# Tipping the scales

## A smart strategy for handling the new class of weight loss drugs

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Optum Rx can help you provide affordable obesity management coverage within the pharmacy benefit.

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For years, pharmacy benefit plan sponsors have faced a dilemma: Should anti-obesity medications be covered under the pharmacy benefit? The basic questions were: do these drugs primarily provide a meaningful change in **health outcomes**, like other medications included within the formulary and plan design? Or do they provide a temporary **cosmetic** benefit to patients, for example, like drugs for facial wrinkles?

In many cases, plans have excluded anti-obesity medications on the grounds they were for cosmetic use - the position being that money spent would not generate a durable clinical benefit.

However, it is well established that overweight and obese individuals are at a higher risk of diabetes, heart disease, and overall poor health.[1] Furthermore, recently a new and more effective class of GLP-1 anti-obesity medications arrived on the scene, including Wegovy® (semaglutide) and Saxenda® (liraglutide).

Injections of these medications are delivering results on par with bariatric surgical interventions – with many patients reporting body weight reduction of 20% or more.[2] If this weight loss can be maintained within a patient population over time, it is reasonable to assume a durable clinical benefit will emerge.

In response to these new medications and emerging clinical research, plans are now revisiting this topic.

We believe plan sponsors should be well informed when determining their approach to managing anti-obesity medications within the pharmacy benefit. Plans should start preparing for an increased demand for these newer medications and develop a program approach that balances providing access with benefit affordability.

Even with the most effective drugs, diet and behavior change programs are foundational to achieving and sustaining weight loss goals. However, market demand will increase as word of mouth continues and new outcomes data emerges. Under these conditions, the rationale for continuing to exclude anti-obesity treatments under a cosmetic exclusion may erode.

Now is the time to begin planning for this new environment. For the balance of this paper, we will examine these new drugs. What are they? Do they work? How much do they cost? And, perhaps most importantly, what is the best strategy to manage them within a pharmacy benefit?

## Understanding the newer anti-obesity medications

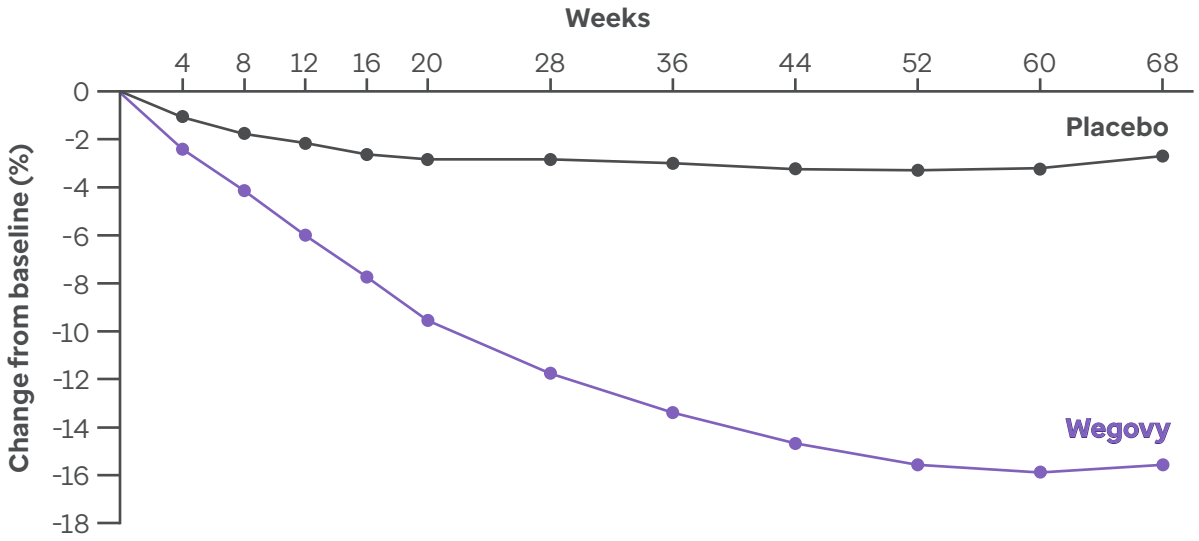
Drugs like Wegovy, Saxenda and Mounjaro™ (tirzepatide) are commonly called **glucagon-like peptide 1 (GLP-1) agonists**. These drugs mimic the action of a hormone called glucagon-like peptide and are involved in regulating appetite and caloric intake.[3]

Interestingly, the active ingredient in these medications was initially studied and approved by the U.S. Food and Drug Administration (FDA) for glucose control in patients with diabetes. Two of the three most recently approved GLP-1 therapies approved for diabetes are now also approved for obesity management under different brand names. Liraglutide is the active ingredient in both Saxenda (anti-obesity) and Victoza (diabetes) while semaglutide is the active ingredient in Wegovy (anti-obesity) and Ozempic (diabetes). Mounjaro (tirzepatide) is currently only indicated for type 2 diabetes. However, it has completed initial Phase 3 clinical trials and is expected to soon apply for and likely eventually be approved for an anti-obesity indication in late 2023 or early 2024.

These agents are demonstrating impressive results with few side effects; weight reductions have been confirmed among patients with and without diabetes.

In the SURMOUNT phase 3 trial of tirzepatide, patients on the highest dose of the investigational anti-obesity medication lost 52 pounds (22.5%) on average.[4]

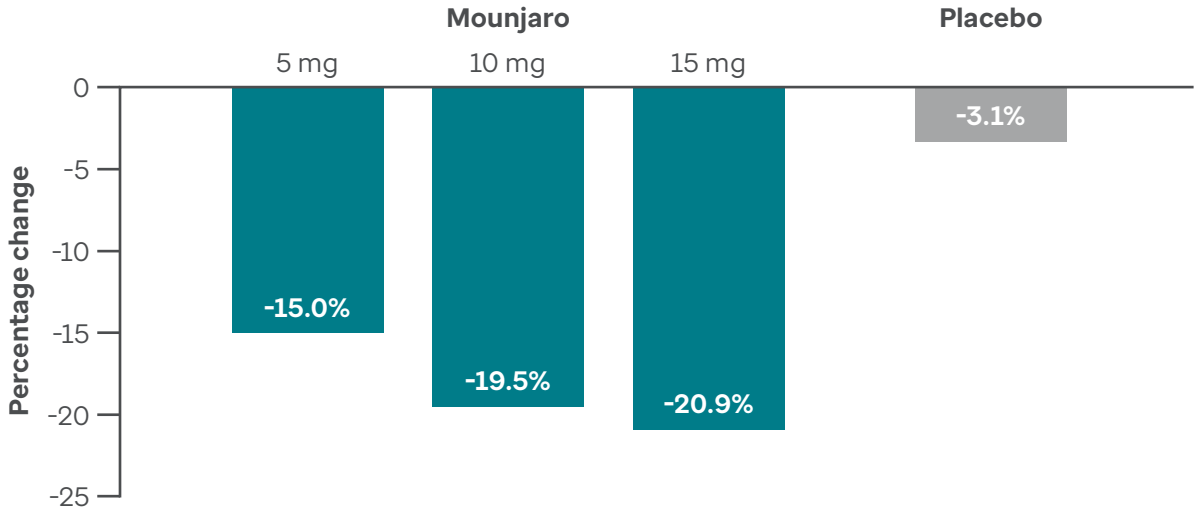
In a pivotal study of Wegovy, 83.5% of those overweight or obese saw ≥ 5% weight loss compared to 31.1% on placebo. Wegovy also demonstrated nearly 15% loss in body weight at 68 weeks compared to placebo. In this study, the treatment arm and placebo arm both adopted a reduced-calorie diet and increased physical activity.




**Mean body weight change from baseline by week**

[Image adapted from: New England Journal of Medicine. Once-Weekly Semaglutide in Adults with Overweight or Obesity. Published March 18, 2021.]

Another closely watched GLP-1 is Mounjaro. Published results show that trial participants who received Mounjaro achieved an even greater reduction in body weight than those using the placebo. Studies show up to 91% of participants achieving ≥ 5% weight loss, with up to 21% average weight loss at maximum dosages of 15mg.




**Mean weight change at 72 weeks**

[Image adapted from: New England Journal of Medicine. Tirzepatide Once Weekly for the Treatment of Obesity. Published July 21, 2022.]

## Are there demonstrated long-term benefits?

Weight loss of 20% is significant, but is there clear data that drug-induced weight loss in patients without diabetes results in a direct health benefit? In August 2023, Novo Nordisk published headline results from their long-awaited SELECT clinical trial measuring cardiovascular outcomes data related to semaglutide use in overweight and obese populations. As largely expected, the results are positive, confirming a reduction in major adverse cardiovascular events (MACE) in 20% of the studied population. Novo Nordisk is expected to release detailed study results in late 2023 and submit for a label indication expansion as well to include cardiovascular benefits.[5]

Achieving successful long-term weight loss is the goal.

With new evidence emerging regarding the cardiovascular protection benefits of GLP-1 medications, we expect increasing debate regarding the categorization of these medications as cosmetic.

Several questions remain unanswered. Is the weight loss achieved sustainable? Who benefits the most from GLP-1 drugs? What about the cost of these medications?

## What about cost?

The GLP-1 class of anti-obesity medications currently available have an average monthly wholesale price of $1349 per month.[6]

In the U.S., 42% of the population is obese and 9.2% is severely obese.[7] Treating just the entire severely obese population, over 30 million people, with GLP-1 medications could increase all current U.S. drug spending by over 50%. Consequently, it is understandable that plan managers responsible for pharmacy budgets are concerned about this potential financial impact.

Like many things in health care, approval of new medications and advances in science can lead to new short-term costs. But meaningful cost-offset (e.g., lower medical benefit costs) may not be experienced until years later. The Centers for Disease Control (CDC) estimate that the direct annual medical cost of obesity is nearly $173 billion in 2019 dollars.[8]

Combining the clinical outcomes data with cost and prevalence of obesity, comorbidities and cardiovascular events yields an interesting viewpoint on the price of GLP-1s. A recent analysis estimates that it would cost a payer $1.1 million dollars, the estimated net cost equivalent of 63 patients treated for a three-year period on a GLP-1, to prevent one heart attack, stroke or cardiovascular death.[9]

The Institute for Clinical and Economic Review (ICER) has also explored this topic. In their evaluation, current pricing for both Wegovy (semaglutide) and Saxenda (liraglutide) exceeded the modeled health-benefit annual pricing benchmark, indicating the current price is too high relative to the health and economic benefits of treating obesity.[10]

A 3-7% reduction in weight reduces the risk for diabetes and improves blood glucose levels in those with diabetes.

As plans look to develop an obesity management strategy, it is clear the positive health impact and correlating financial value of reversing the obesity epidemic one patient at a time is significant if responsibly conducted with affordable drugs and effective support programs. However, if the drugs are not affordable to payers, then how can the drugs be made available to the members who can benefit the most?

## If the drugs work so well, are behavior change programs still as important?

The answer is yes.

Obesity is a modifiable risk factor for diabetes and the more patients move to a healthier weight and diet/lifestyle, the lower their risk of developing diabetes and diabetes-related complications. In fact, just a 3-7% reduction in weight reduces the risk for diabetes and improves blood glucose levels in those with diabetes. Furthermore, in motivated individuals where more aggressive weight loss is needed, additional weight loss continues to yield additional health benefits.[11]

We know how to do this. There is a developing treatment paradigm around diabetes prevention, management, and even reversal. The first two are well established in the medical community, while there is a growing body of research that diabetes can even be reversed through improving metabolic health.[12] The common, but not surprising, thread linking all three is that behavior change can have a substantial impact on clinical outcomes.

Another key factor at play here is the potential weight regain that may occur after patient's discontinuation of a weight loss medication. A recent study has indicated that patients will regain approximately two-thirds of their prior weight loss within a year of a stopping a GLP-1 medication.[13]

We believe plans should consider implementing behavior change programs that address underlying factors related to maintaining a healthier lifestyle. If a patient responds well to drug therapy and adopts healthier behaviors, they can sustain achieved weight loss and improve their health for the long term.

## Considerations for formulary and benefits

The dynamics discussed in this white paper all play a role in how the health care industry responds in developing benefits and formularies. Of course, benefit coverage varies widely based upon market segments. Health Exchange plans do not typically cover weight loss medications as they are not currently considered "essential health benefits" and thus not required to be covered. Similarly, in Medicare, these medications are excluded from coverage as well for treatment of obesity. Commercial plans have more regulatory discretion in developing their benefits, but a significant portion of plans still do not cover these medications.

As we move forward in time and if published research data shows positive long-term clinical outcomes, we are likely to see a payer shift towards consideration of weight loss medications as a covered pharmacy benefit. This shift will likely be driven by a number of factors, including potential regulatory changes and Pharmacy & Therapeutics (P&T) Committee viewpoints regarding the placement of GLP-1 medications for obesity management on formularies. The landscape will inevitably evolve, creating a trickle-down effect of the need for plans to evaluate strategies to appropriately manage utilization if access to the medications increases.

Plans must consider formulary and benefit strategies that deliver financial sustainability, while also ensuring the eligible, highly motivated population has a durable weight loss outcome. This is where an effective, integrated program solution comes into play.

## Introducing Optum Rx Weight Engage

Optum Rx Weight Engage is an innovative weight management solution suite that drives appropriate GLP-1 utilization and guides members toward improved health outcomes. Optum Rx offers a range of solutions for those seeking effective and affordable weight management drug coverage.

Our program starts by managing the foundation of the benefit design and extends into behavior change programs. Plans choose their utilization management strategy, apply enhanced system edits to manage claims, and finally choose whether to connect members into a program designed to deliver behavior change and diet planning education throughout their weight loss journey. This program offers flexibility for clients while delivering comprehensive strategies to manage utilization across a benefit.

- **Risk-stratified utilization management:** Plans have the option to cover the most at-risk obesity populations only. As discussed above, intrinsically motivated and highest responding members benefit the most from weight management solutions and this strategy allows plans to prioritize that population for coverage. Optum Rx has crafted optional clinical criteria with this in mind.

- **Enhanced system edits:** Optum Rx has applied several edits in the adjudication system to curtail off-label utilization and potential oversupply. Edits include stricter refill handler thresholds and quantity limits and updated system configurations for GLP-1s indicated for diabetes to require additional evidence of diabetes diagnosis.
- **Behavior change programs:** Members achieve better outcomes when they are guided, supported, and educated on strategies to maintain weight loss when discontinuing their medication. These outcomes play a huge role in improving overall health and long-term health risks. Behavior change programs connect members to appropriate resources and deliver health coaching support to drive clinical outcomes sustainability.

Optum Rx Weight Engage offers two different behavior change models and plans will have the option to adopt either solution as part of their pharmacy benefit obesity management program. Both leverage a virtual care model, diet and activity planning, and health coaching. The programs differ in how members are prescribed medications and followed throughout their care journey. These two models are:

1. **Member Support:** This model does not impact who can prescribe medications, but instead layers in requirements for members to participate in a custom designed, medication-focused health coaching program. Members must be active participants with positive outcomes to maintain anti-obesity medication coverage over time.
2. **Provider Guidance:** This model limits the prescribing of certain obesity management drugs to a specific group of obesity specialist physicians who oversee structured protocols and programs. These prescribers determine an individualized optimal weight loss plan for each member (which may or may not include a GLP-1) and connects them with a weight loss care team. This model delivers a specialist provider-led approach to managing drug selection and ongoing clinical response oversight and coaching.

## Conclusion: the way forward

Addressing the obesity epidemic requires a collaborative effort from all stakeholders: manufacturers must offer affordable prices, members must be committed to sustaining long-term weight loss, and plans must recognize the value of covering these medications. Optum Rx is dedicated to offering a balanced obesity management program that provides access, manages drug trend and drives clinical outcomes.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