Is it Time to Rethink Obesity Drug Coverage?

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Obesity has been identified as a public health crisis in the United States for years. However, the subpar clinical performance of past weight loss medications has rightly led to access restrictions by plan sponsors that limit exposure to low value options. Recent and pending drug approvals have shown better outcomes within clinical trials that may completely shift how we approach treatment and make a compelling case in favor of coverage of obesity products. It is important for employers to understand the new clinical landscape and potential strategies to manage this expanding drug class.

Obesity Coverage Background

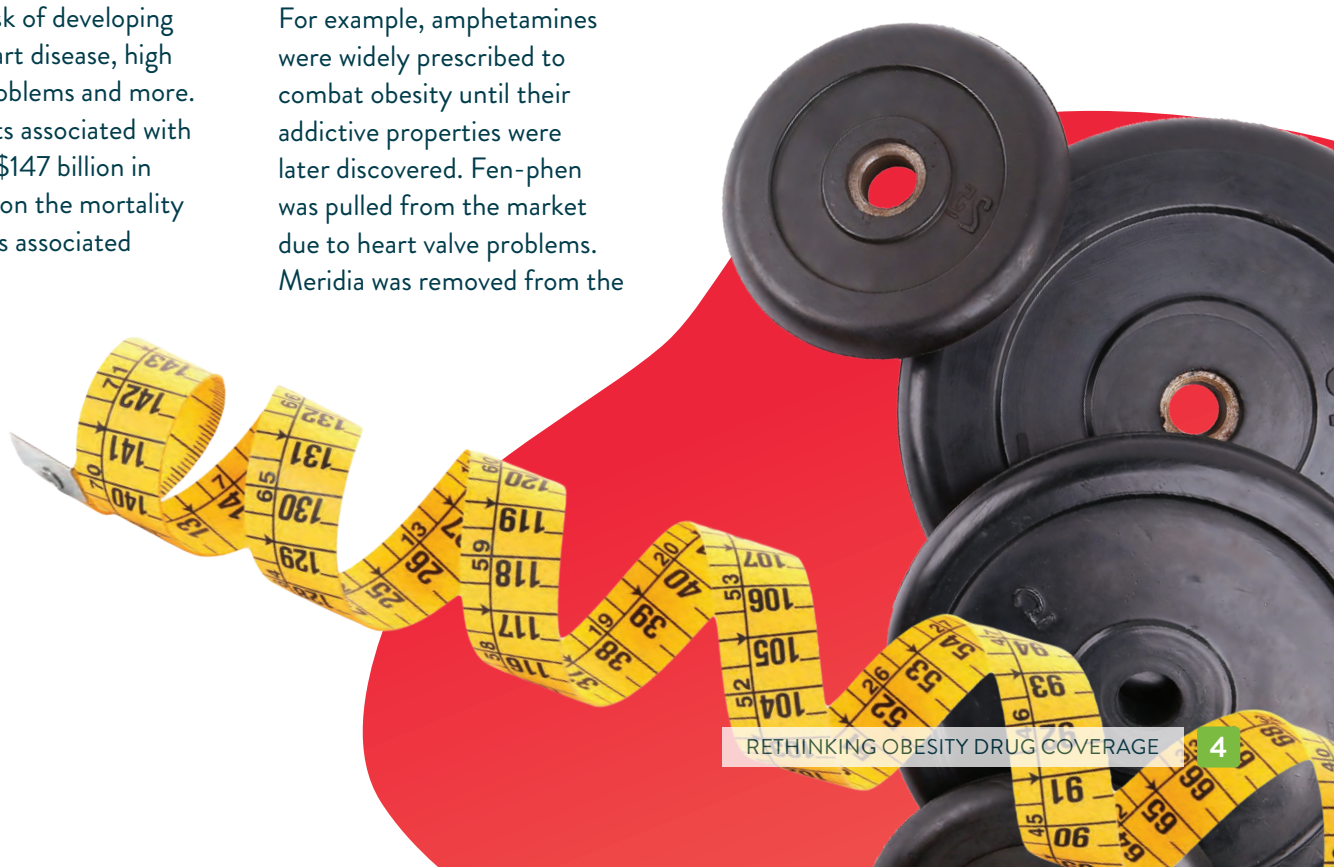
Per the CDC, prevalence of obesity in the United States from 2017-2018 was 42.4%, just under half of the population. That was a drastic increase from around 30.5% back in the early 2000s. It has been shown that being overweight or obese is associated with an increased risk of developing Type 2 diabetes, heart disease, high cholesterol, joint problems and more. Annual medical costs associated with obesity were about $147 billion in 2008; not to mention the mortality and morbidity that is associated with obesity.

Notoriously, obesity drug coverage has been considered cosmetic by employers deciding whether to cover this class of medications or to exclude them altogether. Within the Employers Health book of business, 60% of clients exclude obesity drugs while 25% cover them after prior authorization (PA) with the remainder allowing access without any restrictions. Looking deeper into our clients' costs, the per member per month (PMPM) net spend for employers with PAs on obesity products was $0.85 PMPM, while the plan spend for those without any restrictions was $1.08 PMPM in 2021. As for government-sponsored benefits, Medicare currently excludes obesity prescription drugs while Medicaid covers them.

The success of previous anti-obesity medications, or lack thereof, may explain the resistance of adoption for coverage. Previous medications on the market not only lacked clinically significant efficacy but they also created patient safety issues. For example, amphetamines were widely prescribed to combat obesity until their addictive properties were later discovered. Fen-phen was pulled from the market due to heart valve problems. Meridia was removed from the market because of an increased risk of heart attack and strokes, the very things people are worried about with obesity in the first place. On top of that, many anti-obesity medications reduce weight by less than 5% when adjusting for the placebo-controlled groups of clinical trials. While 5% weight loss has some health benefit, it is often not enough for sustained weight control or to prevent obesity-related comorbidities.

Weight Loss Pipeline Update

Recent FDA approvals in the obesity space may have changed the game and have plan sponsors rethinking their stance on obesity coverage. Wegovy (semaglutide) and Imcivree (setmelanotide) are two medications recently approved and show better efficacy and less safety concerns in clinical trials. It's important to note, Imcivree, which was approved in November of 2020, is different than any other



anti-obesity medication in that it is the first FDA-approved medication for weight management in people with certain rare genetic conditions where patients are unable to feel full. Currently, the manufacturer, Rhythm Pharmaceuticals, offers patient assistance for those who are uninsured, who have temporarily lost insurance coverage, or whose insurance doesn't cover Imcivree. However, employers that generally exclude obesity drugs are recommended to cover Imcivree to be consistent with other genetic disorders that lack treatment alternatives. By ensuring genetic testing via PA, plan sponsors could effectively limit off-label usage for weight loss by those without the condition.

Perhaps the biggest blockbuster approval of the year occurred in June 2021 with the drug, Wegovy. It is a glucagon-like peptide-1 (GLP-1) receptor agonist similar to the medication, Saxenda (liraglutide). GLP-1s first launched for Type 2 diabetes and subsequently gained approval for weight loss due to finding that participants were losing weight in clinical trials. This is because of GLP-1's mechanism of action in which they increase satiety, or the feeling of being full, by delaying the speed of which food leaves the stomach. GLP-1s play a significant role in this phenomenon known as "gastric accommodation" in that they impact the brain's perception of fullness and lead people to reducing food intake.

While Saxenda resulted in modest placebo-adjusted weight loss of about 5%, clinical trials for Wegovy showed that patients lost 15% of their body weight on average and some even lost more than 20%. Double-digit weight loss has significant potential to impact the many conditions associated with excessive weight, such as diabetes, hypertension and depression. While the cost of Wegovy is around $1,400 per month, the downstream clinical and financial benefits could create enough incentive for employers to begin covering the product and drug class as a whole with proper utilization management.

Obesity Class Management Strategies

Although some plan sponsors have historically excluded anti-obesity medications from coverage, it is time to rethink this decision. For employers that would still prefer to remain with the noncoverage approach, PAs and quantity limits on the GLP-1 class would be prudent to curtail the prescribing of anti-diabetic drugs for off-label weight loss purposes that is believed to be occurring in the marketplace.

Instead of complete exclusion though, there can be utilization management strategies put in place on those specific products to drive appropriate use. At a minimum, plan sponsors need PAs in place that require patient weight documentation to eliminate off-label usage by non-overweight individuals. PA criteria should also require documentation regarding the patient's approach to lifestyle modification changes surrounding diet and exercise to mirror the clinical trial requirements.

A more advanced and economical strategy could be to use prior authorizations to steer utilization towards the most effective

medications like Wegovy. One way to accomplish this approach would be to set continuation of coverage criteria to only allow for use if a patient loses 10% or more of their weight after six months of therapy. With this approach employers can feel confident that their spend in the class is primarily going towards effective medication usage.

For employers still considering their options, covering anti-obesity medications can keep clients ahead of the curve. Helping members manage their obesity can potentially lead to productivity gains and fewer sick days for those members due to minimizing comorbid conditions. This can lead to better member outcomes, greater retention and further recruitment due to the recent advancements in this space. With more effective and safer options now a possibility for members, obesity coverage might be as hard to refuse as your favorite dessert.

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