

Obesity Management

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Summary

Currently, obesity is the number one health problem in the United States. Although lifestyle changes and anti-obesity medications can result in modest weight loss, this loss is generally not sufficient for the severely obese patient. Weight loss surgeries such as laproscopic adjustable gastric banding are proving to be efficacious for the morbidly obese patient.

Key Points

- Obesity is the number one health problem in the United States.
- Failure rates of non-surgical approaches are well documented.
- Bariatric surgery significantly improves obesity co-morbidities.
- Bariatric surgery is the treatment of choice for morbid obesity.
- National guidelines exist for bariatric surgery.
- Across the country managed care plan coverage and criteria for bariatric surgery are variable.

OBESITY IS A CHRONIC DISEASE OF multiple etiologies characterized by the presence of excess adipose tissue. The National Institutes of Health and the World Health Organization consider obesity a discrete medical condition that independently affects health. Defining obesity as a disease resulted in insurance coverage for obesity treatments, and expedites approval of new medications as well. Considering obesity a disease can help destigmatize the condition, similar to defining alcoholism as a disease. It can also remove some key economic and regulatory hurdles to prevention and treatment. Since 2002, the IRS has allowed an itemized income tax deduction for expenses related to treatment of a disease, such as obesity. Body mass index (BMI) is used to identify those people who are obese. BMI is a measure of an individual's weight (kilograms) in relation to height (meters squared). A normal BMI is under 25 kg/m².¹ BMIs between 25 kg/m² and 30 kg/m² are considered overweight. Obesity is defined as a BMI greater than 30 kg/m².

There is an epidemic of obesity in the U.S. About 127 million adults, or 1/3 third of our country, are overweight. Up to 60 million adults are obese.¹ According to the American Society of Bariatric Surgery, the latest data show that about 11 million are morbidly obese and are candidates for bariatric

surgery. The prevalence of obesity has more than doubled in 46 years from 13.3 percent to 30.9 percent. The prevalence of morbid obesity has nearly doubled in 12 years (2.9 percent to 4.7 percent).²

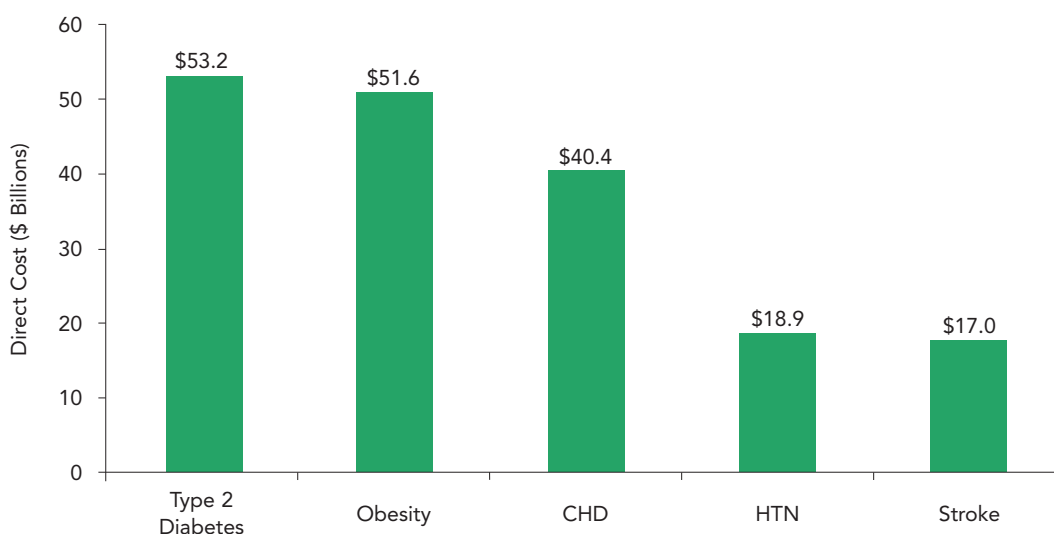
Obesity results in \$100 billion in annual medical costs. The overall costs of obesity are illustrated in Exhibit 1.^{3,4} Six percent of total adult medical expenditures are attributed to obesity.⁵ Seven percent of total Medicare expenditures and 11 percent of total adult Medicaid expenditures are a result of obesity.⁵ Twenty-seven percent of overall increases in medical spending between 1987 and 2001 were attributable to obesity.⁶ Per patient medical costs are higher for obese patients (Exhibit 2).⁷

Obesity is a major contributing factor to high-cost, high-prevalence disease states—type 2 diabetes, hypertension, heart disease, osteoarthritis, gallbladder disease, and cancer.^{1,3,8} Approximately 10 percent of all the U.S. healthcare dollars are spent on some type of obesity-related condition. Exhibit 3 shows the percentage of certain disease costs that are attributable to obesity.³

Societal Interventions

To begin to combat the obesity epidemic, the U.S. Preventative Services Task Force recommends that clinicians should screen all adult patients for obesity

Exhibit 1: The Overall Cost of Treating Obesity Is Quite High

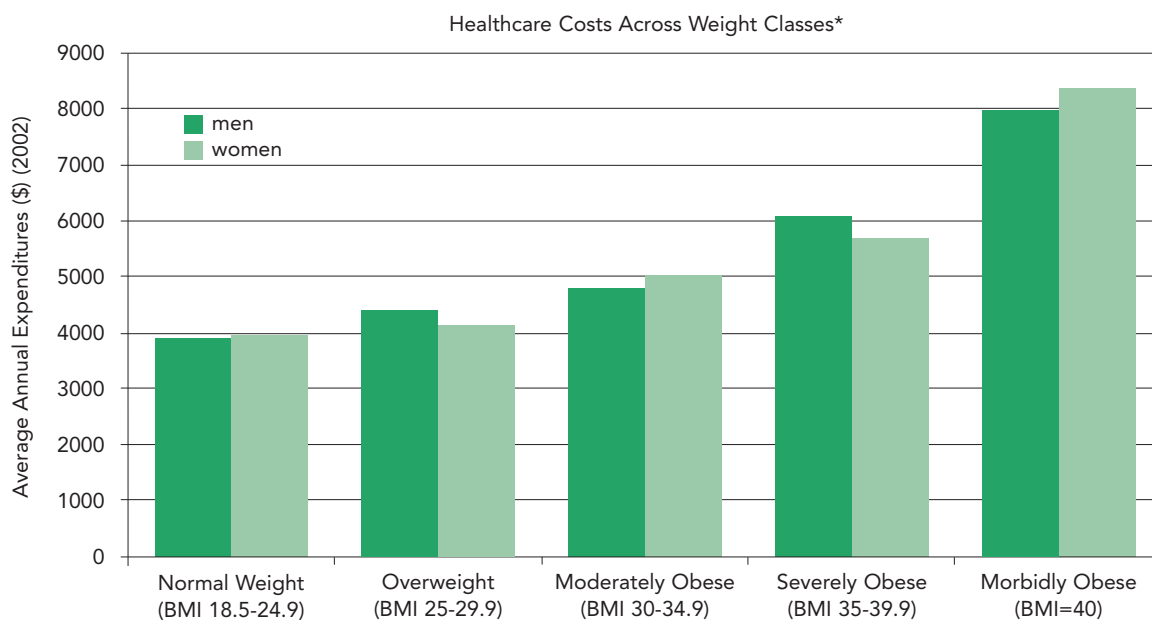


and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.⁹ Another example of a societal intervention is the FDA campaign called Calories Count.

Under this campaign, food nutrition labels have been revised to include larger type size, percentage of daily caloric intake, and total caloric count of packaged food eaten all at one time (candy bar, single serve chips, etc). This campaign has also defined the terms “low”, “reduced”, and “free” of carbohydrates. Other

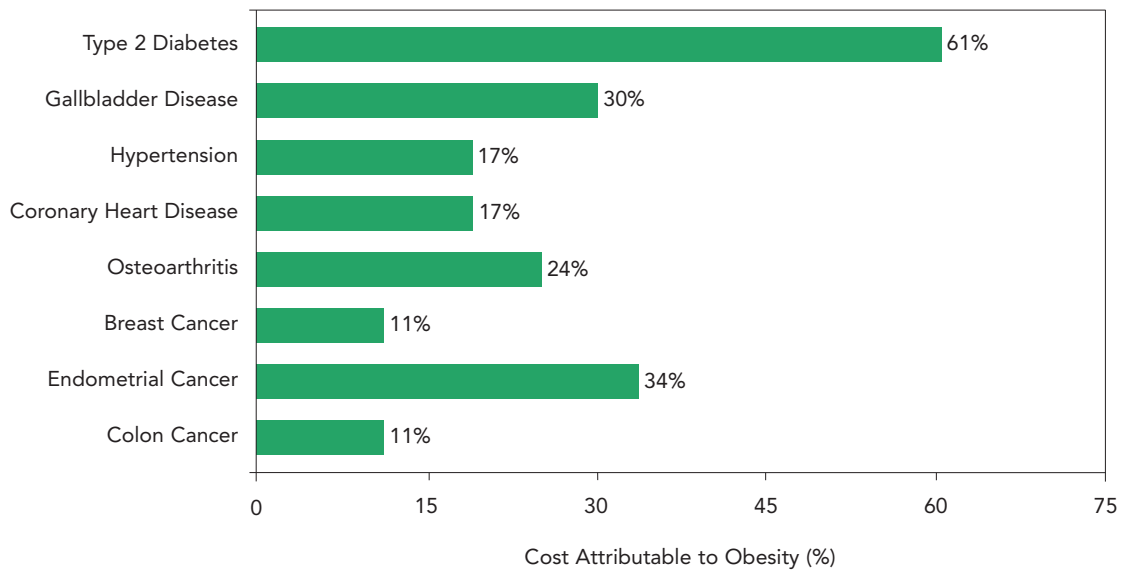
aspects of this campaign are the convening of an Advisory Board to review guidelines for diet drugs, encouraging development of new weight loss drugs, encouraging restaurants to provide more nutrition information on menus, and encouraging food manufacturers to use dietary guidance statements. The FDA has also strengthened the coordination of obesity research and development of healthier foods with other national agencies. A final component of the FDA plan is focused consumer education on influenc-

Exhibit 2: The Treatment Costs per Patient are Higher for the Obese



* Data from Health and Retirement Study, 1996-200, Americans aged 54-69.

Exhibit 3: Percent of Disease Costs Attributable to Obesity



ing behavior, promoting healthier eating choices, and working with private and public sector partners to give consumers a better understanding of food labels.

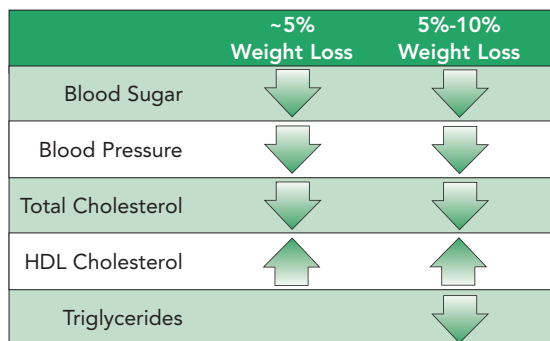
Obesity Treatments

The major categories of treatments for obesity are lifestyle changes (dietary and physical activity), medications, and surgery. With dietary changes and exercise, patients lose five to 10 percent of their starting weight on average.¹⁰⁻¹² This degree of weight loss can help reduce many of cardiovascular risk factors as shown in Exhibit 4. The decrease in blood pressure and glucose comes from weight loss and is irrespective of being on appropriate medical treatments for those comorbid diseases themselves. Unfortunately, once the patient stops a weight loss program, weight gain typically occurs (Exhibit 5).¹³ Commercial weight loss programs such as TOPS and Weight Watchers can

produce weight loss. Regrettably, there is a high attrition rate from these programs (Exhibit 6).¹⁴

The two anti-obesity medications currently approved for long term use are orlistat (Xenical[®]) and sibutramine (Meridia[®]). Short-term use of these agents alone is not much better than diet and exercise. For weight loss medications to be most effective, the patient must also make dietary and physical activity changes. The combination of dietary changes, increased physical activity, and weight loss medications will help lower BMI in many patients by 10 to 15 percent. Combination therapy may not get them under 25 kg/m² but it can get them under 30 kg/m².

Exhibit 4: Impact of Weight Loss on Risk Factors*



* Diet restricted

Exhibit 5: Nonsurgical Weight-Loss Therapy Has Not Been Shown to Result in Long-Term Weight Loss

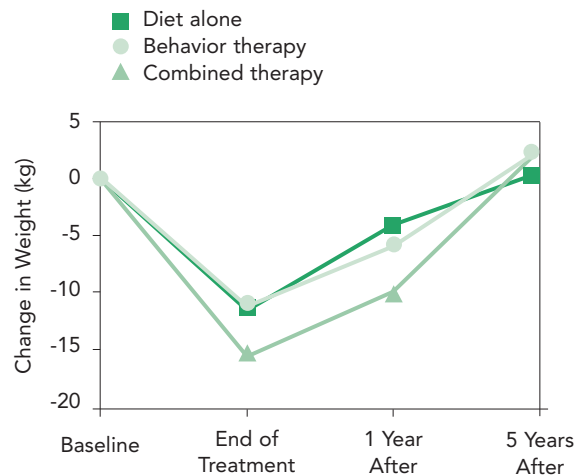
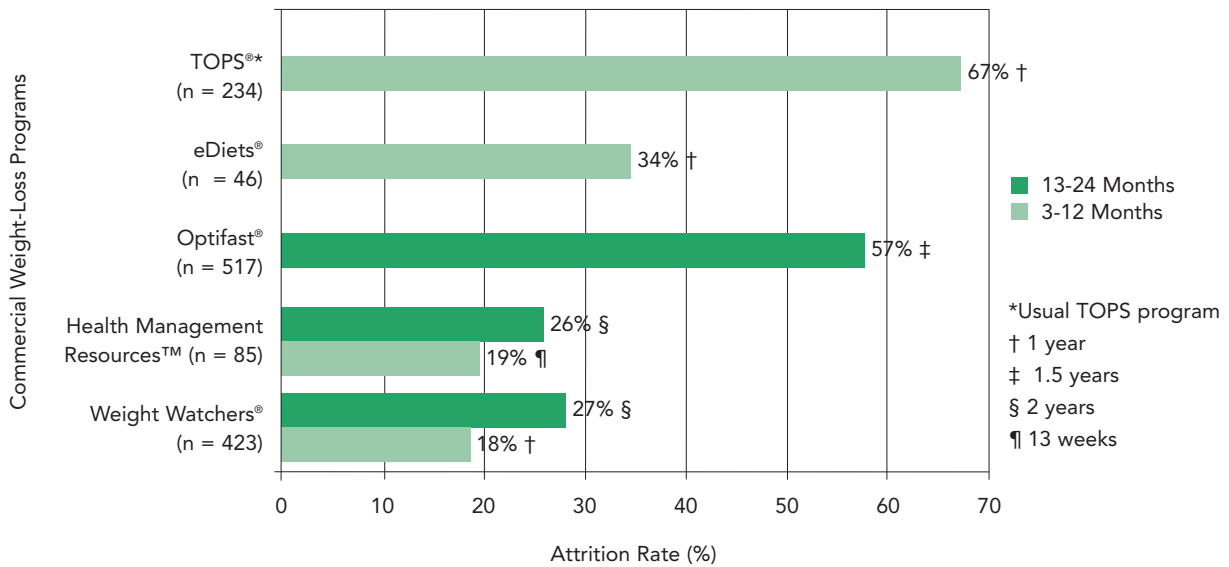


Exhibit 6: High Attrition Rates Limit the Effectiveness of Commercial Nonsurgical Weight-Loss Programs



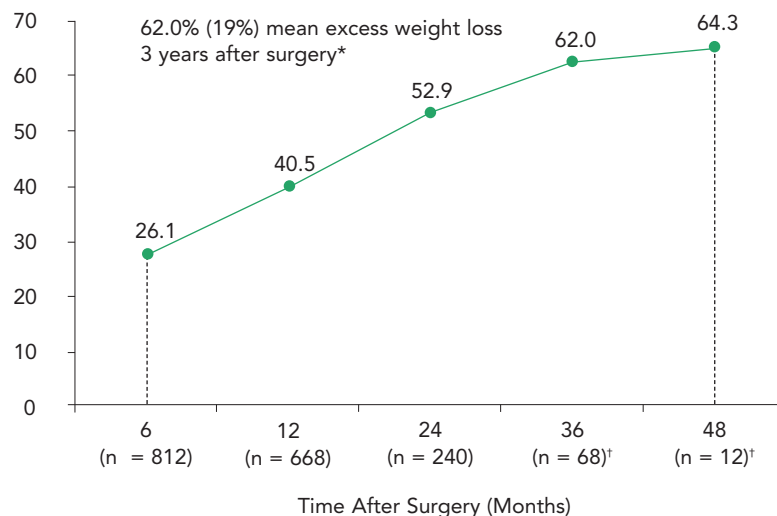
Additionally, weight regain typically occurs once medication is stopped. Adverse effects with these medications may limit adherence. Adherence is both persistence—continuing to take medication and compliance—taking the medication correctly as prescribed on a regular basis.

Bariatric surgery is more effective over time than the other two approaches. Patients can lose as much as 50 percent of their excess weight loss compared to five percent to 15 percent.^{11,12,15} This weight loss can be sustained for up to 10 years. Weight loss surgeries involve

reducing the capacity of the stomach, bypassing parts of the stomach and intestines to prevent nutrient absorption, or a combination. Examples of surgical weight loss procedures include the jejunioileal bypass and vertical band gastropasty. Each year, 120,000 bariatric procedures are done in the United States.

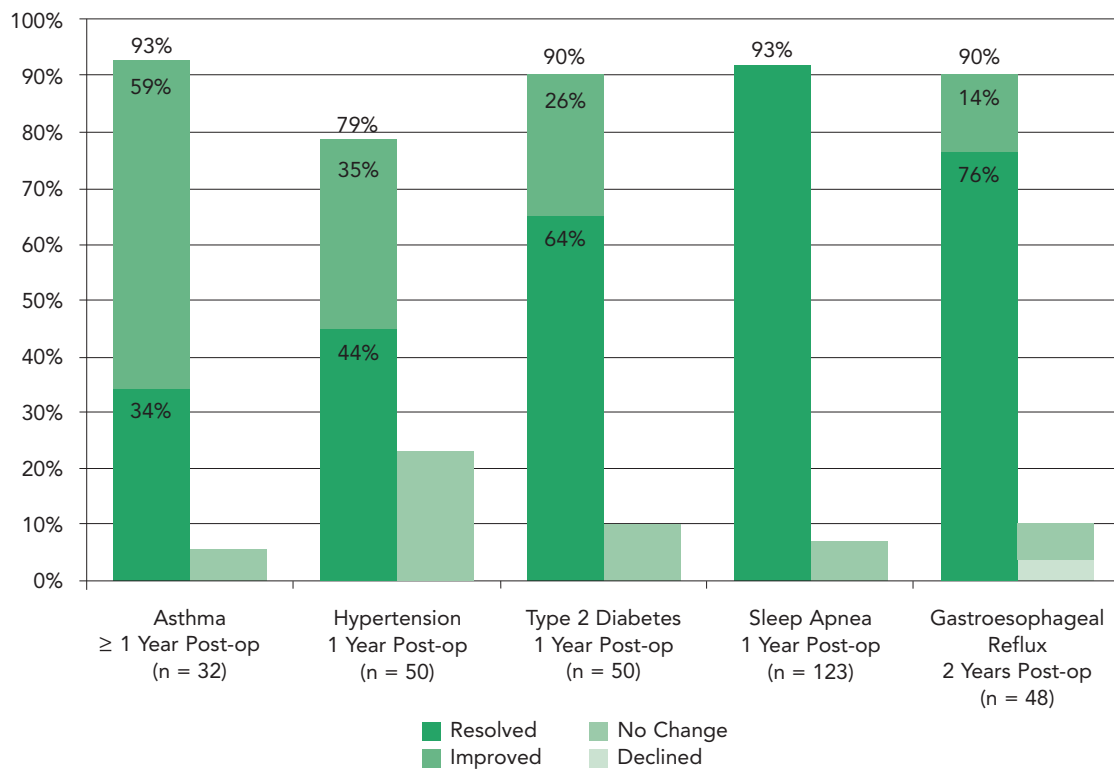
The available data suggest that surgery may be superior to medical treatments for morbidly obese patients. Surgical treatment for obesity in severely obese individuals (BMI 40 kg/m²) results in greater weight loss than does medical treatment.¹⁶ Severely

Exhibit 7: Laparoscopic Gastric Banding Results in Long-Term Weight Loss*



* Significant improvement in percent of excess weight loss vs. baseline was achieved at 12 months (34.5%), 24 months (37.8%), and 36 months (36.2%).
 † Based on a chart review of 1,014 consecutive cases of patients undergoing laparoscopic banding system surgeries. Follow-up data were available for relatively few patients at 36 months (68 of 77) and at 48 months (12 of 14).

Exhibit 8: Laparoscopic Gastric Banding Systems Result in Substantial Reductions in Comorbidities



obese patients lose 20 to 30 kg of weight that is maintained for 10 years and possibly longer, and is accompanied by significant improvements in several comorbid conditions.¹⁶ For patients with BMIs between 35 and 39 kg/m², data strongly support the superiority of surgical therapy however these data cannot be considered conclusive in the absence of a study with a concurrent comparison group.¹⁶ For people between 30 and 40, surgery may or may not be necessary to achieve an acceptable weight. Many health care insurers have developed policies to identify which patients would likely benefit the most from bariatric surgery.

The various bariatric surgery procedures have been compared with each other. The laparoscopic adjustable gastric banding (LAGB) procedure appears to be as efficacious as gastric bypass up to 60 months of follow-up.¹¹ Long-term weight loss with LAGB is seen with a 62.0 percent (± 19 percent) mean excess weight loss three years after surgery (Exhibit 7).¹⁷ The complication rates of gastric bypass are higher than those with LAGB.^{18,19} This includes total complications (23 percent vs. 9 percent), major complications (2.1 percent vs. 0.2 percent), and short term postsurgical death (0.5 percent vs. 0.05 percent). Laparoscopic surgery has some other benefits compared with open gastric bypass including a shorter hospital length of

stay, reduced recovery time, reduced incidence of wound complications (infections, hernias, dehiscence), and higher member satisfaction.

Both gastric bypass and LAGB procedures result in sustainable weight loss, which is an important outcome. Another important outcome of weight loss surgery is the reduction in comorbidities. As shown in Exhibit 8, LAGB can result in a significant resolution or improvement in asthma, hypertension, type 2 diabetes, sleep apnea, and gastroesophageal reflux.²⁰⁻²³

Reduction of comorbidities is an important outcome in terms of medical costs. Although bariatric surgery is costly, the reduction in comorbidities should reduce costs. Claims data cost analyses of bariatric surgery are being done but are not yet published. This information that can help managed care make better decisions about the use of these weight loss procedures.

Several professional organizations have produced favorable consensus statements recently on bariatric surgery. This includes the National Institutes of Health (NIH) Consensus Development Conference (2004), American Society for Bariatric Surgery (ASBS) Consensus Conference (2004), Blue Cross® Blue Shield® Association Technology Evaluation Center Assessment (2007), and ECRI Institute (2004).^{2,24-26}

The key finding of the NIH consensus statement is that bariatric surgery can be considered for appro-

priate patients (BMI ≥ 40 kg/m² or BMI between 35 and 39.9 with high-risk comorbidities).²⁴ The risk-benefit assessment before surgery should include weight-loss potential, likelihood of improvement in comorbidity measures, psychological effects, and likelihood of perioperative/long-term complications or mortality. A multidisciplinary team evaluation including medical, surgical, psychiatric, and nutritional expertise is needed. This statement recommends that patients seeking surgical therapy be considered for treatment in a non-surgical program with integrated components of a dietary regimen, appropriate exercise, behavioral modification and support before surgery. This consensus statement also notes that patients who undergo weight loss surgery require lifelong medical surveillance.

The key findings in the ASBS consensus statement are:

- bariatric surgery is the most effective therapy available for morbid obesity;
- bariatric surgery can result in improvement or complete resolution of obesity-related comorbidities;
- it can be cost-effective before the fourth year of follow-up; and
- candidates should not be required to have completed formal non-operative obesity therapy as a precondition for the operation.²

Contrary to this surgeon point of view, non-operative therapy is probably appropriate for most patients in terms of an initial treatment step. Like the NIH statement, this group noted a multidisciplinary team should evaluate patients for appropriateness of surgery.

The key finding of the Blue Cross/Blue Shield Tech Assessment that was done at the beginning of 2007 is that LAGB surgery results in substantial weight loss of approximately 40 percent excess weight loss at one year with a substantial reduction in comorbidities.²⁵ As previously discussed, this assessment also noted that LAGB surgery is less risky than gastric bypass. Greater short-term weight loss with gastric bypass may be outweighed by operative risks.

The ECRI Institute assessment noted that three years after adjustable gastric banding, patients lose a clinically significant amount of weight.²⁶ In some patients, adjustable gastric banding results in the improvement or resolution of type 2 diabetes, hypertension, and sleep apnea. This assessment also stated that patients experience large improvements in quality of life when assessed up to four years after adjustable gastric banding.

For the morbidly obese patient, surgery may be a first option instead of wasting time and money trying other avenues. To achieve a significant weight loss and reduce comorbidity risks and costs in patients

with BMIs over 40, they need a surgical procedure to an appropriate weight.

Because major lifestyle changes are required after weight loss surgery, patients require a pre-operative psychiatric consultation. The patient has to be ready to not only manage themselves post-operatively but also for the long term. The multidisciplinary team carrying for the obese patient should include nutrition counselor, exercise counselor, and psychologist or psychiatrist. Patients should also be offered support group meetings.

Managed Care Coverage

Across the county managed care plan coverage and criteria for bariatric surgery is variable. Overall 180 million lives in the U.S. are now covered under some type of managed care medical policy making them eligible, if they meet the clinical criteria, for the LAGB. Fifteen commercial payers added LAGB policies covering 22 million lives in 2007. The Centers for Medicare & Medicaid Services (CMS) made a national coverage decision in 2006.

To approve a bariatric procedure, most plans are going to require documentation of previous medically supervised weight loss attempts, absence of correctable causes of weight gain such as thyroid disease, comorbidities, current weight, and current medications. Most of the plans require that the patient be at least 100 pounds over their ideal body weight or have the BMI over 40 kg/m². If the BMI is between 35 and 40, there have to be documented comorbidities. Some plans require the patient have functional impairment related to his/her weight. Some also have a duration requirement (i.e., obesity has been present for five years).

Conclusion

The United States has an obesity epidemic. Although lifestyle changes and anti-obesity medications can provide modest weight loss, many severely overweight patients will need bariatric surgery to achieve an acceptable weight. For people with a BMI over 40 kg/m², surgery is probably the treatment of choice. Successful, sustained weight loss requires a multidisciplinary approach by health care professionals and major lifestyle changes by the individual. **JMCM**

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