study of 4,000 patients, medical treatment was compared

Exhibit 2: Degrees of Obesity



*Interchangeable terms: clinically severe obesity, extreme obesity, morbid obesity. BMI, body mass index.

Exhibit 3: Medical Complications of Obesity



with various surgical procedures over a 10-year period (Exhibit 7).⁷ Unlike non-operative treatments, surgical treatment leads to sustained weight loss over at least 10 years. Some weight regain does occur over time but the patient does not rebound back to their baseline weight. For people who suffer from severe obesity, surgery is the only method of sustained prolonged weight loss.

The cost benefit of surgery has been compared to not operating. At three years, the initial higher cost of surgery is offset when compared to not operating.⁸ At five years, the most cost savings is seen for cardiovascular disease with more modest savings for endocrine, respiratory, cancer, and infection (Exhibit 8).⁸

The volume of bariatric surgeries in this country has been increasing dramatically.⁹ Approximately

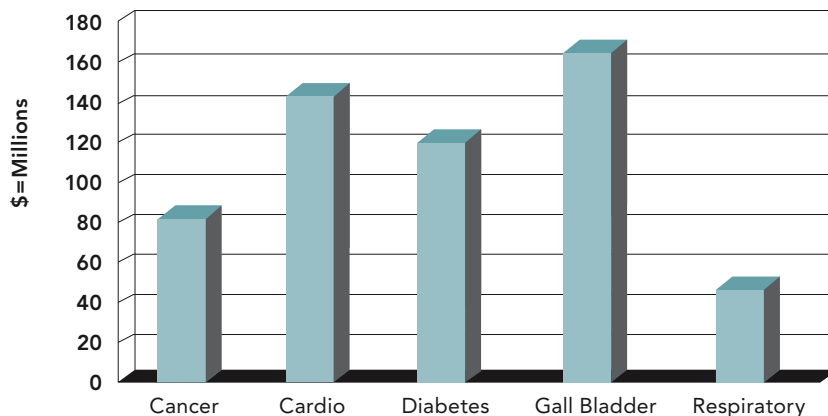
Exhibit 4: Relative Risk of Death/Disease With BMI 40 vs BMI 20-25

Relative Risk >5	Relative Risk 2 to 5	Relative Risk 1 to 2
Type 2 diabetes	All-cause mortality	Cancer mortality
Dyslipidemia	Hypertension	Breast cancer
Obstructive sleep apnea	Myocardial infarction and stroke	Prostate and colon cancer in men
Breathlessness	Endometrial carcinoma in women and hepatoma in men	Impaired fertility
Excessive daytime sleepiness	Gallstones and complications, including cancer	Obstetric complications, including fetal abnormalities
Obesity hypoventilation syndrome	Polycystic ovary syndrome	Asthma
Idiopathic intracranial hypertension	Osteoarthritis (knees)	Gastroesophageal reflux
Nonalcoholic steatohepatitis	Gout	Anesthetic risk

Exhibit 5: Cost of Care Increases With BMI: Tricare Prime Health Plan

4.3 million beneficiaries under age of 65 yrs

Annual Health Problems and Costs Associated With Overweight and Obesity



Annual medical care associated with tobacco use= \$564 million and high alcohol consumption=\$425 million

Reference: 5

200,000 bariatric operations will be done in the United States in 2008.

The criteria for bariatric surgery are outlined in Exhibit 9.¹⁰ People with Class III obesity are the prime candidates. As surgeries have become safer, adolescents and the elderly are now being considered for operation.

Exhibit 10 illustrates the patient flow leading up and beyond surgery. The average patient who arrives at a bariatric clinic has been on four to five supervised diets, all of which have failed, weight has returned, and the patient has investigated bariatric surgery for a year. Surgeons prefer to see that patients have a past history of weight loss, which identifies ability to comply with lifestyle and dietary changes.

Because surgery is a lifelong change, patients need to have thought this decision through thoroughly. A psychologically prepared patient with realistic expectations is very important to successful post-surgery weight loss and maintenance. The patient has to be committed to the changes that will be required. Substance abuse and any psychological issues must be resolved before surgery can proceed.

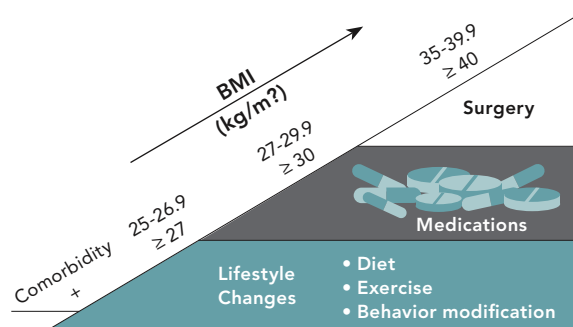
A team approach is integral pre-, peri-, and post-surgery. The surgery is one step of many – the surgery team is one group of many providers. Follow-up has to be coordinated with the patient’s primary care providers. Remember that severe obesity is a chronic relapsing condition. It can be treated with surgery, but is not cured.

Pre-surgery evaluation and preparation may include support group attendance, pulmonary clearance,

cardiology clearance, upper endoscopy, dietary counseling, physical therapy consultation, psychiatric evaluation, smoking cessation, and assessment of patient readiness and attitude. The psychiatric evaluation of the patient will include screening for eating disorders (anorexia, bulimia), substance abuse, and major psychiatric disorders that could lead to poor post-operative outcomes, and assessment of the family support system. Some insurers are requiring personality testing to identify the patient’s potential for behavior modification.

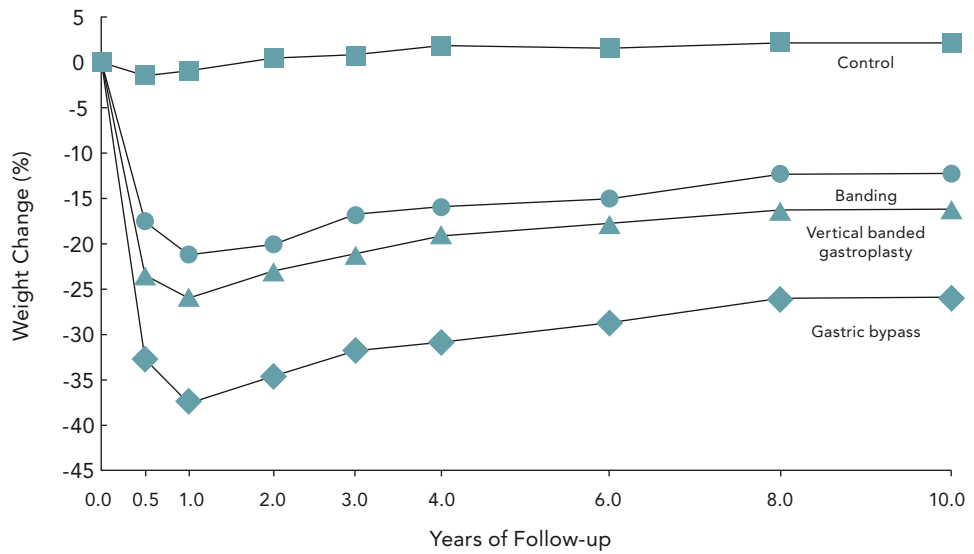
Typically, a greater percent age of weight loss is seen in patients with higher baseline BMI, reduced subjective hunger, better physical function, and increases in leisure time physical activity.¹¹ These four factors account for approximately 30 percent of variance in weight loss outcome. “Non-hungry eating”

Exhibit 6: Obesity Treatment Pyramid



Reference: 6

**Exhibit 7: Swedish Obesity Study (SOS):
10-Year Weight Loss**



No. of Subjects

	0.0	0.5	1.0	2.0	3.0	4.0	6.0	8.0	10.0
Control	627	585	594	587	577	563	542	535	627
Banding	156	150	154	153	149	150	147	144	156
Vertical banded gastroplasty	451	438	438	438	429	417	412	401	451
Gastric bypass	34	34	34	34	33	32	32	29	34

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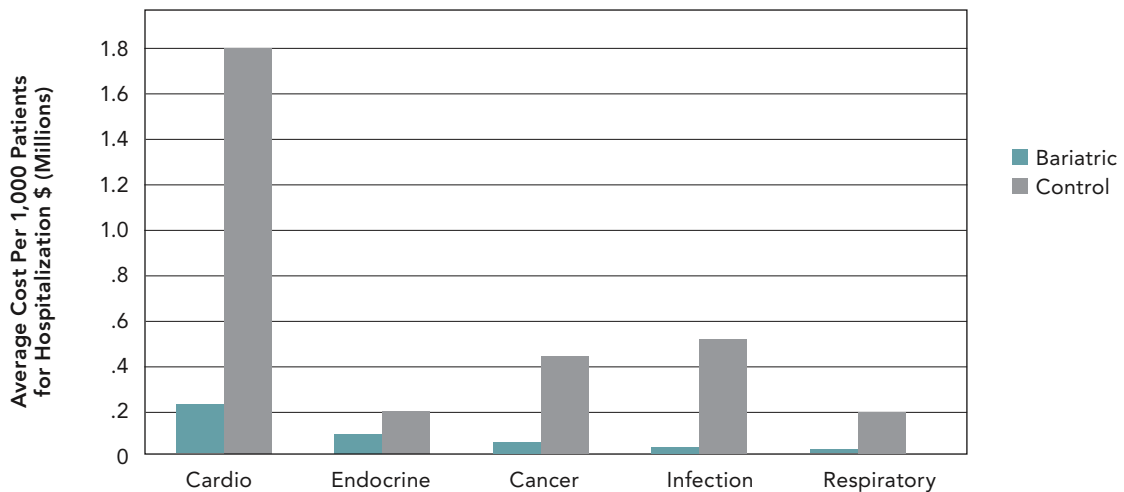
and symptoms of depression are related to poorer percentage weight loss.

Surgery results in weight loss by changing the amount of food someone can eat (restriction) or changing the way food is handled by the body (malabsorption). Bariatric surgery is either restricted, malabsorptive, or a combination. The majority of

the surgeries conducted in the United States are laparoscopic adjustable gastric band (LAGB) surgeries or Roux-en-Y gastric bypass (RYGB) surgeries (Exhibit 11).

RYGB is a longer operation, requires a longer length of stay, and has a higher mortality and initial cost, but results in greater weight loss, at least initially

Exhibit 8: Cost Savings in Surgically Treated vs Conventional Therapy at 5 Years



N= 1118. 5-yr follow-up (1986-2002).

Reference: 8

(Exhibit 12).¹²⁻¹⁷ At five years, the weight loss with these two procedures is approximately equivalent.¹⁵

Despite different rates of perioperative risks and weight loss, both LAGB and laproscopic RYGB were found to be cost-effective at <\$25,000/QALY.¹⁷ In an analysis based on the assumption of a 45-year-old female with BMI of 40 kg/m², the benefit of higher excess weight loss of laproscopic RYGB is outweighed by the low rate of operative mortality of LAGB.¹⁷ The complication rates of these two procedures are shown in Exhibit 13.¹⁸

Exhibit 14 shows the multi-organ benefits of bariatric surgery.^{19,20} In these particular series, gastric issues were greater after surgery. There are many studies showing that hypertension and dyslipidemia have high rates of resolution with bariatric surgery. Digestive complaint is one adverse event of bariatric surgery. In patients with preexisting comorbidities, post surgical medication cost savings can be \$2,000 per year or more.²¹

Type 2 diabetes remissions will occur within one to two years in a large percentage of patients who have bariatric surgery. In one study published in 2008, 70 percent of patients who received a gastric band had remission of type 2 diabetes within two years.²² In a study of RYGB, 54 to 97 percent of patients with type 2 diabetes had remission.²³ The rate of resolution varies by how long diabetes has been present, and disease severity. One hundred

Exhibit 9: Criteria for Bariatric Surgery

- BMI>40 kg/m² or BMI>35 kg/m² with significant obesity-related comorbidities
- Age 16-65 yrs
- Acceptable operative risks
- Documented failure at nonsurgical approaches to long-term weight loss
- A psychologically prepared patient with realistic expectations:
 - A well-informed and motivated patient
 - Commitment to prolonged lifestyle changes
 - Supportive family/social environment
 - Resolution of alcohol or substance abuse
 - Absence of active psychosis and untreated severe depression

Reference: 10

percent of those who had impaired fasting glucose but not yet diabetes remitted.²³ Seventy-six percent of patients discontinued or decreased anti-diabetic medication use one year after LAGB.²⁴ Bariatric surgery can be used to prevent diabetes in patients who are overweight but are not yet diagnosed with diabetes.²⁵

Patients who have bariatric surgery are more likely to be alive in 10 to 15 years compared with patients who are obese but do not have surgery. They are less likely to have cancer or die of coronary artery disease.^{7,26}

Managed care and third party coverage for bariatric surgery has increased significantly. Centers for Medicare & Medicaid Services made a national

Exhibit 10: Patient Flow and Total Care

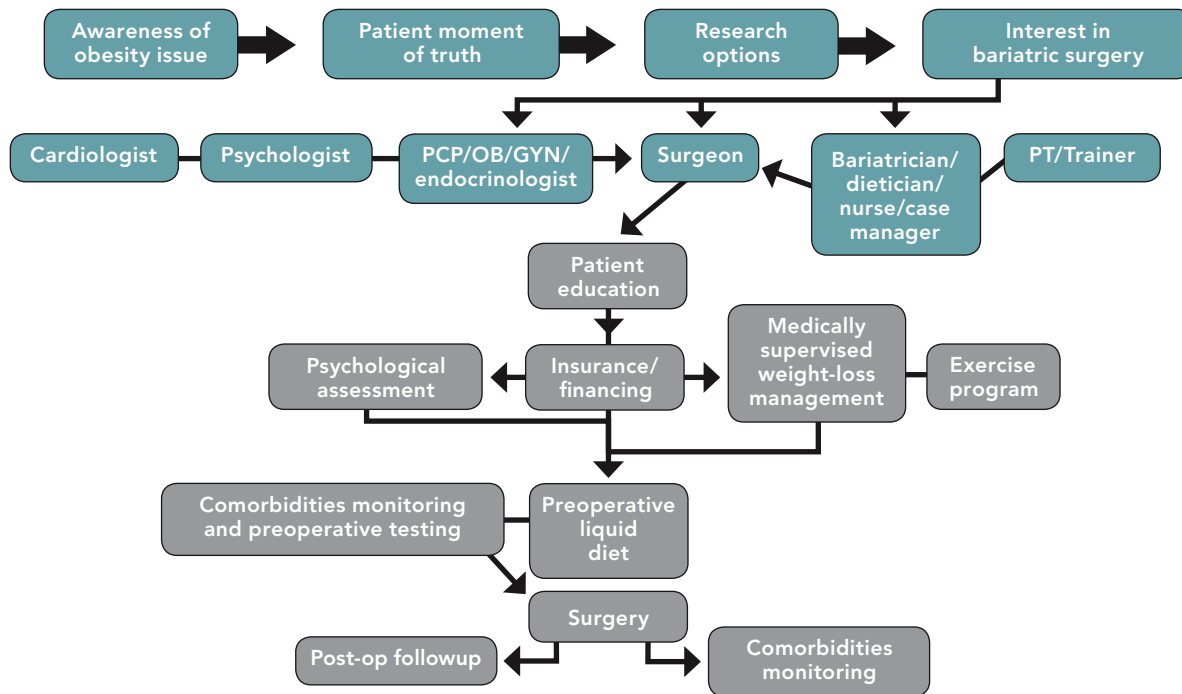
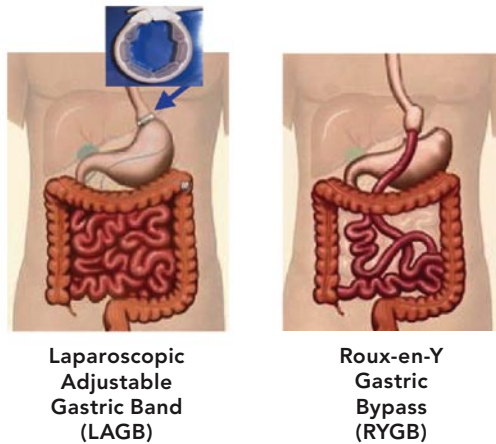


Exhibit 11: Surgical Therapy: Operations for Severe Obesity



Laparoscopic Adjustable Gastric Band (LAGB)

Roux-en-Y Gastric Bypass (RYGB)

coverage decision in 2006. The Blue Cross® Blue Shield Association® issued a positive Technology Evaluation Center assessment of bariatric surgery in 2007. Among commercial payers, 15 payers added coverage for 22 million lives in 2007. Approximately 180 million lives overall have some type of coverage for bariatric surgery.

Every insurance company has different requirements for bariatric surgery. The common ground is psychiatric evaluation, dietary evaluation, diet mandates (vary from none to 12 months), and medical necessity letter.

Post-operative care is almost as intense as pre-operative care. Patients will be seen frequently in the year after surgery, then approximately every six months for another year, and once or twice a year thereafter

Exhibit 12: Comparative Operative Factors RYGB and LAGB

	Mean Operating Time (min)	Mean Length of Stay (days)	Postoperative Mortality (%)
RYGB	162-209	2.3-4	0.5
LAGB	42-66	<1-1	0.1

Cost	
LRYGB	\$27,560
LAGB	\$16,200

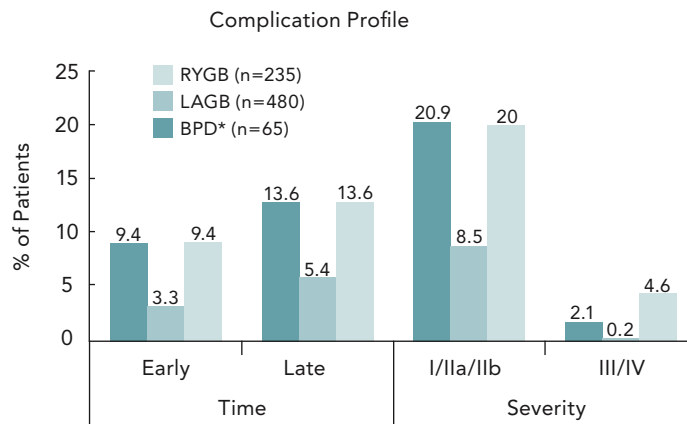
*Within 30 days of procedure.

depending on the type of surgery. Nutritional status is the primary issue monitored over time with RYGB, and need for band adjustment with the LAGB. Patients who do not maintain their follow-up lose less weight.²⁷

Conclusion

Bariatric surgery requires pre-, peri-, and post-operative multidisciplinary care. Positive outcomes can be optimized – and negative outcomes minimized – through a process-driven team approach. There are clear benefits for bariatric surgery in appropriate patients and there are cost savings. In a risk/benefit analysis, there is no clear advantage to RYGB or LAGB. The benefits of surgery include overall mortality reduction, weight loss, and comorbidity resolution. **JMCM**

Exhibit 13: Complication Rates



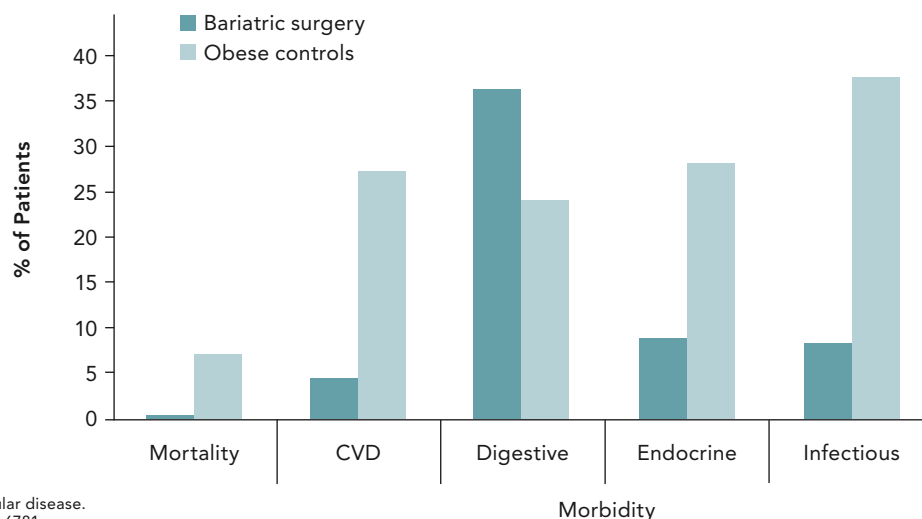
Severity Grades

- I Minor complication
- IIa Requires drug therapy, transfusion, or prolonged hospital stay (>2x normal)
- IIb Requires therapeutic imaging, therapeutic endoscopy, or reoperation
- III Lasting disability, organ resection, or anastomotic revision
- IV Death

*BPD, biliopancreatic diversion with or without duodenal switch
 P<.001 for LAGB vs RYGB and BPD for all times and severity grades.
 Reference: 18

Exhibit 14: Multiorgan Benefits of Bariatric Surgery

Initial Weight Loss Range (Mean) = 20.9% – 40% (35.6%)



CVD, cardiovascular disease.
P<.001 for all; N=6781.
Observational 2-cohort study.

References: 19, 20

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