Obesity: Effective Treatment Requires Change in Payers' Perspective

Rhonda Greenapple, MSPH; Jackie Ngai, MS

Rhonda Greenapple

Background: Obesity is an increasing problem in the United States, and the health problems attributed to it have a significant economic impact on the healthcare system, as well as on patients' quality of life. In addition, childhood obesity is increasingly becoming a prominent diagnosis.

Objective: To identify physician and payer reactions to the profiles of 4 new obesity products in development and the potential that these will be prescribed by physicians and reimbursed by payers. This article examines payers' and physicians' perspectives in effective treatment options for this epidemic.

Method: A 2008 online survey conducted by Reimbursement Intelligence was completed by 42 physicians who are advisors to Pharmacy & Therapeutics Committees and see an average of 435 obese patients monthly, as well as 17 payers who represent more than 100 million covered lives. This research was double blinded to conceal product and client identification. Qualitative and quantitative data were collected from the survey responses.

Results: Based on the physician and payer survey responses, morbid obesity is expected to grow in the next 2 years. About 80% of morbidly obese patients have type 2 diabetes, but more than 75% of payers do not track patients who are obese, morbidly obese, or those with the metabolic syndrome. Despite its effect on business productivity and the cost of care, healthcare professionals and payers continue to have varying perspectives related to its prevention and treatment. Physicians would like to have more treatment options, but payers perceive them as ineffective and find the safety and adverse effect profiles unfavorable.

Conclusion: There is a clear need for multiple treatment alternatives to combat obesity that include plan member access to weight-loss options, such as prescription medications and bariatric surgery. There needs to be an increase in educational support from manufacturers of products for obesity, as well as increased awareness of products in the pipeline. [*AHDB.* 2010;3(2):88-94.]

Obesity is associated with many chronic diseases and is classified as a disease by several organizations, including the World Health Organization, the National Institutes of Health, the US Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).[1-4]

Observational epidemiologic studies have established a relationship between obesity and the risks for cardiovascular disease (CVD), non–insulin-dependent diabetes mellitus, certain types of cancer, gallstones, certain respiratory disorders, and an increase in overall mortality. Diabetes is on the rise in the United States, and approximately 90% of diabetes cases are attributed to excess weight.[5,6] Recent studies have also stated that pediatric obesity is on the rise, particularly among black and Latino populations, as well as those from lower socioeconomic groups.[7] New research has linked endoplasmic reticulum stress to a high-fat diet; this condition is overly activated in obese people and triggers aberrant glucose production in the liver, a step in the path to insulin resistance.[8]

Health problems attributed to obesity have a significant impact on the US healthcare system in terms of direct and indirect medical costs. Direct medical costs include preventive, diagnostic, and treatment services, whereas indirect costs relate to morbidity and mortality. In 2000, the CDC estimated that obesity-related healthcare costs totaled $117 billion.[9]

In October 2008, Reimbursement Intelligence conducted an online survey titled Payer and Physician Evaluation of Obesity Treatments, with the goal of examining the perspectives of commercial and government health plans on obesity. Respondents included

Ms Greenapple is President and Founder, and Ms Ngai is a medical writer for Reimbursement Intelligence, Madison, NJ.

payers representing more than 100 million covered lives, as well as 42 physicians who treat nearly 500 obese and/or morbidly obese patients monthly.

Obesity Prevalence

According to the CDC, more than one third of US adults (more than 72 million persons) can currently be categorized as obese—a body mass index (BMI) ≥30 kg/m^2—or morbidly obese.[10] Of more concern, 30.1% of children aged 2 to 19 years are overweight or obese.[7,11] Adults aged 40 to 59 years had the highest obesity prevalence compared with other age-groups, including approximately 40% of men in this age-group and 41% of women (**Figure 1**).[12]

In July 2009, a Robert Wood Johnson Foundation report indicated that obesity rates increased in 23 US states and did not decrease in a single state in the past year.[13]

The rate of obesity in school-aged children is rising, which will incur increased healthcare costs from use of the medical system and disease comorbidities. A recent study demonstrated that 61% of obese children aged 5 to 10 years have ≥1 risk factors for CVD, and 27% of children in that age-group have >2 CVD risk factors.[14] Currently, 20 states have passed legislation requiring BMI screening for children and adolescents to facilitate early intervention and improve healthy eating habits.[13] It is critical for health plans to manage obesity in younger patients, because it can save future costs that can extend for more than 60 years.

Obesity is also higher among black women and men compared with other demographics, who also have a greater incidence of diabetes and CVD.[10,15] This has created a need for intervention to stop the obesity epidemic. Based on a plan's unique patient population, the incidence and cost of obesity can be significant.

Calculation of BMI is the primary criterion for assessing obesity.[7] Easily calculated in the clinical setting, BMI correlates significantly with body fat, morbidity, and mortality.

Obesity-Related Comorbidities

A BMI of 25 kg/m^2 is the generally accepted threshold for identifying a patient at increased risk for obesity-related diseases, most notably type 2 diabetes, hypertension, and CVD. For those with a BMI above 25 kg/m^2, each extra 5 kg/m^2 results in an increased overall mortality risk of approximately 33%.[7] More than 80% of deaths estimated to result from comorbidities associated with obesity occur in patients with a BMI of at least 30 kg/m^2.[2]

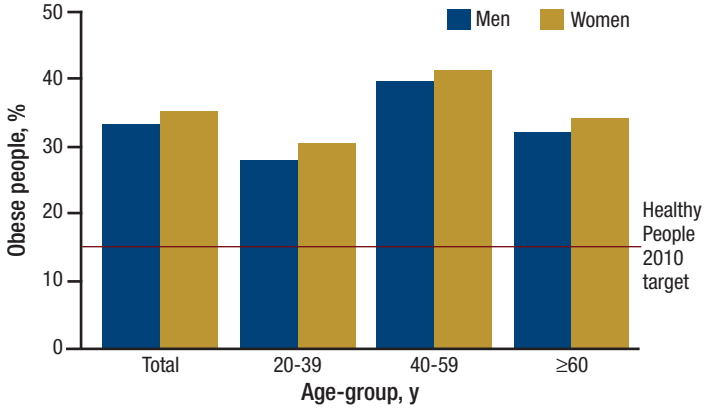
Increasing research shows that obesity-related comorbid conditions are becoming more prevalent. Researchers at Monash University recently established the link between obesity and diabetes.[16] Pigment epithelium-derived factor (PEDF, SerpinF1) was identified as a link between obesity and insulin resistance; increasing PEDF causes type 2 diabetes complications, while blocking the inhibitor reverses the effects.[16] The link will help other researchers develop better options for the treatment of obesity and diabetes.

The incidence of diabetes is on the rise, and so are the risks of comorbidities and associated illnesses. The

KEY POINTS

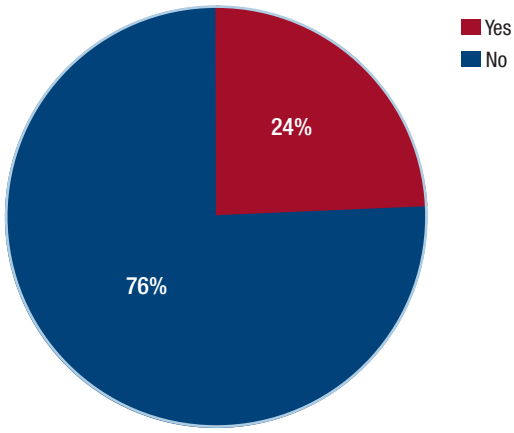
- More than one third (>72 million) of US adults can currently be categorized as obese. In 2000, the Centers for Disease Control and Prevention estimated that obesity-related healthcare costs totaled $117 billion.
- This article discusses the results of a recent survey of payers representing >100 million covered lives, as well as 42 physicians who treat nearly 500 obese patients monthly to examine their perspectives on obesity management.
- Only 24% of payers are tracking obese and morbidly obese patients, making it difficult to provide intervention and case management.
- Weight-loss drugs are not covered by many employers, because they are seen as "lifestyle drugs" or drugs that lack efficacy.
- Many physicians consider a 5% to 10% weight reduction in 6 months as needed to show efficacy of a new treatment plan. In contrast, payers require 18% weight loss to place a product on formulary.

Figure 1 Obesity Prevalence, by Age (≥20 years) and Sex, and the Healthy People 2010 Obesity Target, 2005-2006



Note: Obesity is defined as body mass index ≥30 kg/m^2.
Source: Centers for Disease Control and Prevention. Revised December 4, 2007. www.cdc.gov/nchs/data/databriefs/db01.pdf.

Figure 2 Is Your Plan Tracking Patients with Obesity, Morbid Obesity, or Metabolic Syndrome?



metabolic syndrome is characterized by the following risk factors[17]:

- Abdominal obesity
- Atherogenic dyslipidemia: blood fat disorders—high triglycerides, low high-density lipoprotein cholesterol, and high low-density lipoprotein cholesterol levels—that foster plaque buildups in artery walls
- Elevated blood pressure
- Insulin resistance or glucose intolerance (ie, the body cannot properly use insulin or blood glucose)
- Prothrombotic state (eg, high fibrinogen or plasminogen-activator inhibitor type 1 in the blood)
- Proinflammatory state (eg, elevated C-reactive protein levels in the blood).

A predecessor to type 2 diabetes and CVD, the metabolic syndrome is a cluster of illnesses that needs to be prevented, treated, and managed.

Results of our Payer and Physician Evaluation of Obesity Treatments survey show that just 24% of payers are currently tracking obese and morbidly obese patients, making it difficult to provide intervention.

Payer and Physician Evaluation of Obesity Treatments: Survey Results

Despite the importance of identifying and intervention with the population, results of our Payer and Physician Evaluation of Obesity Treatments survey show that just 24% of payers are currently tracking obese and morbidly obese patients, making it difficult to provide intervention and case management (**Figure 2**).

Health plans are more likely to identify these patients through other disease management initiatives for the metabolic syndrome, coronary artery disease, diabetes, and arthritis, for which data are being collected.

Although drug treatments for obesity are currently available, and promising new drug treatments are in development, payer respondents believe that bariatric surgery is more effective than medications for obesity therapy. Eighty-eight percent of payers indicated that their plan covers bariatric surgery, whereas nearly 50% of these payers report that less than 20% of employers cover drugs under a commercial plan. Payers are therefore far more likely to cover surgery than weight-loss medications.

This disparity may stem from the safety and efficacy "baggage" of past and current pharmacologic treatments for obesity, such as sibutramine (Meridia); the combination of fenfluramine and phentermine (fen-phen); and orlistat (Xenical), now available over the counter as alli.

In July 1997, researchers at the Mayo Clinic reported 24 cases of heart valve disease in patients who were taking fenfluramine-phentermine.[18] The FDA requested that fenfluramine hydrochloride (Pondimin) and dexfenfluramine hydrochloride (Redux) be withdrawn from the market in September 1997.[18]

Sibutramine was the first subsequent drug approved by the FDA for the treatment of obesity. According to the FDA, the long-term effects of sibutramine on morbidity and mortality associated with obesity have not been established. The drug also increases the sympathetic drive, heart rate, and blood pressure, which limit its use in hypertensive patients.[19]

Impact of Obesity on Employers

Several studies have addressed obesity from the viewpoint of employers. Results of a study that examined whether there is a progressive correlation between BMI, healthcare costs, and absenteeism showed that employees with a high BMI were more likely to have other health risks and took twice as many sick days than those who do not have a high BMI (8.45 vs 3.73 days, respectively).[20]

When total mean medical costs were analyzed by BMI level, a J-shaped curve was produced. The mean healthcare costs for the BMI-related at-risk population was $6822 compared with $4496 for the not-at-risk population.[20] The most important differences in healthcare costs were for employees aged ≥45 years. The excess cost associated with high BMI risk was $3514 overall.[20]

Obesity also has a substantial impact on healthcare costs for employers. In 2000, the estimated annual direct medical expenditures for obesity alone were $61 billion, accounting for a 12% increase in healthcare

spending from 1987 through 2001.[21] Additional studies showed an annual loss of 39.2 million more workdays among overweight and obese people compared with lean people (ie, BMI ≤25 kg/m^2).[21] Obesity also drives 85% of the total cost of treating type 2 diabetes, and 45% of the cost of treating hypertension, and points toward a $1500 increase per overweight or obese employee in annual healthcare costs.[22]

Based on the measurable impact of obesity on corporations' bottom lines, many companies are willing to offer increased benefits to the most at-risk employee population to help reduce or eliminate escalating costs related to overweight and obesity. Despite the significant medical costs associated with obesity, many employers are not covering weight-loss drugs. Nearly half of health plans indicated that merely ≤20% of their customers (ie, employers) cover obesity drugs (**Figure 3**). However, initiatives to help employers combat obesity in the workplace are emerging. Recently, the CDC launched the LEANWorks website, which contains tools and resources to help businesses implement an effective worksite obesity prevention and weight-control program.[23]

Reimbursement Issues Affect Treatment Options

Currently, weight-loss drugs are not covered by many employers, because they are seen as "lifestyle drugs" or drugs that lack efficacy. For a durable outcome, an obese member must make a lifestyle change. Coverage is often linked to or associated with a concurrent lifestyle change, such as a gym membership or a formulary approval for a specific period, after which, if a weight-loss goal is achieved, continued coverage is granted.

In the Reimbursement Intelligence study, payers reported that a limited number of employers cover these products under commercial plans (Figure 3). Many plans also use higher copayments and utilization restrictions to manage these products.

Reimbursement issues have had a measurable impact on physicians' treatment plans. Respondents to the Reimbursement Intelligence study ranked reimbursement as equally important to efficacy (65.9% vs 68.3%, respectively) and safety (61.0%) in their decision to prescribe—or not prescribe—weight-loss drugs (**Figure 4**).

Evaluation of New Weight-Loss Treatments

Based on survey responses, payers and physicians will be considering new drug therapies, many of which are now in late-stage development. However, their expectations regarding the level of weight loss that will be achieved with these potential new treatments vary considerably.

More than half of the physicians responding to the Reimbursement Intelligence study considered a 5% to 10% weight reduction as a minimum threshold to demonstrate the effectiveness of a new treatment plan after 6 months (**Figure 5**). In contrast, payers indicated that a minimum of 18% weight loss would influence their decision to place a product on their formulary and be reimbursed by the plan.

Figure 3 Percentage of Employers Who Cover Weight-Loss Medications

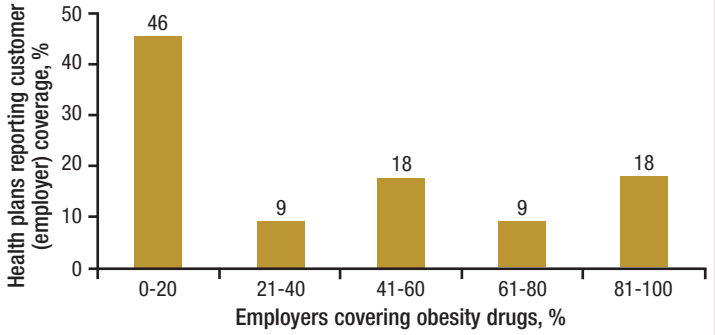


Figure 4 Influences on Physician Treatment Decision-Making

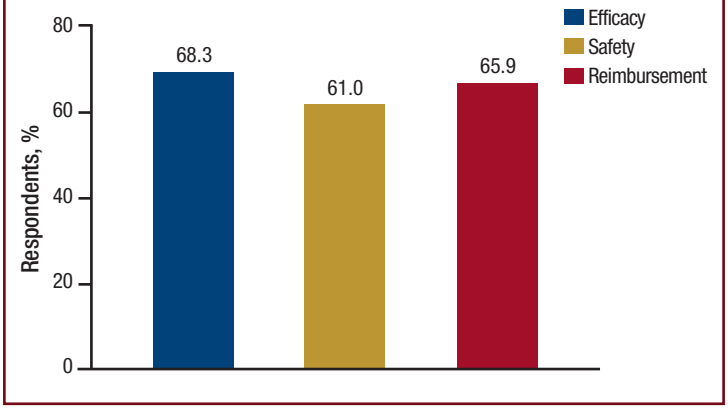


Figure 5 Minimum Weight-Loss Threshold for Demonstrating Effectiveness (Physicians)

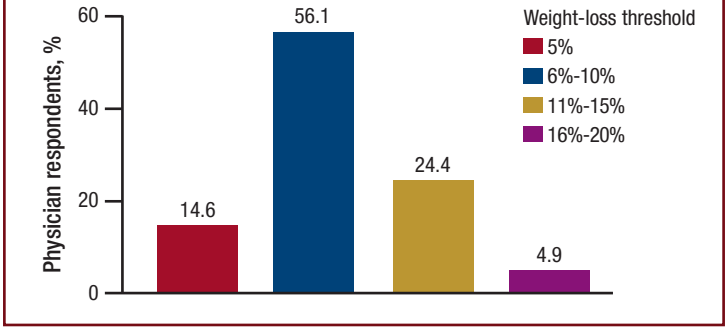


Figure 6 Payers' Comparison of Bariatric Surgery vs Weight-Loss Medication Efficacy

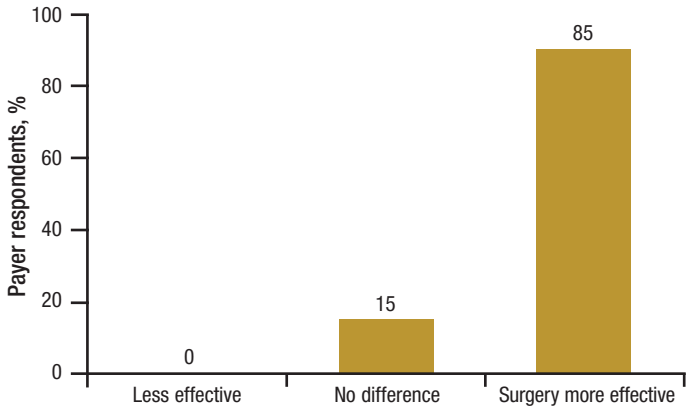
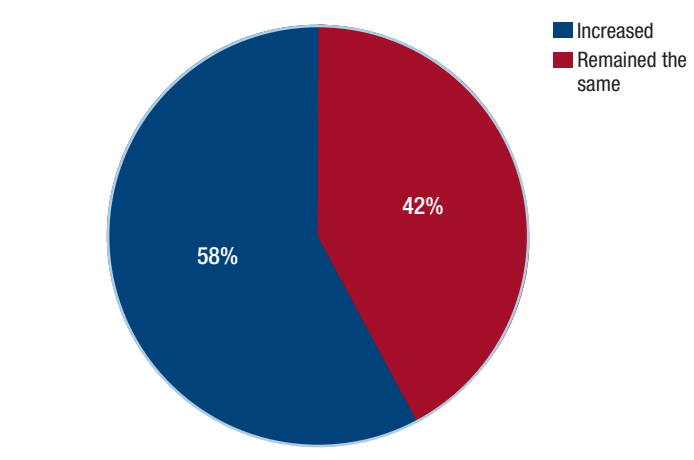


Figure 7 Bariatric Surgery Coverage in the Past 2 Years



The study asked payers and physicians to evaluate 4 pharmacologic products currently in the later stages of development:

- Naltrexone sustained release (SR)/bupropion SR
- Zonisamide SR/bupropion SR
- Lorcaserin hydrochloride
- Phentermine plus topamax.

Although physicians, and their patients, desire a variety of treatment options, payers require increased efficacy to consider formulary placement and the removal of utilization restrictions. In our survey, primary and secondary end points identified by respondent payers for new treatment options that influence coverage were:

- Long-term management of weight loss (1-2 years)
- Efficacy better than individual genetics
- Lower levels of cholesterol and blood pressure
- Tolerability, adverse events, and side effects.

Although the 4 drugs assessed in the study presented weight-loss results of 5% to 12%, nearly half of the payers surveyed indicated that they would be very unlikely to include the 4 drugs on their formulary. If covered, payers would most likely place all products on their third tier, and 50% to 90% of payers would implement prior authorization or quantity limit to control utilization. In contrast, between 23% and 35% of physicians stated that they would be very likely to prescribe some of these products (that are currently in development).

Nearly half of the payers surveyed indicated that they would be very unlikely to include the 4 drugs on their formulary.

Surgical Treatment Options

Bariatric surgery is considered when the patient's BMI is ≥40 kg/m^2 and the patient cannot lose excess weight through other methods, or when BMI is ≥35 kg/m^2 and is associated with comorbid conditions.

About 90% of physicians participating in the Reimbursement Intelligence study reported that they refer less than 20% of their patients for bariatric surgery. Conversely, nearly 85% of payers believe that bariatric surgery is more effective than prescription medication for obesity management (**Figure 6**). More than 40% of payers also indicated that bariatric surgery coverage has increased in the past 2 years (**Figure 7**).

New Approach to Childhood Obesity

A new modality worth further investigation is a new approach to the management of childhood obesity that involves secondary care or "referral-based specialized visits" by primary care teams within community health centers.[7] This new model for obesity care was developed by a team at the Healthy Weight Clinic in Massachusetts. This model promotes obesity management by combining the principles of a medical home, utilizing health information technology, and improving reimbursement to enhance the quality of care and improve outcomes.[7]

A Change in Perspective Needed

Currently, the majority of payers and healthcare providers hold differing viewpoints with regard to what constitute the most effective treatment options for obesity. Whereas payers set the formulary bar high for new products by seeking ambitious primary and secondary end points, physicians remain in search of flexible, effective treatment options for patients at varying levels of the obesity spectrum.

Significant steps must be taken by payers and by employers toward the availability and coverage of a variety of affordable treatment options to achieve a measurable level of obesity prevention and reduction among children and adults.

Conclusion

The past 20 years have witnessed a dramatic increase in obesity in the United States. Obesity has a major impact on disability, productivity, and life expectancy. Clearly, this is a multifaceted problem that demands an equally multifaceted solution—including lifestyle changes, drug treatments, and surgical options—to address and improve the health outcomes of obese and morbidly obese persons. No one-size-fits-all option is likely to have the efficacy needed to reduce the mounting healthcare costs and comorbidities associated with obesity. ■

Disclosure Statement

Ms Greenapple is a consultant to Celgene, Shire, and Takeda.

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STAKEHOLDER PERSPECTIVE

Payers' Incentives Are Not Aligned to Address the Obesity Epidemic

PAYERS: Payers are acutely aware of the rise in the prevalence of obesity and the economic impact associated with this phenomenon, in particular the medical costs to the healthcare system. But payers' motivations and incentives are not aligned to address the obesity epidemic in a meaningful way.

The deleterious health consequences of obesity are manifested years after the initial diagnosis or risk identification. Because payers often have a short tenure of coverage for obese members, they are not likely to pay for long-term preventive care for a disease process that will most likely manifest years down the road, unless they can realize a significant benefit in the shorter-term. Although a modest reduction in weight on an obese member can significantly reduce visceral fat (ie, fat surrounding the internal organs) and reduce comorbid risks, such modest improvements often fall below the threshold of outcome achievement in payers' benefit guideline consideration and renewal criteria.

Pharmaceutical interventions that do not achieve significant and persistent weight reductions are viewed by payers as marginally effective and often are tied to sequential criteria in the consideration for surgical (ie,

Continued

STAKEHOLDER PERSPECTIVE *(Continued)*

bariatric) interventions. Surgical interventions in obese patients have demonstrated short-term, durable benefits in terms of comorbid risk reduction, but long-term data are still relatively scarce.

Until payers align their incentives and agree to provide consistent and universal coverage for earlier, preventive interventions, even beginning with the adolescent population, the ability to address the growing epidemic of obesity in a meaningful way will not reach its full potential.

PATIENTS: Weight management, especially for those who are overweight (≥25 kg/m^2) and obese (≥30 kg/m^2), is difficult, because so many contributing factors influence this process. The pace of daily living, the ease and accessibility of fast foods, and the often sedentary lifestyle are just a few of these influences. Couple these with the increased financial burden associated with weight-reduction modalities, gym memberships, specialty food programs, and coinsurance of medical interventions, and the durability and success of any weight-reduction program diminishes over time.

Weight management, in particular weight reduction, is a long-term lifestyle commitment. Currently, our healthcare system encourages members to have and maintain healthy lifestyles, but as of now it does not incentivize these choices in a form of taking a position, such as zero copays on weight-loss drugs, free gym memberships, or discounts on specialty foods; rather, obese members bear a greater cost-sharing portion of such healthy lifestyle choices.

Jeff Januska, PharmD
Director of Pharmacy
CenCal Health
Goleta, CA

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