

# *Balancing The Scales*

INSIGHT GUIDE

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**A Comprehensive Guide for  
Healthcare Payers on the  
Value & Viability of New  
Weight Loss Medications**



**Goodroot**



**With the burden of obesity-related costs weighing heavily on their balance sheets, healthcare payers are now faced with the dilemma: should they cover these new, high-cost weight loss medications that are garnering significant attention? These drugs, which include Ozempic, Wegovy, and the newly launched Mounjaro, among others, are being touted as potential game-changers in weight management across various platforms, including Instagram and TikTok.**

This curiosity is being stoked further by celebrity endorsements and infiltrating the realm of Hollywood glamour, as evidenced by a recent Oscars joke suggesting Ozempic as the secret behind the audience's impressive physiques. Moreover, direct marketing by spas and clinics, offering these treatments for weight loss, is also broadening public access and interest, potentially impacting the overall demand and usage patterns for these drugs.

If you're an employer or plan sponsor contemplating whether to cover these drugs, keep reading. We're diving deep into these emerging medications, evaluating their potential impact on healthcare costs and answering the pressing question: Are these high-cost weight loss drugs a worthy investment for healthcare payers?

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### **About Goodroot**

Goodroot is an interconnected community of companies making every interaction between human and health accessible, affordable and seamless. Goodroot's community, which includes AlignRx, Breez, CoeoRx, Emry, Penstock, RemedyOne, Sola and Nuwae — delivers transformative tech and proactive services that enable clients, partners and patients to reap more value from the money spent on health. We're laser-focused on holistically reinventing healthcare, one system at a time, to improve affordability and accessibility for patients. To date, we've removed over \$1 billion in wasteful and unnecessary spending from the industry.



### About AlignRx

AlignRx partners with pharmacy benefit consultants, employer groups, TPAs and health plans to offer pharmacy solutions and insights that improve performance, drive savings and deliver better outcomes across the pharmacy benefits value chain. Our robust Rx consulting team—made up of industry experts, data analysts and clinical pharmacists with decades of industry expertise and complete pharmacy landscape command—are in your corner year-round. We develop creative cost-containment opportunities, optimize pharmacy spend and value, recover owed dollars and ensure PBMs are meeting contractual guarantees. Our PBM procurement process is the most meticulous in the industry, ensuring every important detail is accounted for within the contract.



### About RemedyOne

RemedyOne is a formulary and rebate optimization company that cuts through the complexity that exists within modern pharmaceutical programs. Our clinically driven approach enables our team, which includes veteran pharmacists and an in-house Pharmacy and Therapeutics Committee, to assess new drugs, understand their cost and implications and make formulary recommendations based on research, insight and efficacy. We work with PBMs, health plans, employer groups and TPAs to provide clinical guidance and cost savings at every stage of the formulary and rebate management process.



### About Nuwae

Nuwae is leveling the playing field and changing the game when it comes to controlling the cost of prescription drugs. We believe that there should be one price for a drug, no matter who is paying. Our cutting-edge solutions are designed to lower the cost of prescription drugs by redeeming the tarnished “pharmaceutical rebate” into a force for good. We’re solving the issues that drive drug prices to astronomical levels, ultimately lowering out-of-pocket costs and providing equitable access and outcomes for patients. Our mission is grounded in the belief that access to important medications should not be seen as a luxury or a benefit for select patients, and that no one should have to ration their medication due to cost.



### About Sola

Sola Health delivers intuitive human-centered health plans and superior care at a lower cost. We’re breaking the mold, freeing employers and employees from unaffordable healthcare and raising the bar for benefits in the workplace by delivering refreshing, on-demand health experiences employers—and their teams—love.

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## Obesity is a Disease

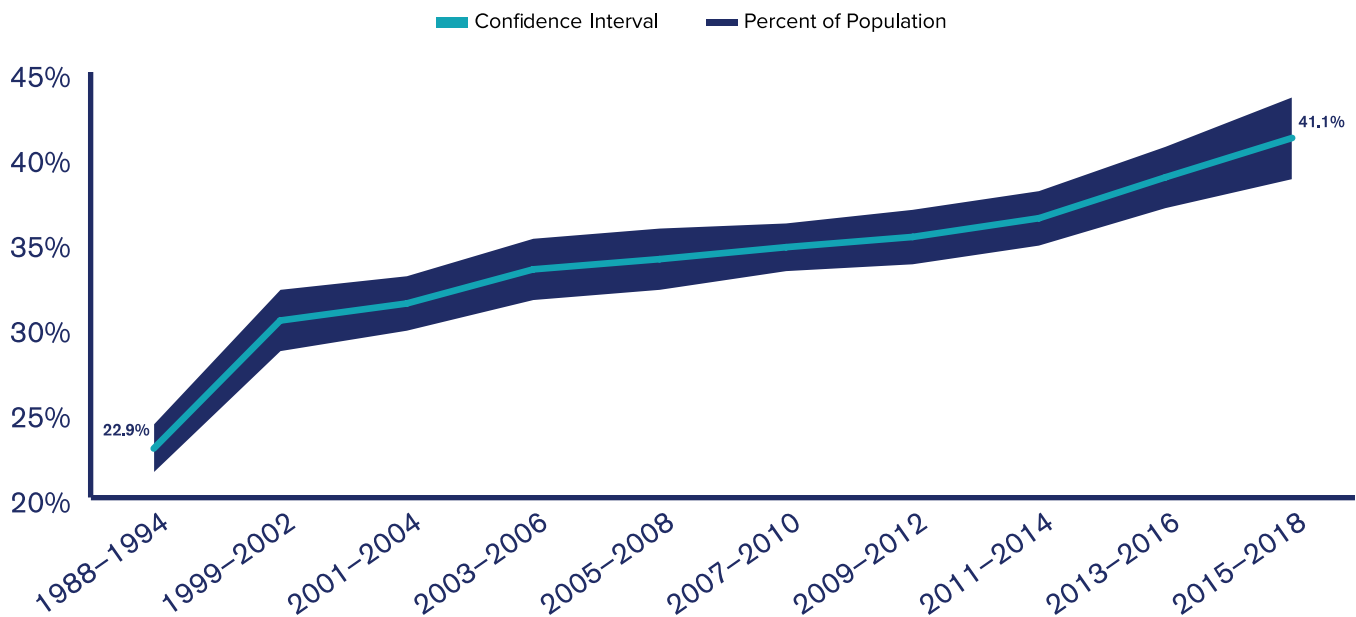
Obesity is not merely an issue of appearance or convenience; it's a complex health condition with multiple contributing factors, including behavioral aspects, genetic predispositions, hormonal influences and underlying medical conditions. The regulation of body weight is a nuanced process, not simply a matter of consuming fewer calories and increasing physical activity.

Our bodies harbor hundreds of hormones and signaling molecules intricately involved in weight regulation. It's these biological elements that challenge the conventional wisdom of 'eat less, move more.' As individuals begin to lose weight, the body initiates a process known as metabolic adaptation. This is essentially the body's defense mechanism against weight loss, aimed at maintaining energy balance and survival, and making it difficult for those with obesity to reach a healthy weight.

Obesity has far-reaching consequences. It's linked to heightened risks of over fifty disease states and conditions, including diabetes, heart disease, stroke and certain types of cancer. In 2013, the American Medical Association officially acknowledged obesity as a chronic disease, underscoring these significant health implications.

Looking back over the past two decades, the surge in obesity rates is alarming. According to the Centers of Disease Control, adult obesity rates have risen from 30.5% of the U.S. population in 2000 to a staggering 41.9% in 2020. The escalating prevalence of obesity—and pre-obesity—underlines the urgent need for comprehensive strategies to address this national health crisis.



**The Obesity Rate of the U.S. Population Has Almost Doubled in Recent Decades**

Source: Centers for Disease Control and Prevention Health, 2020-2021

## The Newest “Miracle” Drugs

The recent spotlight in the realm of anti-obesity drugs has centered around Ozempic and Wegovy, often called “miracle weight loss drugs.” These self-administered, semaglutide injections are both produced by Novo Nordisk, but their FDA approvals differ. Ozempic is approved for the treatment of type 2 diabetes mellitus, whereas Wegovy—a higher dose version—is sanctioned for chronic weight management in patients who are either obese (BMI > 30) or overweight (BMI > 27) and have certain other risk factors. Despite these distinctions, physicians have not shied away from prescribing both drugs for weight loss, leading to periodic supply shortages due to high demand.

Novo Nordisk also offers an oral semaglutide tablet, Rybelsus. While it’s currently only approved for type 2 diabetes treatment, it’s seeking FDA approval for weight loss. Despite its strict daily morning regimen, which requires administration on an empty stomach and prior to consuming anything other than water, it’s a non-injectable option that may hold promise.

Back in 2014, Novo Nordisk introduced Saxenda, another weight loss medication containing the active ingredient liraglutide, originally approved under the name Victoza for type 2 diabetes. However, its daily subcutaneous injection and relatively lesser weight loss results when compared to Wegovy and Ozempic limit its market appeal.

Then there’s Mounjaro, the latest addition to this category, containing the active ingredient tirzepatide. Manufactured by Eli Lilly and approved for type 2 diabetes, Mounjaro distinguishes itself from the pack with two distinct mechanisms of action to achieve exceptional weight loss results. Industry analysts are already predicting it could become one of the top-selling drugs in history, with projected annual sales topping \$50 billion.

## More in the Pipeline...

In addition to Rybelsus and Mounjaro, which are currently seeking FDA-approval, there is a pipeline of drugs following a similar mode of action undergoing clinical trials for obesity. The trend for these agents is to first obtain approval for treating type 2 diabetes before seeking endorsement for weight loss. Currently Lilly and Novo Nordisk have drugs in clinical trials for obesity. Amgen and Pfizer have also entered the arena with their own promising drug candidates under study.

## How Do They Work? What's Going on Inside our Bodies?

In the pharmaceutical world, the latest weight-loss medications, originally approved for diabetes treatment, belong to a class known as incretin mimetics. These include Wegovy, Ozempic, Rybelsus and Saxenda, all of which are glucagon-like peptide 1 (GLP-1) receptor agonists. Their mechanism of action is intriguing: they mimic a naturally occurring substance in our bodies, which is triggered by food consumption. This substance boosts insulin release, slowing sugar output from the liver, delaying digestion and curbing appetite, making you feel full longer.

Introducing an external version of this substance stimulates this internal mechanism, tricking our bodies into believing they have been fed, without food intake. As a result, those on these medications tend to eat less and, when coupled with a balanced diet and regular exercise, can experience significant weight loss. Thus, these incretin mimetics are playing a pivotal role in the current weight management narrative.

Mounjaro works a bit differently, leveraging that previously mentioned dual-action mechanism for achieving its results. First, it engages the GLP-1 agonist pathway, the same mechanism used by Wegovy, Ozempic, Rybelsus and Saxenda. What sets Mounjaro apart, however, is its unique second mechanism. This involves the glucose-dependent insulinotropic polypeptide (GIP) receptor, which enhances insulin secretion and manages lipid and glucose metabolism. This dual-action approach has shown superior glycemic control and weight loss results, outpacing semaglutide in comparative clinical trials.

Given the encouraging data, Eli Lilly is in the process of submitting the final documents to the FDA to gain approval for Mounjaro as a weight loss treatment. This promising development underscores Mounjaro's potential as a formidable player in the weight management sphere.



## The Good

The weight loss results achieved with these medications have been nothing short of remarkable. Clinical trials for Wegovy, a weekly injectable, indicated that patients lost an average of **14.9%** of their body weight over a 68-week period. This breakthrough is noteworthy because, before 2021, there wasn't a single FDA-approved anti-obesity medication that demonstrated double-digit efficacy in weight loss. Studies involving diabetic patients using Rybelsus, the daily oral version of semaglutide, recorded a more modest weight loss of **5-7%** over one year. However, in the ongoing oral semaglutide trial for weight loss, a considerably higher dosage is being administered. It is anticipated that with this higher dosage, the results will align more closely with those reported for the injectable versions.

Let's not forget the other daily treatment, Saxenda, which has been on the market for the longest out of these agents. Studies have shown that 85% of patients have lost **9.2%** of their body weight after one year. However, the necessity for daily injections could potentially affect the product's efficacy, as maintaining such a regimen may pose adherence challenges for patients.

The most impressive results have been reserved for the final mention: Mounjaro. Currently marketed as a weekly injectable for diabetes treatment, Mounjaro has shown superior outcomes in clinical trials among all these agents. Patients reported losing between **15%** and **20.9%** of their body weight after 72 weeks on the medication. The FDA is reviewing the drug application for weight loss indication, with approval anticipated before the close of 2023. A key insight from the clinical trials of these medications is that weight loss percentages are intrinsically linked to both the dosage and the duration of treatment. Moving forward, it's likely that manufacturers will explore additional clinical trials with higher dosages to optimize results, and potentially secure the much-sought-after title of 'top performer' in the weight loss category.

## The Bad

Like most medications, these "miracle" weight-loss drugs are not without side effects. Side effects manifest as gastrointestinal disturbances, which include nausea, vomiting, diarrhea, constipation and abdominal pain. Clinical trials reveal that **15%** to **45%** of patients experienced a gastrointestinal side effect while on these medications, with the incidence escalating as the dosage increased. Interestingly, these side effects—which can be severe—may inadvertently contribute to the efficacy of these drugs, as many patients report a diminished appetite while on the medication.

Unfortunately, a patient's ability to persist with these new treatments seems to be intrinsically linked to their weight loss success. Early evidence suggests a tendency for individuals to regain the lost weight once they discontinue the medication.

## The Ugly

The packaging for some of these drugs explicitly advises against usage by patients with a personal or familial history of medullary thyroid carcinoma, or those with a personal history of multiple endocrine neoplasia. These promising anti-obesity drugs also come with a warning about an elevated risk of acute



pancreatitis and pancreatic cancer following exposure. Additionally, there's a warning about potential links to increased risks of gallbladder or biliary diseases. The FDA is also currently examining the need for regulatory action based on recent reports of intestinal obstruction in the FDA Adverse Event Reporting System (FAERS). The long-term implications of using these drugs, which alter the body's metabolic processes, remain unknown. The results of ongoing clinical trials and retrospective studies based on the FAERS database will be essential in determining whether the safety concerns associated with these weight loss drugs are manageable, particularly for long-term use. It's important that patients considering the use of these drugs for weight loss to speak to their doctor concerning their personal risks.

Lastly, managing obesity, like any chronic disease, requires careful monitoring and expert clinical oversight. The surge in people seeking these drugs through unverified online sources, including online pharmacies offering non-existent "generic" versions, is alarming. These compounded injectables bypass essential FDA evaluations for safety and efficacy, presenting risks of inaccurate dosing, improper formulation, and contamination. Therefore, it's vital for individuals to avoid acquiring this drug without a valid prescription or professional medical advice, and to only trust reliable, authorized sources to ensure safety.

## Treatment Cost

A four-week supply of these medications comes with a significant price tag.

Drug Name	Manufacturer	Type of Drug	FDA Approved for weightloss?	Type of Medication (oral/Injection)	Cost per 4-week Supply
<b>Ozempic</b>	Novo Nordisk	Semaglutide	No	Injection	<b>\$1,100</b>
<b>Wegovy</b>	Novo Nordisk	Semaglutide	Yes	Injection	<b>\$1,600</b>
<b>Saxenda</b>	Novo Nordisk	Liraglutide	Yes	Injection	<b>\$1,600</b>
<b>Mounjaro</b>	Eli Lilly	Tirzepatide	Seeking	Injection	<b>\$1,600</b>

*The pricing data for a four-week supply of Ozempic and Mounjaro, as presented in the above chart, reflect their current costs associated with diabetes management.*

## Is Such High Pricing for These Agents Justified?

The Institute for Clinical and Economic Review (ICER) suggests that, for Wegovy to be deemed cost-effective, its annual pricing should range between **\$7,500** and **\$9,800**. While this may still present a financial burden for uninsured patients, ICER's recommended monthly cost of around **\$750** could potentially encourage more insurance providers to include weight-loss agents in their coverage plans.

## The Cost of Obesity—A Trillion Dollar Problem

According to a 2018 report by The Milken Institute, obesity-related complications resulted in **\$1.39 trillion** worth of direct medical treatments and indirect productivity losses due to chronic diseases in the U.S. This staggering figure doesn't even account for additional costs associated with obesity-induced health conditions, such as the strain on families, potential income loss, and the involvement of caregivers.

*Milken* lists the following total costs (direct and indirect) attributable to specific obesity-related health conditions in the U.S. for 2018:

Health Condition	Total Cost
Hypertension	\$455 Billion
Type-2 Diabetes	\$251 Billion
Chronic Back Pain	\$186 Billion
Osteoarthritis	\$179 Billion
Alzheimer's or Vascular Dementia	\$81 Billion
Gallbladder Disease	\$65 Billion
Coronary Heart Disease	\$43 Billion
Stroke	\$21 Billion

A 2015 study from the National Institutes of Health provides an estimated economic burden of obesity-related comorbidities in the U.S, detailing the annual incremental costs for individuals with obesity compared to those without. The list derived from this study presents the projected first-year incidence costs (2013) tied to obesity-related comorbidities. To reflect the current economic climate, these figures have been adjusted for inflation to represent values in 2023 dollars, providing a more accurate depiction of the financial strain imposed by obesity today.

Comorbidities	Incremental Cost (2013)	Incremental Cost (2023)
Pre-diabetes	\$2,266	\$2,946
Diabetes	\$3,258	\$4,237
Dyslipidemia	\$2,052	\$2,668
Depression	\$4,373	\$5,687
Sleep apnea	\$7,122	\$9,262
Hypertensive diseases	\$3,728	\$4,848
Myocardial infarction	\$24,887	\$32,364
Coronary artery disease	\$11,611	\$15,099
Angina	\$11,620	\$15,111
Ischemic stroke	\$15,265	\$19,851

## Navigating the Complex Landscape of Healthcare Coverage for Anti-Obesity Drugs

Navigating the landscape of healthcare coverage for obesity treatments presents a complex picture, particularly as it relates to commercial plans. Currently, public healthcare payers such as Medicare and most Medicaid programs do not extend coverage for anti-obesity medications, which has inadvertently set a precedent for commercial plans. These commercial entities have taken cues from CMS' stance, opting not to cover these drugs as standard, albeit with some exceptions under certain circumstances. However, this could potentially change with the proposed Treat and Reduce Obesity Act. If passed, this Senate bill would extend Medicare Part D coverage to include obesity therapeutics. This extension would not only expand access to these medications for those aged 65 and older but could also set a new standard for coverage, influencing commercial plans. But despite the potential implications, the bill has remained in a state of limbo in Congress for several years, leaving the coverage landscape for obesity complex.

In the private sector, the perception of obesity drug coverage is undergoing a shift. Historically viewed as cosmetic and therefore often excluded, private health insurers are becoming increasingly cognizant of the high healthcare costs linked to obesity. While this awareness has spurred an investment in weight reduction strategies, there is still a considerable journey ahead before universal acceptance of weight loss medication coverage becomes the norm among healthcare payers.

### Payers: To Cover or Not to Cover

Employers and plan sponsors shoulder a substantial portion of obesity-related expenses, prompting the question: Could these weight loss drugs be a solution? Covering weight loss medications will be a significant expenditure for payers on the pharmacy benefit but could potentially result in long-term savings. Recent research supports this perspective: a retrospective cohort study involving over **200,000** commercially insured patients demonstrated that those using weight loss medications had decreased healthcare costs in the second year, whereas untreated patients saw rising costs. This evidence suggests that payers could experience an early return on investment when choosing to cover anti-obesity medications. The decision to cover will be up to the plan sponsor. Keep reading to learn what you should be thinking about as you consider or opt out of covering anti-obesity drugs.





## Not Covering? Here's What You Need to Know

If you're an employer or a health plan not planning to cover anti-obesity medications, it's important to get on the same page as your PBM. Given that prescribers are already initiating off-label usage of these drugs, it's crucial to clearly communicate with your PBM—and check your PBM contract—to ensure drug utilization controls are in place to ensure that these drugs are only used for patients who have diabetes.

Although a PBM may list the drug on their formulary, the decision to provide coverage for the medication still falls upon the plan sponsor. According to one benefits consulting firm, the trend for the majority of plans remains to exclude weight loss drugs with only about **25%** of them providing coverage after prior authorization and another **10-15%** allowing coverage without PA.

## 2023 Commercial Formularies for the Top 5 PBMs

Are they covering weight loss drugs?

PBM	Drugs Covered	Prior Authorization (PA) Required
CVS Caremark Performance Drug List – Standard Control	Wegovy, Saxenda	May require PA
Express Scripts National Preferred Formulary	Wegovy	Included in Weight Management Care Value program
Humana	Not covered	N/A
Optum Premium Standard	Wegovy, Saxenda	PA required for both
Prime Therapeutics Net Results	Wegovy, Saxenda	PA required for both



# 9 Ways to Lower Costs

*If you are planning to cover these drugs, here are some ways to lower costs in the short term:*

- 1 Implement prior authorization and comprehensive coverage guidelines to assure appropriate access to weight loss medications. For example, limiting coverage to those with a BMI of 40 or above, or a BMI of 30 or above accompanied by a weight-related health condition. It's important to check with your PBM or health plan to determine if they can incorporate this kind of special eligibility criteria (For example, only providing coverage for members with morbid obesity).
- 2 Employers may opt to include a requirement for employee participation in weight management programs to access coverage for anti-obesity medications. The program might incorporate elements like nutritional counseling, physical exercise regimens and psychological support to facilitate behavior change towards healthier eating and regular physical activity.
- 3 It's critical for plan sponsors to carefully consider their PBM formulary and utilization management programs and ensure that these medications are prescribed to those who truly need them.
- 4 Require reauthorization to ensure members are having a positive response to the drug.
- 5 Consider a step-therapy approach where members first try lower cost anti-obesity medications before moving onto higher-cost alternatives.
- 6 Negotiate lowest-net-cost PBM formulary changes to purchase these new anti-obesity medications at the best possible price.
- 7 Partner with a PBM that supports the systematic use of manufacturer copay cards. By enrolling members in copay cards for non-specialty drugs, it's possible to lower the costborne by the employer.
- 8 International filling could potentially lower costs for employers covering these drugs due to differences in pricing across various global markets.
- 9 Ensure you're getting appropriate rebates for, where available, from your PBM.

## Fully Insured Employers—Consider Self-Funding to Unlock the Power of Data

Regardless of whether employers choose to cover anti-obesity medications, they should be prepared for potentially significant premium increases in the coming year. It's crucial that plan administrators proactively inform their groups about potential cost hikes well ahead of time. Too often, groups aren't alerted about premium increases until a mere 30 days before renewal. Switching to a self-funded plan can help. Groups are informed of any potential premium increases well in advance, giving appropriate time to strategize and adjust budgets. And when you move from a fully insured plan to a self-funded one, you're not only gaining control of healthcare costs, you're also tapping into data that can offer profound insights into healthcare trends within your workforce. This shift can illuminate the key factors driving your healthcare costs up and provide the opportunity to align coverage decisions with data.

### Claims Data:

This data can highlight high-cost claims or patterns of healthcare utilization that contribute to cost increases. For instance, if obesity-related conditions are significantly contributing to your claim costs, it may be beneficial to consider implementing weight management programs and/or coverage for anti-obesity drugs.

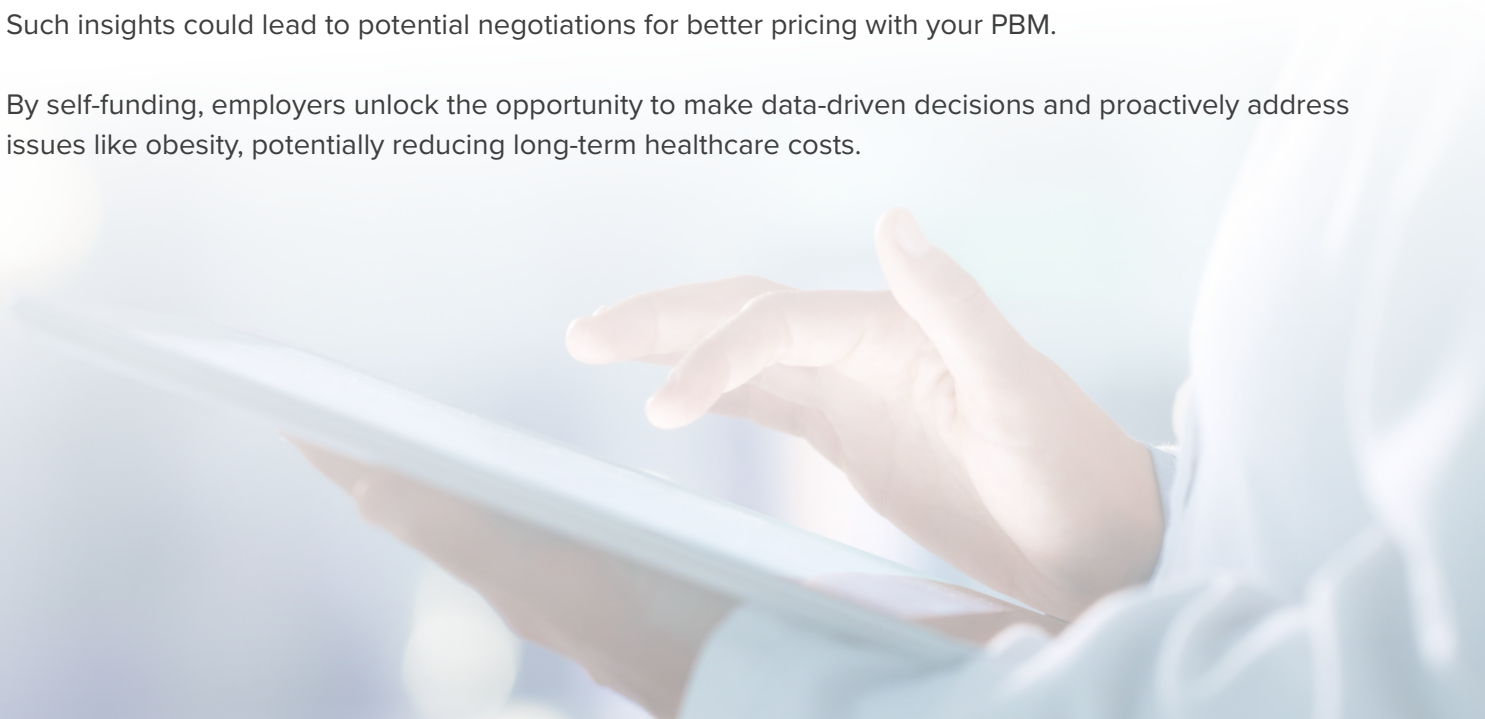
### Network Utilization:

Insights into employees' utilization of the healthcare provider network can help identify areas of improvement. For instance, it may be necessary to incorporate more specialists in obesity to cater to the specific needs of employees.

### Pharmacy Data:

This data provides insights into the types of medications used by employees and their associated costs. Such insights could lead to potential negotiations for better pricing with your PBM.

By self-funding, employers unlock the opportunity to make data-driven decisions and proactively address issues like obesity, potentially reducing long-term healthcare costs.





## Patients

The choice to use the newest miracle weight-loss treatments is not an easy one. Clinical research shows these drugs can aid overweight patients in losing significant weight. However, these benefits come with their own set of costs—financial and physical alike. Optimal results frequently necessitate higher dosages, which in turn can cause amplified side effects.

Moreover, the use of these weight-loss medications may become a lifelong commitment for those aiming to maintain their weight loss. This path demands significant dedication from patients, and some may find the associated side effects intolerable over time. Online testimonies underscore that these drugs may not be for everyone, but they undeniably work wonders for those who can tolerate them.

Wegovy and Saxenda have implemented savings programs to provide financial relief for patients whose private insurance doesn't cover these medications. Additionally, these programs are available to those with private insurance who seek to lower their out-of-pocket costs for these treatments. However, these savings are not applicable to patients under federal or state healthcare programs such as Medicare, Medicaid, or TRICARE. The medications solely FDA-approved for type 2 diabetes treatment—Ozempic, Rybelsus, and Mounjaro—offer similar savings programs. However, these require that the medication be included in your private insurance coverage to qualify for the copay discount.

Many insurance companies and healthcare programs require a process of prior authorization for these drugs, alongside an appropriate diagnosis matching the requested medication. Consequently, patients seeking weight loss treatment with Ozempic, Rybelsus or Mounjaro without a corresponding type 2 diabetes diagnosis may face the stark reality of covering the full cost out-of-pocket.





## In Conclusion

In the face of rising obesity rates and the associated healthcare costs, the industry is at a pivotal juncture. The emergence of new, weight loss medications—each promising substantial health benefits—presents a compelling case for inclusion in healthcare coverage. But the upfront expenditure from payers is significant and coverage decisions should not be made lightly.

Plan sponsors, employers and other stakeholders must consider each drug's effectiveness, potential side effects and cost burden. With comprehensive evaluation and careful strategy, these medications could become a transformative tool in the fight against obesity—a trillion-dollar problem that shows no sign of abating. As we navigate this complex landscape, it's crucial to remember the end goal: improving the health and well-being of those we serve, while responsibly managing healthcare costs.

# Balancing the Scales

The Value & Viability of  
New Weight Loss Medications

