

# The Role of Managed Care Organizations in Obesity Management

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**O**besity (body mass index [BMI]  $\geq 30$  kg/m<sup>2</sup>)<sup>1</sup> is a challenge for all healthcare stakeholders. Gaining weight is easy; losing excess pounds, however, is difficult for most people, and it is especially hard as individuals get older and their metabolism slows naturally. People who lose weight the old-fashioned way—by cutting back on intake and increasing exercise—often regain some or all weight that they originally lost or gain even more. For people who are obese or extremely obese (BMI  $\geq 40$  kg/m<sup>2</sup>), diet and exercise are often insufficient to create the magnitude of change they need.<sup>2</sup> They may need additional tools.

Managed care organizations (MCOs) have 3 methods to help their members move toward optimal weight and better health: health and wellness/lifestyle modification activities, prescription weight-loss drugs, and bariatric surgical interventions.<sup>3,4</sup> Not all MCOs cover all of these interventions.<sup>5</sup> This article examines available evidence for weight-loss drugs and bariatric surgery and highlights MCO strategies and concerns.

## National Policy, Medical Acceptance

More than 25% of American healthcare expenses are attributed to the rise in the prevalence of excess weight and obesity.<sup>6,7</sup> Because of this and obesity-related medical complications, the US Department of Health and Human Services and the Department of Agriculture jointly established Dietary Guidelines Advisory Committee; they have characterized obesity as this century's greatest threat to American health.<sup>8</sup>

In June 2013, in an effort to elevate awareness of the importance of obesity management, the American Medical Association (AMA) House of Delegates declared obesity a disease. This was done despite concerns voiced by its Committee on Science and Health that BMI (the measure most often used to diagnose obesity), is, in its

## Abstract

In the United States, obesity is characterized as this century's greatest healthcare threat. The American Medical Association and several other large organizations now classify obesity as a disease. Several federal initiatives are in the planning stages, have been approved, or are being implemented to address the disease. Obesity poses challenges for all healthcare stakeholders. Diet and exercise often are insufficient to create the magnitude of change patients and their attending healthcare providers need. Managed care organizations (MCOs) have 3 tools that can help their members: health and wellness programs focusing on lifestyle changes, prescription weight-loss drugs, and bariatric surgical interventions. MCOs are addressing changes with national requirements and are responding to the availability of new weight-loss drugs to help their members achieve better health. A number of factors either deter or stimulate the progress of weight loss therapy. Understanding how MCOs are key to managing obesity at the local level is important for healthcare providers. It can help MCOs and individual healthcare providers develop and coordinate strategies to educate stakeholders and better manage overall care.

*Am J Manag Care. 2016;22:S197-S208*

For author information and disclosures, see end of text.

opinion, imperfect.<sup>3</sup> The committee noted that BMI is a crude predictor of cardiometabolic health and mortality.<sup>9</sup> The AMA took action in response to the increasing number of physicians urging them to do so, believing this would force MCOs to provide coverage of the many bariatric services not covered at the time. With this endorsement, the hope was that insurers would improve coverage of the full range of obesity interventions,<sup>10</sup> especially because many prescribers rank reimbursement as important as efficacy and safety when they prepare to prescribe weight-loss interventions.<sup>11</sup> Several organizations, including the National Institutes of Health,<sup>12</sup> the Obesity Society,<sup>1</sup> the American Association of Clinical Endocrinologists,<sup>13</sup> and the Endocrine Society,<sup>14</sup> have declared obesity a disease and recognize its complex nature. These organizations also have acknowledged the need for a variety of treatment and prevention interventions.<sup>3,12-14</sup>

Notably, a well-structured 2013 systematic review found that individuals with grade 1 obesity (BMI 30-35 kg/m<sup>2</sup>) and individuals of normal weight (BMI 18.5-25 kg/m<sup>2</sup>) have similar risks of all-cause mortality. Individuals who are heavier than 35 mg/kg<sup>2</sup>, however, are at increased risk of mortality.<sup>15</sup> Increased weight has also been shown to increase stigma, risk of mood disorders, poor body image, and bad eating habits,<sup>16</sup> as well as cause stress and decrease activity.<sup>17,18</sup> A newer tool, the Edmonton obesity staging system, has been used on a small scale since 2011; it addresses some of the BMI's shortcomings and augments clinical assessment. Its 5-point ordinal scale incorporates the individual's obesity-related comorbidities and functional status. Studies have shown it to be a strong, independent predictor of increasing mortality, and its clinical utility is evolving.<sup>19</sup> However, until experts develop a better measure of obesity, many stakeholders will continue to use BMI.

In 2014, the AMA House of Delegates took a further step to bring obesity into the limelight, resolving to campaign for patient access to all evidence-based obesity treatments, including pharmacotherapy.<sup>20</sup> These actions have no regulatory repercussions and are symbolic. Regardless, they heightened awareness of the nation's obesity problem and its ramifications. One possible measure of the impact of the AMA's actions may be the number of physicians certified as American Board of Obesity Medicine (ABOM) Diplomates since 2013. ABOM is the only organization that certifies physicians in obesity management, and the increasing number of certified providers reflects increasing acknowledgment that obesity is a complex disease that requires a special skill set to manage. The orga-

nization reports a record number of physicians applied to take the 2015 ABOM certification exam—a 27% increase from 2014. Today, ABOM has certified more than 1200 physicians from a wide range of medical specialties (eg, internal medicine, family medicine, endocrinology, and pediatrics) in North America.<sup>21</sup>

Other evidence highlighting the impact of obesity on society can be found in legislative and regulatory initiatives. In 2013, the Treat and Reduce Obesity Act was introduced in the US House of Representatives and Senate. If it had passed, this bill would have improved Medicare beneficiaries' access to weight-loss counseling and new prescription medications for chronic weight problems. Despite bipartisan support, it failed to gain the traction it needed to pass. It was reintroduced in May of 2015 and is without any recent action. This bill would require the Secretary of Health and Human Services to make recommendations to Congress within one year of its implementation, and every 2 years afterwards, to combat obesity; it remains in committee at this time.<sup>22</sup> A different federal action, the Medicare Shared Savings Program (MSSP), has established accountable care organization (ACO) measures that track BMI screening and follow-up. Experts estimate that more than 4 million Medicare beneficiaries will be affected.<sup>23-25</sup> In addition, to be accredited as an ACO by the National Committee on Quality Assurance (NCQA), organizations need to track BMI screening and follow-up. Screening for being overweight or obese is now on the nation's healthcare radar.

One ramification of the Affordable Care Act (ACA) passage was the creation of guidelines for preventive coverage with no cost share to members, based on US Preventive Services Task Force (USPSTF) recommendations. The ACA requires USPSTF A or B recommendations to be covered as preventive care. Because the USPSTF recommends screening all adults for obesity,<sup>26</sup> patients with a BMI of 30 kg/m<sup>2</sup> or higher should be offered or referred to intensive, multicomponent behavioral interventions. A range of obesity interventions should be covered. However, a 2014 study, funded by the Robert Wood Johnson Foundation, of states' classification of services as "essential" under the ACA found that 23 states categorized bariatric surgery as an essential health benefit, but only 5 states classified medical obesity treatment as essential.<sup>27</sup> These efforts are influencing coverage changes affecting the care of patients who are overweight or obese.

Since 2014, all health plans serving federal employees are required to cover weight-loss drugs.<sup>28</sup> Additionally, individual and small-employer group exchange plans

are required to cover intensive behavior counseling for patients with a BMI greater than 30 kg/m<sup>2</sup>. In the summer of 2015, the National Conference of Insurance Legislators resolved that state legislatures should provide for coverage of the full range of obesity treatment, including pharmacotherapy and bariatric surgery.<sup>29</sup> More changes are expected to follow.

### Managed Care Strategies

Historically, few FDA-approved medications have been specifically indicated for weight loss. Phentermine (Adipex-P) as a single agent was the only approved drug for weight management, but its long-term effectiveness was not established; most phentermine studies were shorter than 6 months in duration, and none of the studies met the FDA's current efficacy benchmarks.<sup>30</sup> Until mid-2012, orlistat (Xenical) was the only FDA-approved pharmacotherapy available for long-term use in the United States.<sup>31</sup> Since 2010, however, the FDA has approved 4 new obesity medications (lorcaserin [Belviq], phentermine/topiramate [Qsymia], bupropion/naltrexone [Contrave], and liraglutide [Saxenda]) based on approval criteria that each drug was associated with sustainable weight loss of 5% or more (on average or in more than 50% of patients treated).<sup>32-35</sup> In the managed care setting, certain facts about weight-loss drugs inform decisions:

- Long-term studies of the older noradrenergic agents (phentermine, diethylpropion, phendimetrazine, and benzphetamine) with long treatment durations, adequate sample sizes (more than 50 participants), or acceptable attritions are not available.<sup>30</sup>
- Many of the newer drugs were approved based on studies of longer duration that demonstrated sustained weight loss and durability of effect, and additional studies are being conducted.<sup>32-35</sup>
- Plans must consider the number of patients who may need or want these drugs, the potential for good outcomes, comparable drugs, and necessary support programs.<sup>36</sup>

### Pharmacotherapy

Often considered lifestyle drugs in the past, obesity-directed pharmacotherapy was routinely excluded from prescription benefit programs. For example, when the Medicare Part D program was created in 2003,<sup>37</sup> it contained a blanket exclusion for “agents when used for anorexia, weight loss, or weight gain.”<sup>38</sup> The Centers

for Medicare and Medicaid Services (CMS) reinforced this exclusion in July 2008, indicating the Part D benefit would not cover “agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose, ie, morbid obesity).”<sup>39</sup> Since Medicare Advantage plans (private insurance companies with federal contracts to provide Medicare benefits) were, and still are, allowed to exceed the scope of the Part D-defined benefit, some beneficiaries have coverage.<sup>23</sup> Attempts to amend Medicare coverage have been unsuccessful.<sup>22</sup>

In 2008, most health plans reported that fewer than 20% of employee benefit plans allowed coverage for obesity medications<sup>11</sup>; however, poor coverage for obesity medications has been identified as a key barrier to the innovation driving manufacturers to develop and introduce even better therapies than those currently available. Manufacturers are reluctant to invest in drugs that will rely primarily on out-of-pocket payments.<sup>23</sup>

A 2008 survey queried payers who represented approximately 100 million covered lives and 42 physicians who treat approximately 500 patients monthly who are obese. It found that payers continued to categorize weight-loss drugs as lifestyle drugs, or drugs that lack efficacy. Although physicians considered any treatment associated with weight loss of 5% to 10% over 6 months effective, payers required evidence of weight loss of 18% to add a pharmaceutical to their formularies. Payers indicated that they considered bariatric surgery more effective; 88% of payers covered weight-loss surgery. Plans that did cover weight-loss drugs often used high copayments and utilization restrictions to manage these products.<sup>11</sup> It is unclear if physician beliefs have changed in the intervening years. Limited pharmacotherapy coverage leaves clinicians and patients with substantial gaps in their options.

In January 2015, several media outlets reported that although two-thirds of adults are overweight or obese, coverage of weight-loss medications is limited. This report noted one-third of companies did not cover anti-obesity drugs, one-third covered approved drugs with restrictions to limit their use, and one-third covered all FDA-approved weight-loss drugs without restrictions. A spokesperson for America's Health Insurance Plans, a trade association, indicated that variability of insurer coverage of anti-obesity drugs emanated from questions about safety and effectiveness evidence.<sup>40,41</sup> One analyst referred to a 2014 study<sup>42</sup> as support for the insurers' position.

Notably, the effort to define obesity as a disease may have negative consequences. A study by Hoyt and colleagues found that defining obesity as a disease—implying

that bodies, physiology, and genes are malfunctioning—encourages perceptions that weight is unchangeable. The researchers enrolled 185 patients in one study and 182 patients in a subsequent (second) study. The study randomized patients to read a *New York Times* article discussing the AMA's decision to categorize obesity as a disease or read an article offering standard information-based public health messages about weight. Then, they conducted a third study that sent a different message: that obesity is *not* a disease. Findings revealed that participants were more likely to see themselves as healthier and eat more unhealthy food if their overweight status was classified as a disease. For the researchers carrying out the study, the findings implied a sense of demotivation in the subjects with excess weight. The study authors concluded, "this message [that obesity is a disease] cultivates increased body satisfaction, but also undermines beneficial self-regulatory processes in obese individuals." When patients saw their weights as fixed, they also inferred the problem was out of their control. This perception increased with increasing body weight.<sup>42</sup>

### Managed Care Considerations

MCOs consider a number of factors when determining formulary placement of drugs. Concerns regarding long-term durability, long-term patient adherence, and impact on meaningful clinical end points have all been considered by MCOs in coming to the formulary determinations. Good quality evidence of long-term effectiveness is critical. Currently, most evidence for weight-loss drugs is for periods of one year or less. A 2014 meta-analysis, however, provided some evidence of the long-term effectiveness of anorexic drugs.<sup>30</sup>

This meta-analysis included studies published before September 2013 and defined long-term use as use for one year or more. It determined that long-term use of obesity medications, as an adjunct to lifestyle interventions, produced weight loss ranging from 3% for orlistat and lorcaserin to 9% for maximum-dose (15/92 mg) phentermine/topiramate ER compared with placebo. It found the proportion of patients achieving clinically meaningful (weight loss  $\geq 5\%$ ) results was 37% to 47% for lorcaserin, 35% to 73% for orlistat, and 67% to 70% for maximum-dose phentermine/topiramate-ER. A key finding was that patients who took these drugs had improvements in cardiometabolic risk factors better than the placebo groups. However, none of the studies included demonstrated reduced cardiovascular morbidity or mortality. This meta-analysis also found noradrenergic medications (phentermine, diethylpropion, phendimetrazine, and benzphetamine, which have only

been approved for short-term use) were most frequently used long term and off label by providers. The meta-analysis concluded that discontinuing medication in patients who do not respond with weight loss of at least 5%, and who, therefore, have little prospect of long-term benefit, could decrease risks and costs for patients.<sup>30</sup>

### Adherence: a Concern

MCOs have often cited adherence and persistence to medications as rationale for preventing coverage of weight-loss medications, noting that real-world evidence has not been generated to support outcomes consistent with the randomized controlled trials. Although no studies have been published specifically assessing adherence to weight-loss medication, a few have looked at adherence to weight-loss programs in managed care. These may form models by which incentives to increase adherence to weight-loss drugs could be developed. All of these drugs require adherence to lifestyle interventions to be effective. For example, a 2013 study by Rothberg and colleagues evaluated 3 interventions intended to result in weight loss. In this study, an MCO identified 1138 adult patients who were obese and offered them paid enrollment in weight-management programs. The plan also volunteered to move participants into better (enhanced) benefit levels. Participants selected an in-house intensive medical weight-management program (n = 153), a commercial weight-loss program (n = 439), or a commercial pedometer-based walking program (n = 432). The offer was declined by 114 members. The researchers assessed BMI, blood pressure, lipids, glycated hemoglobin (A1C) or fasting glucose, and per-member per-month costs one year before and one year after program implementation.<sup>43</sup>

At one year, 79% of participants remained in their preferred programs and had attended more than 80% of required sessions. All participants experienced improved clinical outcomes and reduced rates of increase in direct medical costs, compared with the 10% of members who declined participation. Women were more likely to choose the commercial weight-loss program, while men preferred the pedometer-tracked walking program. The researchers found that in the short-term, these interventions were not cost-saving and pharmacy costs were unchanged; however, participants' direct medical costs did not grow over one year, while non-participants' costs did. In addition, researchers projected that, over time, this program would recoup the investment and save money.<sup>43</sup>

A February 2016 study by Patel and colleagues assessed financial-incentive designs to increase physical activity

and enrolled 281 adult employees with BMIs of 27 kg/m<sup>2</sup> or more and a mean BMI of 33.2 kg/m<sup>2</sup>. The researchers randomly assigned participants to one of 4 arms (control group with daily feedback or 1 of 3 financial-incentive programs with daily feedback). The financial incentives included a gain incentive (\$1.40 given each day the goal was achieved), lottery incentive (daily eligibility [expected value approximately \$1.40] if goal was achieved), or loss incentive (\$42 allocated monthly upfront and \$1.40 removed each day the goal was not achieved). Participants were given a 7000-step daily goal and followed for 13 weeks initially, and then 13 weeks with daily performance feedback but no incentives. A key component of the program was use of smartphone technology to monitor steps, an intervention that the researchers described as requiring little effort from participants.<sup>44</sup>

Participants in the control group met their goals 30% of the time. Participants in the gain-incentive, lottery-incentive, and loss-incentive groups met their step goals 35%, 36%, and 45% of the time. Although the loss-incentive group had a significantly greater mean proportion of participant days achieving the goal than control, the adjusted difference in mean daily steps was not significant. During follow-up, at least 95% of participants completed the 13-week intervention, but daily steps decreased for all incentive groups and were similar to control levels.<sup>44</sup>

Aside from financial incentives, MCOs continue to explore other cost-effective and easy-to-implement strategies to improve adherence and compliance for their large member populations. One area that has been explored is the use of technology to counsel or encourage patients to lose weight or maintain weight loss. A 2006 study of weight-loss interventions in a managed care setting randomized patients (n = 1801) to 1 of 3 arms: usual care (which included low-cost weight-management programs), 30 mailers, or 30 phone interventions. The researchers followed the study intervention and patients' participation in other weight-related programs for 24 months.<sup>45</sup>

Patients in the mail and phone groups reported weight losses of 2.2 kg and 2.4 kg, respectively, at 18 months, while those in the usual care group reported a median loss of 1.9 kg. Thus, all groups lost a similar amount of weight. The researchers found similar results at 24 months, with weight losses of 0.6 to 1 kg reported. They saw that participation dropped after 6 months, and those who continued to participate were more likely to lose or maintain their weight. The cost-effectiveness of phone counseling was \$132/kg of weight lost, and for mail and

usual care, cost-effectiveness was approximately \$72/kg of weight loss. These researchers concluded that to be successful, interventions need strong behavioral messages and engagement strategies.<sup>45</sup>

With mail and phone communication rapidly becoming outdated, interventions that use modern technology are the next step in weight-loss interventions. In 2015, Levine and colleagues published a systematic review that assessed technology-assisted weight-loss interventions in the primary care setting. Studies evaluated were published between January 2000 and March 2014. They found 16 studies, 12 of which reported positive results of 0.08 to 5.4 kg of weight loss compared with controls. In these studies, 5% to 45% of patients lost at least 5% of baseline weight. Forty-four percent of the trials used physicians as the lead healthcare clinician, although programs led by other personnel tended to have better results. Most of the studies had patients monitor their own weight, and 63% employed web-based applications.<sup>46</sup>

The researchers found that interventions with clinician-guided software or feedback from personnel seemed to be associated with more weight loss than fully automated interventions. Only 1 study with a fully automated program was a positive trial; 11 of the studies with personnel-delivered feedback were positive. Because self-monitoring, in-person and remote feedback, and targeted, structured lifestyle coaching are proven weight-loss tools, this was not surprising. Unfortunately, only 2 of the studies used publicly available technologies, and the authors noted that, in terms of pragmatism, many of the interventions were intrusive or inflexible.<sup>46</sup> However, these types of interventions still hold promise.

The studies described above demonstrate that lifestyle interventions and the use of various tools can help clinicians offer potential benefits to patients trying to lose weight, but they remain an adjunct to an overall weight-loss plan. Most patients lost only small amounts of weight during these studies. The Endocrine Society's clinical practice guideline unequivocally states that using approved weight-loss medication (vs no pharmacologic therapy) promotes long-term weight maintenance and amplifies adherence to behavior changes. They reiterate that weight-loss drugs ameliorate comorbidities such as hypertension, dyslipidemia, type 2 diabetes (T2D), and obstructive sleep apnea.<sup>47</sup>

#### **Patient Education**

Patients' understanding of their care remains a linchpin to achieving desired outcomes for any chronic condition.



■ **Table 1.** Patient Education Resources for Weight-Loss Drugs<sup>3,6,32-35,48-54</sup>

Weight-Loss Drug	Counseling Aides
<b>Liraglutide</b>	Risk Evaluation and Mitigation Strategy (REMS) to communicate the potential risk of adverse effects, including medullary thyroid carcinoma and pancreatitis that could occur during treatment with liraglutide. As part of the program, the manufacturer provides a Medication Guide that can be dispensed with each prescription. It is part of the product's labeling and a helpful counseling template.
<b>Lorcaserin</b>	Clinicians can refer to the package insert for patient counseling guidelines.
<b>Naltrexone/bupropion</b>	Medication Guide included in its labeling.
<b>Phentermine/topiramate</b>	REMS to increase awareness of congenital malformations, specifically, orofacial clefts, in infants exposed to phentermine/topiramate during the first trimester of pregnancy. As part of the program, the manufacturer provides a Medication Guide. The FDA requires pharmacies to dispense the Medication Guide with each prescription. It is part of the product's labeling and a helpful counseling template.
<b>Sympathomimetic anorexiant (benzphetamine, diethylpropion, phendimet- razine, and phentermine)</b>	Each drug's label includes information that clinicians need to share with patients.

Understanding the pathophysiology of the condition, including the reasons for the chosen approach and the benefits and risks of the treatments, helps better engage patients in their care. In addition, these patients are more likely to succeed in achieving mutually agreed-on goals. Healthcare providers, such as pharmacists and physicians, need to work closely with patients to ensure they understand the tools available to them and use the tools correctly. With pharmaceuticals, patients need comprehensive counseling and close monitoring. Each product has unique side effects and properties, and clinicians need to be familiar with key counseling points (Table 1<sup>3,6,32-35,48-54</sup>).

Obesity is like other chronic conditions and remains a challenge to manage. The prospect of making lifelong changes is daunting for patients, and interventions are costly for healthcare payers. Health at Every Size (HAES) is a trans-disciplinary movement that proposes a shift in focus to weight-neutral outcomes. Proponents have conducted randomized, controlled clinical trials and found significant and clinically relevant outcomes. These include improved blood pressure, blood lipids, health behaviors, and psychosocial outcomes. Advocates for HAES indicate that the program achieves these health outcomes more successfully than weight-loss treatment and with less stigma than weight-focused programs.<sup>16</sup>

Patient success is often contingent on support from the healthcare team. Clinical management interventions, often called intensive behavioral therapy (IBT) and/or lifestyle modification, are covered elsewhere in this supplement. Although clinical trials of IBT often have promising results, they generally yield modest effects on glycemic control, cardiovascular risk factors, and

BMI.<sup>36,55-59</sup> Documented success in real-world settings has been elusive.<sup>23</sup> Interventions used in clinical trials are often more resource-intensive than the typical healthcare plan will cover. Unreimbursed expenses associated with training time for the multidisciplinary team and multiple-patient visits for office visits or group sessions make this approach less tenable for many providers and health systems.<sup>14,23</sup> Physicians often lack the tools or support systems to address weight management and are forced to manage its consequences instead.<sup>13,14</sup>

As more effective long-term medications become available, guidelines for the management of obesity have been in a state of flux. Several guidelines are now available that address obesity (Table 2<sup>1,43,47,54</sup>). They advocate for a weight reduction of 5% or more and to prevent further weight gain; weight loss of this magnitude can significantly improve T2D, cardiovascular disease, and quality of life. Some also recommend medications approved for chronic weight management as an adjunct to behavioral therapy for diet and exercise. The guidelines also make an important tangential point: medications that patients who are overweight or obese take for comorbidities may have adverse effects on their BMIs.

### Bariatric Surgery

For many patients who have been unsuccessful in achieving their weight-loss goals, bariatric surgery remains an intervention of last resort. Recent published studies have shown the positive impact of bariatric surgery on patients with T2D who were not obese. Increasingly, bariatric surgery is being considered as an earlier treatment choice. Most widely used methods of bariatric surgery

■ **Table 2.** Guidelines for Overweight and Obesity Management<sup>1,43,47,54</sup>

Guideline	Includes Bariatric Surgery	Includes Pharmacotherapy
<b>2013 American Heart Association, American College of Cardiology, and the Obesity Society Joint Guideline (for adults)</b>	Adults with a body mass index (BMI) $\geq 40$ kg/m <sup>2</sup> or BMI $\geq 35$ kg/m <sup>2</sup> with obesity-related comorbid conditions who have not responded to behavioral treatment with or without pharmacotherapy	No
<b>2015 Endocrine Society, the European Society of Endocrinology, and the Obesity Society Joint Guideline for the Pharmacologic Management of Obesity</b>	Individuals with BMI $\geq 40$ kg/m <sup>2</sup> or individuals with BMI of $\geq 30$ kg/m <sup>2</sup> and comorbidities	Yes
<b>2014 Veterans Administration/ Department of Defense Clinical Practice Guideline for Screening and Management of Overweight and Obesity</b>	Offer as adjunct to comprehensive lifestyle intervention <ul style="list-style-type: none"> <li>• Adult patients with a BMI <math>&gt;40</math> kg/m<sup>2</sup> or those with BMI 35-39.9 kg/m<sup>2</sup> with 1 or more obesity-associated conditions.</li> <li>• Some adult patients with BMI <math>\geq 35</math> kg/m<sup>2</sup> to improve certain obesity-associated conditions</li> </ul>	Offer as adjunct to comprehensive lifestyle intervention, when lifestyle interventions alone do not produce the desired weight loss: <ul style="list-style-type: none"> <li>• Phentermine/topiramate extended-release to patients with BMI <math>\geq 30</math> kg/m<sup>2</sup> and to those with a BMI <math>\geq 27</math> kg/m<sup>2</sup> who also have obesity-associated conditions</li> <li>• Orlistat or lorcaserin to patients with BMI <math>\geq 30</math>kg/m<sup>2</sup> and to those with BMI <math>\geq 27</math> kg/m<sup>2</sup> who also have obesity-associated conditions</li> <li>• Orlistat, lorcaserin, combination phentermine/topiramate extended-release to patients with obesity-associated conditions</li> <li>• Continued medication use for weight maintenance to patients who achieve weight-loss goals</li> </ul>

rely on either restrictive methods, such as laparoscopic adjustable gastric banding or sleeve gastrectomy, or mal-absorptive methods, such as Roux-en-Y gastric bypass or duodenal switch procedures. Bariatric surgery is associated with up to a 75% to 80% loss of the patient’s excess weight. Only gastric bypass surgery has demonstrated long-term efficacy (although it is sometimes not sustained) for patients who are morbidly obese, but it has associated morbidity and mortality risks.<sup>23</sup> Not everyone is a candidate for surgery. Surgeons will screen patients to ensure they are healthy enough to tolerate the selected surgical procedure, and they will also screen for psychological health and the ability to understand the need to make major lifestyle changes after surgery.<sup>60</sup> Long-term risks include bowel obstruction, dumping syndrome (diarrhea, nausea, vomiting), gallstones, hernias, hypoglycemia, and malnutrition.<sup>2</sup>

Many MCOs do not cover bariatric surgery for the same reasons weight-loss medications have faced barriers. Early bariatric surgery had a number of problems and outcomes were not guaranteed. State and federal legislation have increased the requirements for many MCOs to cover at least some of the procedures, but complete insurance coverage remains unavailable for many patients. Improvements in operative techniques and post-operative

management, such as the development of laparoscopic surgery, have reduced much of the post-operative morbidity and associated costs. This has caused some MCOs to rethink their coverage positions and open coverage to some, if not all, procedures.<sup>23,61,62</sup> A number of studies provide data about long-term outcomes (Table 3<sup>61-65</sup>).

By comparing the indications for weight-loss drugs and the indications for bariatric surgery, it is clear that patients with BMIs of 35 kg/m<sup>2</sup> or higher with weight-related illnesses now have the option between surgery and FDA-approved drugs.<sup>1,32-35</sup> For most patients with a BMI between 30 and 35 kg/m<sup>2</sup>, medication is the only option besides support programs.

Notably, whether treatment is medication or surgery, both remain tools that should be viewed as bridges to facilitate weight loss, allowing patients to make lifestyle and dietary changes to guarantee long-term success. Without permanent lifestyle and dietary change, no intervention has long-term success. Patients will typically return to their pre-intervention weight and often rebound to a higher weight.

**Managed Care and Pharmacologic Coverage**

Several determinants influence MCO decisions to add—or not to add—a weight-loss drug to the formulary.

■ **Table 3. Studies of Long-term Follow-up After Bariatric Surgery**<sup>61-65</sup>

Lead Author	Study Size	Years of Follow-up	Key Findings
<b>Sjöström 2004</b>	4047 (2 years) 1703 (10 years)	10	<ul style="list-style-type: none"> <li>• After 2 years, control group's average weight increased 0.1%; surgery group's weight decreased 23.4%</li> <li>• After 10 years, control group's average weight increased 1.6%; surgery group's weight decreased 16.1%</li> <li>• The surgery group's energy intake was lower and physical activity was higher than control group's</li> <li>• Surgery group's rates of recovery from type 2 diabetes (T2D), hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, and hyperuricemia better than control group's</li> <li>• Hypercholesterolemia was similar between groups</li> </ul>
<b>Adams 2012</b>	1156	6	<ul style="list-style-type: none"> <li>• At 6 years, Roux-en-Y gastric bypass (RYGB) surgery patients lost 27.7% of their initial body weight compared with 0.2% gain in control group 1 and 0% in control group 2</li> <li>• 94% and 76% of patients receiving RYGB surgery maintained at least 20% weight loss 2 and 6 years after surgery, respectively</li> <li>• T2D remission rates 6 years after surgery were 62% in RYGB surgery group, 8% in control group 1, and 6% in control group 2</li> <li>• Incidence of T2D throughout course of study was reduced after RYGB surgery compared with control groups</li> <li>• 33 (7.9%), 13 (3.9%), and 6 (2%) participants were hospitalized with bariatric-related complications in RYGB surgery group and 2 control groups, respectively</li> </ul>
<b>Ricci 2015</b>	4160	2-5.4	<ul style="list-style-type: none"> <li>• Average body mass index (BMI) fell from 45.2 kg/m<sup>2</sup> at start of observation period to 31.7 kg/m<sup>2</sup> at end</li> <li>• Relative risk of T2D, hypertension, and hyperlipidemia decreased, with relative risks of 0.33, 0.54, and 0.33, respectively</li> <li>• BMI decrease of 10 kg/m<sup>2</sup> resulted in decreased hypertension risk</li> <li>• Risks of all cardiovascular outcomes plateaued 20-40 months after surgery</li> </ul>
<b>Bolen 2012</b>	22,693	5	<ul style="list-style-type: none"> <li>• Surgery patients were 1.9 times more likely to experience a serious adverse clinical outcome and 1.3 times more likely to be hospitalized within one year of surgery</li> <li>• Patients were at elevated risk for serious events for 4 years, and for less serious outcomes and hospitalization for 5 years</li> <li>• Some complication rates were lower for patients undergoing laparoscopic surgery; researchers favored this approach</li> <li>• Planned procedures (eg, skin reduction) peaked in first 2 postsurgical years and remained elevated through year 5</li> <li>• Surgery patients had a 55% decreased risk of obesity-related comorbidities in first year post-surgery; their risk stayed low through 5 years</li> </ul>
<b>Kolotkin 2012</b>	323	6	<ul style="list-style-type: none"> <li>• Surgery patient's health-related quality of life (HRQOL) was significantly improved in most aspects at 6 years compared with 2 nonsurgical obese groups</li> <li>• Participants' HRQOL was relatively stable through year 6 despite some weight regain</li> </ul>

**Table 4**<sup>7,22,30,65-72</sup> illustrates some of the deterrents and triggers encountered by MCOs in making their coverage decisions.<sup>7,23, 31,65-73</sup> MCOs rely on evidence to make decisions, and often it takes time for researchers to assemble the type of information needed. As data documenting the cost benefit of medical weight management accumulates, and federal mandates to increase coverage are implemented, managed care coverage will increase.

**Examining the Triggers for Coverage**

Several triggers—federal mandates, quality measures, and guidelines—are currently being developed, publi-

cized, and implemented. As all stakeholders in obesity become more aware of available interventions and the potential for successful weight reduction, acceptance will grow. Regarding cost savings, Cawley and colleagues demonstrated that health plans could expect savings of approximately \$2000 per year in medical costs when a patient whose BMI exceeds 40 loses at least 5% of baseline weight; the greatest savings accrue from the first 5% of weight loss. Patients who have comorbid T2D also benefit from reduced risk of progression to significant comorbidities, so the savings are expected to be greater.<sup>74</sup> Given the steep rise in T2D medication prices over the



■ **Table 4. Determinants That May Influence Formulary Decisions About Weight-Loss Drugs and Surgery**<sup>7,22,30,65-72</sup>

Deterrents	Activators
<ul style="list-style-type: none"> <li>• Concerns about poor efficacy of early agents</li> <li>• Memory of adverse effects associated with early drugs, and especially                             <ul style="list-style-type: none"> <li>» Fenfluramine/phentermine’s association with valvular heart damage, primary pulmonary hypertension, and other severe complications associated with long-term use and its withdrawal from the market</li> <li>» Rimonabant’s depression and suicidal reactions and its withdrawal from the European market in 2008</li> <li>» Sibutramine’s association with cardiovascular risks and its withdrawal in 2010</li> <li>» Orlistat’s propensity to cause bloating, flatulence, and diarrhea</li> </ul> </li> <li>• Low rates of insurance reimbursement, despite clinical guidelines recommending anti-obesity drugs</li> <li>• Lack of evidence from registry trials demonstrating sustained and meaningful weight loss and its impact on chronic medical conditions</li> <li>• Physicians’ perceptions of obesity as a chronic condition, but knowledge gaps about weight reduction’s impact and beliefs that it is best managed with life-style interventions</li> <li>• Concerns about bariatric surgery’s financial burden, with average cost of approximately \$20,000 per procedure and an eligible population of 14.5 million adults</li> <li>• Historical experience with catastrophic complications from bariatric procedures, with costs per case in the hundreds of thousands of dollars</li> <li>• Lack of coverage by Affordable Care Act Exchange benchmark plans</li> </ul>	<ul style="list-style-type: none"> <li>• Federal/state coverage mandates</li> <li>• Growth of quality-driven healthcare initiatives (eg, NCQA, HEDIS, Star measures)</li> <li>• Guidelines that recommend weight-loss medications and bariatric surgery</li> <li>• Perception that weight-loss medications will eventually be mandated to be covered</li> <li>• Competitor coverage by other payers</li> <li>• Real-world evidence pilot programs</li> <li>• Pharmacy benefit manager support</li> <li>• Physician/patient demand</li> <li>• Employer demand</li> <li>• Published data demonstrating improved mortality in post-bariatric surgery patients</li> <li>• Documented medical cost offsets associated with drug use or bariatric surgery</li> </ul>
<p>HEDIS indicates Healthcare Effectiveness Data and Information Set; NCQA, National Committee for Quality Assurance.</p>	

last 2 to 3 years, with prices increasing more than 25% for the category, pharmacologic cost offsets will allow the cost offset from surgery to accrue quicker. Actual cost savings to the plan and members will also occur in a timeframe meaningful to most MCOs.

In the elderly population alone, Medicare could save a considerable amount of money if seniors with BMI greater than 30 (or >27 with at least 1 weight-related comorbidity) lost 10% to 15% of their weight using weight-loss drugs. Permanent weight loss of 10% to 15% is estimated to save \$9445 to \$15,987 in gross per capita savings over a lifetime, \$8070 to \$13,474 over 10 years. Even if patients regain some weight, Medicare could accrue estimated savings of \$7556 to \$11,109 over each patient’s life, \$6456 to \$8911 over 10 years.<sup>75</sup>

Additionally, medically supervised weight loss can significantly decrease medication expenses associated with obesity comorbidities, especially T2D. Cawley’s 2012 research retrospectively analyzed data from 589 obese patients, mean age 49, who participated in a weight-loss program for at least 16 weeks between 2009 and 2012. At baseline, patients took an average of 4.6 medications, of which 1.6 were for hyperlipidemia, gastrointestinal reflux disease, hypertension, or T2D. Patients chose from 3 types of 1200-calorie-a-day meal plans after counseling: 40% chose complete meal replacement, 40% chose 800 calories

from meal replacements plus one regular meal, and 20% followed a tailored healthy diet. The program offered weekly physician visits and weigh-ins, counseling sessions with a dietitian and an exercise physiologist, and group education and discussion sessions. Patients in all arms lost roughly 17.5% of their initial body weight. The average overall monthly wholesale cost of the studied medications fell from \$150 to \$77, with the largest reduction in T2D medications. One shortcoming of this study is that it did not factor in the annual cost of the weight-loss program (\$2000/patient).<sup>7,74</sup>

Increasingly, guidelines promote use of weight-loss medications for initial weight loss and for long-term weight maintenance. They indicate that weight-loss medications ameliorate comorbidities and amplify adherence to behavior changes. Prescribing these drugs may improve physical functioning and allow individuals who are obese to engage in more physical activity.<sup>47</sup>

**Conclusion**

Obesity is a chronic condition with multiple factors, internal and external to the individual, contributing to its development and maintenance. Regardless of the contributing factors, obesity is a primary driver of health-care costs because of its association with many comorbid conditions. Studies have demonstrated that losing weight to a normal range, at nearly any age, results in improved

health and quality of life and leads to cost savings. More studies are needed, however, to identify long-term (5- to 10-year) gains achieved by employing weight-loss strategies, including pharmacologic, conservative, or surgical ones.

However, because obesity is a complex condition with multiple contributing factors, the most effective approach to achieving successful long-term weight loss would seem to be a multidimensional/multipronged one, using all currently available tools. It seems reasonable to consider pharmacologic management, in addition to vigorous lifestyle and dietary management, and possible surgical interventions for all individuals with obesity. Clinicians will need to tailor this multimodal approach to individual patients. Pharmacists can play a crucial role in bridging the gap between patients and their physicians and educating them about the various resources at hand to better optimize their care.

The cost-effectiveness of the interventions needs to be addressed. Current studies lack the economic evidence to support many MCOs providing coverage for pharmacologic, surgical, or even conservative lifestyle interventions. It is paramount that pharmaceutical manufacturers invest in longer-term studies that will demonstrate not only the clinical efficacy of the medications, but the cost-effectiveness of the products long-term to garner greater MCO coverage. Surgical procedures also need to demonstrate meaningful and timely medical cost offsets in a real-world setting. As the population ages, obesity becomes ubiquitous, and demand for coverage of perceived efficacious therapies grows; it is imperative that evidence be developed to allow for reasonable coverage policies to be made.

**Author affiliation:** SelectHealth, Salt Lake City, UT.

**Funding source:** This activity is supported by educational grants from Novo Nordisk and Takeda Pharmaceuticals U.S.A., Inc.

**Author disclosure:** Dr Schaecher has no relevant financial relationships with commercial interests to disclose.

**Authorship information:** Concept and design, drafting of the manuscript, and critical revision of the manuscript for important intellectual content.

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