

Pharmacy Insights 2024 Q1

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Healthcare Landscape - A Focus on Diabetes

As the healthcare landscape has evolved to value-based care, employers, payers and pharmacy benefit managers (PBMs) have implemented new strategies to improve quality of care and affordability. Ninety percent of the nation's \$3.5 trillion in annual health care expenditures are for chronic and mental health conditions.¹

Who really controls your drug spend? It is not the PBM formulary alone, nor is it providers or hospitals. Looking across all stakeholders, we should begin and end with each patient's individual journey. Their genetic code. Their lifestyle choices, especially smoking, eating a healthy diet, and exercise. Each individual makes decisions like these that can help prevent diabetes and heart disease. That's why, now more than ever, it is imperative that healthcare is focused on the patient journey.

Educating and empowering individuals to take better control of their health starts with engagement and a comprehensive approach that considers both affordability and quality of care. Engaging them early in the journey is vital to prevent disease progression and comorbidities that will ultimately be much more costly if left untreated.

More than 37 million people in the United States have diabetes, representing 12% of the population. Predictive modeling indicates that 8 million people are undiagnosed. Due to lifestyle choices, it is estimated that 96 million adults have pre-diabetes, representing over 35% of the adult U.S. population.²

A newly diagnosed patient with Type 2 diabetes will incur an average annual healthcare spend of \$25,000. If not well controlled with first line medication and lifestyle changes, patients can progress to more expensive self-injectables that cost as much as \$40,000 per year. If insulin is added, the cost doesn't increase significantly. But it does indicate disease progression, specifically microvascular and macrovascular damage that can cause poor blood circulation, damage to the retina, heart disease, stroke, kidney failure and amputation of feet or legs.³

Heart disease is the No. 1 cause of death in the U.S., according to the Centers for Disease Control and Prevention. Nearly 860,000 Americans die every year from heart disease and stroke combined, representing one-third of all-cause mortality. The cost

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of care for these diseases is a significant burden, costing our health care system \$200 billion per year and resulting in an additional \$130 billion in lost productivity for employers.³

Patients with diabetes are typically treated with drugs to manage their blood glucose (sugar). Consideration should also be given to managing their triglycerides (the most common type of fat) and cholesterol.

Standard treatment guidelines include close monitoring of cardiovascular disease, and many patients are placed on a drug such as an ACE inhibitor to control their blood pressure and improve blood circulation. This is vital to ensure adequate blood circulation to their kidneys and lower extremities (legs and feet).

The year 2021 marked the 100th anniversary of the discovery of insulin, a lifesaving therapy for millions of people. Insulin prices have increased 600 percent over the last 20 years causing many consumers to be at risk of non-adherence due to cost.⁴

Solving the Affordability Issue - Legislation Influence

The Inflation Reduction Act, a spending package Congress approved in 2022, capped insulin out-of-pocket costs at \$35 for Americans with Medicare.

This does not apply to consumers with commercial insurance plans who may pay the full price for medications under high-deductible plans. For these individuals, out-of-pocket expenses can be \$1,000 or more a month on insulin alone.⁵ Eli Lilly, a manufacturing pioneer in diabetes treatments, recently announced a 70% cost reduction for two of its most popular insulin products, Humulin and Humalog, for uninsured patients and those with private health insurance. Lilly also reduced the price for its generic lispro from \$126 to \$25 a vial. These price reductions are expected to improve medication adherence since individuals will be better able to afford them. These changes follow efforts by the federal government, the California state government, non-profits and some companies to make insulin more affordable for the more than 7 million Americans with diabetes who require it.⁶

Lilly's actions have placed significant pressure on their competitors, Novo Nordisk and Sanofi. Making their insulin more affordable to cash-paying patients will encourage pharmacies like Mark Cuban's Cost Plus Drug Co. and Blueberry Pharmacy to add them to their low-net-cost formularies.⁶

CivicaRx, a non-profit drug manufacturer owned by several Blues plans, intends to manufacturer affordable insulins in 2024. Civica will produce three insulins: glargine, lispro and aspart, which are comparable to Lantus, Humalog and Novolog, respectively. They will be available in vials and prefilled pens. Civica plans to set a recommended price of no more than \$30 per vial and no more than \$55 for a box of five pen cartridges, a significant discount to prices charged to uninsured individuals today. Their policy for pharmacies and others who choose to distribute Civica insulins reflects its philosophy that prices to consumers should be fair, reasonable and transparent, and no higher than the public, recommended price.⁷

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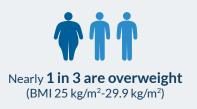


Science of Obesity

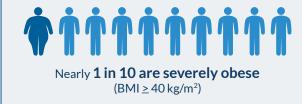
Obesity is recognized as a chronic disease and a significant threat to public health by national organizations such as the American Association of Clinical Endocrinology, American College of Endocrinology and American Medical Association.¹⁻³

Nearly 3 in 4 U.S. Adults are Obese or Overweight ⁴⁻⁶

The Center for National Health Statistics found that in adults aged 20 years between 2017 and 2018 4-6

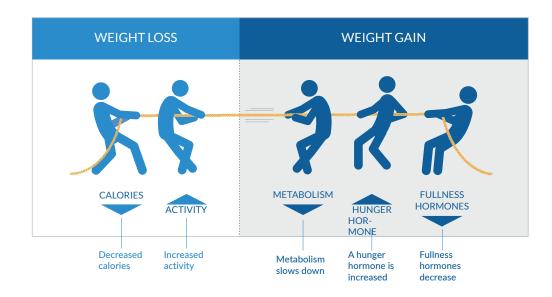






The Tug-of-War of Weight Management

Even if people with obesity achieve weight loss through calorie reduction, it can be difficult to maintain because of the body's metabolic and hormonal responses. In people with obesity, the body will try to put the weight back on for at least 12 months after weight loss.⁷





Clinical Guidelines for Treatment of Obesity

Evidence-based guidelines from AHA/ACC/TOS suggest a stepwise approach to obesity management, which may include pharmacotherapy or bariatric surgery.³

Evidence Based Guidelines for Adults⁷

Treatment	BMI Category (kg/m²)				
ireatment	25-26.9	27-29.9	30-34.9	35-39.9	<u>≥</u> 40
Diet, physical activity, and behavior therapy	Yes, with comorbidities	Yes	Yes	Yes	Yes
Pharmacotherapy		Yes, with comorbidities	Yes	Yes	Yes
Surgery				Yes, with comorbidities	Yes

ACC=American College of Cardiology; AHA=American Heart Association; TOS=The Obesity Society. ^a Yes alone means that the treatment is indicated regardless of presence or absence of comorbidities. The solid arrow signifies the point at which treatment may be initiated.

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Partner Spotlight

On occasion, our newsletter will include insight from key McGriff partners. This quarter, we would like to showcase Dr. Paul S. Bradley, M.D., Scripta Insights.

About Dr. Bradley

Paul S. Bradley, M.D., is a Magna Cum Laude graduate of Tulane University and of the Emory School of Medicine. He is a practicing board-certified Internist and co-founder and Chief Medical Officer of Scripta Insights. Scripta was born out of Dr. Bradley's frustration with the impact that the high costs of prescription drugs were having on the health of his patients.

When he's not seeing patients and overseeing Scripta's P&T Committee, Dr. Bradley also serves as a Clinical Assistant Professor at Mercer Medical College, and is Principal Investigator at Meridian Clinical Research in Savannah, GA. He has led more than 100 pharmaceutical trials. Dr. Bradley is a member of the American Medical Association, American College of Physicians, Georgia Medical Society, and is certified by the American Board of Internal Medicine.





What Employers Should Know About Popular Weight Loss Drugs

How Obesity Impacts the Workplace

Obesity is a chronic disease that impacts more than four in ten American adults, according to the Centers for Disease Control and Prevention (CDC). By 2030, nearly half of U.S. adults are expected to be obese. According to the CDC, in 2019, medical costs for adults with obesity were, on average, \$1,861 higher than for adults with a healthy weight.

In healthcare, obesity-related costs alone exceed \$173 billion a year, with an additional \$8.65 billion attributed to employee absenteeism. Obesity also increases the risk of developing other conditions like diabetes, heart disease, and cancer: conditions that cost the US healthcare system over \$500 billion a year.¹²

Overview of Popular Weight Loss Drugs

The drug therapy class known as glucagon-like peptide-1 receptor agonists, or GLP-1 has roots that date back to 1964 and research on insulin response. Insulin is a hormone that helps the body manage glucose (sugar) from food. Insulin helps to move glucose out of the bloodstream and into our cells to be used as fuel for our body. Patients with type 2 diabetes cannot make and use insulin effectively, resulting in too much glucose in the bloodstream, which can have harmful consequences. The GLP-1 drugs help stimulate insulin to keep our blood sugar in check.

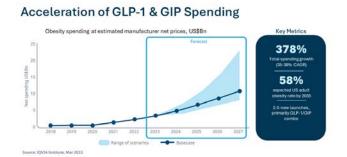
These drugs work by lowering an individual's blood sugar levels. While GLP-1 drugs have not been extensively tested on individuals with obesity, they have the side effect of sending fullness signals to the brain, which produces an anti-appetite effect leading to weight loss. However, individuals may need to take these drugs indefinitely to maintain any weight loss benefits. Other side effects include nausea, vomiting and diarrhea. Weight loss is topof-mind with news coverage of GLP-1s, a growing obesity epidemic, with over 42% of Americans living with obesity. Obesity is a complex disease that needs comprehensive care approach to see meaningful outcomes.²

Considerations for Weight Loss Drugs

The popularity of weight loss drugs has become a national phenomenon in the United States. This trend has made its way into the workplace, with employees increasingly asking their employers about coverage for popular drugs used for weight loss, such as Wegovy. Employers have traditionally not covered weight loss drugs. Data from the International Foundation of Employee Benefit Plans (IFEBP) revealed that only 22% of employers cover prescription weight loss drugs, although the percentage is higher for employers with 5,000 or more employees. In comparison, 45% of employers surveyed cover bariatric surgery and 32% cover weight management programs.

GLP-1 medications have had a dynamic impact on the treatment landscape for diabetes and obesity. Currently, three GLP-1s are approved by the FDA and specifically marketed for weight loss: Wegovy (semaglutide), Saxenda (liraglutide) and Zepbound (tirzepatide), currently approved for treating diabetes. With even more significant weight loss efficacy, Mounjaro is expected to be approved by the FDA for weight loss by the end of Q1 2024.

The use of GLP-1s has skyrocketed over the past few years, and the upward curve shows no sign of slowing. Drug spend for this class could reach more than \$77 billion in global sales by 2030.3 Plan sponsors should consider a coverage strategy that includes three key elements: coverage criteria, cost containment, and clinical care.





Successful Management of GLP-1 Coverage

• Strict PA criteria to ensure appropriate use, prevent off-label use, and adherence to FDA guidelines. Prior authorization criteria can vary by insurer, but some standard guidelines are listed below:

Diabetes	Physician confirmation of diabetes diagnosis OR Prior anti-diabetic medication use
Obesity	Physician confirmation of BMI > 30 kg/m2 OR BMI > 27 kg/mg2 + comorbidity (i.e. hypertension, type 2 diabetes, dyslipidemia) AND Behavioral modifications

BMI = Body Mass Index

- Step therapy requirement to steer toward lower cost medications
- A narrow GLP-1 prescriber network to ensure appropriate prescribing and support of individuals
- Pairing drug coverage with a program to engage individuals in a coaching program to support lifestyle changes needed to achieve and maintain clinically appropriate weight
 - Require enrollment within a diet/exercise/nutritional coaching program for three months before a GLP-1 drug is covered

Side Effects From GLP-1 Medications

- Gastroparesis (stomach paralysis)
- Pancreatitis
- Intestinal blockage
- Reduction in lean body mass (muscle wasting)
- Acute kidney injury
- Thyroid cancer
- Diabetic neuropathy
- Gallbladder disease
- Hair loss

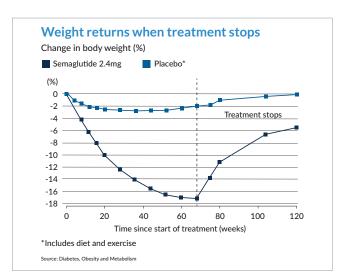
Long-Term Benefits

Obesity can lead to conditions such as type 2 diabetes, high blood pressure, high cholesterol, heart disease, cancers, sleep apnea, depression, and anxiety, among others.⁴ It wasn't until 2013 that the American Medical Association officially identified obesity as a chronic condition in and of itself.⁵

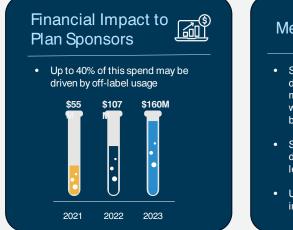
While offering an obesity management solution is a worthy goal for benefits leaders, it's important to recognize what success looks like. A 10% weight loss seems like a reasonable goal however it is more complicated that just a number on a scale. The health benefits of weight loss that can be achieved within a 5-10% weight loss range can be significant for those with other diseases. It's important that prescribers monitor other biomarkers like blood sugar levels, A1C, and blood pressure to get a full picture of an individual's health.







GLP-1 / GIP Diabetes and Weight Loss Drugs



Member Impact Shortages of GLP-1s forcing

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- Shortages of GLP-1s forcing diabetic patients to switch medications that have been working well to improve their blood sugar
- Surge in PA requests causing delays for members to get their legitimate prescriptions approved
- Unknown long-term health
 implications

How Plan Sponsors Can Address the Issue?

- Work with your PBM to ensure PA criteria includes chart notes and/or lab tests to validate a diabetes diagnosis
- Employ an external diabetes/wellness education solution like Virta, Noom, or Wondr

Plan sponsors should check with their Pharmacy Benefit Managers (PBM) or health plan to determine if care appropriateness strategies will impact rebate guarantees or other contracted performance or guarantees. It's important to consider the potential for significant improvement of health and the overall positive impact on healthcare spend. Cost savings associated with ensuring appropriate patient care could outweigh any rebate impact. Many large insurers are implementing obesity support programs to help support the efforts of individuals working toward maintaining a healthy weight. This is a positive direction and evidence of the kind of value-based strategies that Pharmacy Benefit Managers (PBM) are considering, in an effort to illustrate their value in regard to controlling costs and improving clinical outcomes.

Cigna recently launched a new program designed to effectively manage the cost of obesity therapy by capping the annual price increases for the GLP-1 drug class at 15% for employers and plans participating in a weight loss management program. This is the first financial guarantee available in the market for the drugs and could insulate employers from surging costs while increasing patient access and support. The cap is possible through agreements that Express Scripts made with drugmakers Novo Nordisk and Eli Lilly. It will be managed under their Evernorth division.⁷

As a result, employers and plans participating in Evernorth's weight management program EncircleRx won't see more than a 15% annual increase in spending on Novo's Wegovy and Lilly's Zepbound, according to Cigna. In comparison, health plans are seeing the annual cost trend for weight loss drugs hit 40% to 50%, a spokesperson for the insurer said. Cigna is gambling that it will be able to successfully control medical costs for members of EncircleRx, the <u>weight loss management program Express</u>. <u>Scripts launched</u> last summer amid spiking demand for GLP-1s. EncircleRx ties access to GLP-1s with lifestyle modification services like coaching.⁷

SafeGuardRx, Evernorth's portfolio of value-based condition management programs, includes hepatitis C, diabetes and other diseases, across 14 value-based programs, including EncircleRx, which is dedicated to obesity, diabetes and cardiovascular disease. They report a success of \$6.4 billion in savings last year, according to its website.⁸ Employers pay a monthly fee to enroll their workers in the program.

As such, Cigna could generate savings by improving members' health outcomes and avoiding more expensive medical care down the line. If they can improve these individuals' blood sugar and cardiovascular health there could be long-term benefits for the individual's health, resulting in lower medical costs. Cigna isn't the only insurance provider with a weight management program that includes management and access to GLP-1s. <u>UnitedHealth</u> and <u>Elevance</u> launched their own programs in January and February, respectively, for employer clients of their PBMs.



Clinical Information for GLP-1 Agonists

Semaglutide, the active ingredient in Ozempic and Wegovy, was developed to provide a longer-acting alternative to Liraglutide, the active ingredient in Victoza and Saxenda. Ozempic, Victoza, Wegovy and Saxenda are all selfinjectable drugs in a class of medications called glucagonlike peptide-1 (GLP-1) agonists.

While Ozempic and Victoza are indicated to treat type 2 diabetes, Saxenda and Wegovy, their higher-strength versions, have been FDA approved to treat people without diabetes who have an obesity diagnosis or are overweight with weight-related medical problems.

In my clinical trial and primary care exam room experiences, it is evident GLP-1 agonists suppress appetite, effectively helping most patients lose weight. My patients often describe the effect profoundly as, "I'm just not hungry". The acceptance of a "shot" for weight loss, however, has exceeded my wildest expectations. We used to beg diabetic patients to start "the needle." Now, I have patients asking me about it all day long.

Typically, with these medications, the higher the dose, the higher the weight loss achieved. But it's not a magic bullet. In clinical trials, patients were also required to be on a reduced-calorie diet, with a 500-calorie-a-day deficit, and exercise 150 minutes weekly. Also, the drugs only work when a patient is taking them, and weight gain should be expected if the medication is stopped.

My patients often describe the effect profoundly as, "I'm just not hungry."

This class of medications does not come without side effects. Nausea and constipation are the most frequent but are usually manageable. As the use of these medications increases, so do concerns about potential complications. A known rare complication I have seen in my practice, pancreatitis, has been associated with costly hospital stays.

However, unlike earlier weight-loss medications, these drugs have no known negative cardiovascular effects; in fact, they have been shown to lower the risk of major cardiovascular events.



The Projected Cost of "Miracle" Weight-Loss Drugs

For self-funded health plans, the rising cost of these prescription drugs is a major concern. Ozempic has gained acceptance on most formularies. Its price has risen from ~\$660 per month when it first hit the market to ~\$860 a month. Wegovy is currently \$1,600 per month-that's \$19,000 a year-and most plans do not cover it. As a maintenance therapy, this class of drugs will be a recurring annual cost for plans that choose to cover. Plus, there's the added expense of monthly office visits, labs, dietitian consults, etc.

While plans may not have budgeted for the unforeseen uptick in utilization of these high-priced drugs in 2022, many actuaries did adjust their forecasts, accordingly, for 2023. But, with obesity affecting 42% of U.S. adults and rising, according to the CDC, what could this look like for you in 2024 and beyond?

Here's an example of what it may look like for your plan, based on several different models we've analyzed along with our Scripta proprietary data: For a plan with 1,000 primary members and 2,000 total lives, we can estimate 670 people are eligible for GLP-1 agonists. If in 2022, approximately 2.5% of that eligible population used one of these medications at ~\$10,300 per member, the cost of this drug class would've been an estimated ~\$175K.

Now, if that usage increases to 5-10% in 2023 or 50% of the eligible population in 2024, as some models suggest, the cost could rise to ~\$350K-\$700K annually or even ~\$3.5M per year for a plan of this size by 2024.



"The acceptance of a 'shot' for weight loss has exceeded my wildest expectations."

Scripta Savings Strategies

This isn't the first diet drug craze. Back in the Fen-Phen days, I saw everyone with a prescription pad writing scripts for that drug combo-including ophthalmologists and radiologists. Plans will need to prepare for the wave of utilization that's coming for this new class of weight-loss drugs and put smart strategies in place now to mitigate a potential financial avalanche.

Member Out-of-Pocket Costs

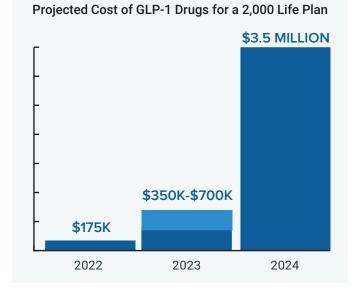
In all my years of experience as a practicing clinician, I've found patients are more successful at sticking with a weight-loss regimen when they have "skin in the game." The amount of "skin" can differ from member to member and will be specific to your population's demographics, but in general, I've found patients are willing to pay \$100 monthly out of pocket to achieve weight loss. Much less than that, and adoption falls of significantly.

That said, it's important to be aware of any manufacturer coupons available for these weight-loss drugs and understand how they impact your members' out-of-pocket costs. For example, Novo Nordisk, the manufacturer of both Ozempic and Wegovy, offers a \$150 coupon for Ozempic that can be applied to each prescription fill, allowing members to pay as little as \$25 per month. The company also offers a \$225 coupon for Wegovy (\$500 without insurance), which can bring the member's cost per fill down to as little as \$0.

Paying \$0-\$25 per month with a coupon, the member is not likely to feel the cost of taking this medication unless the copay is set high. With the \$225 coupon, the plan design must ensure the copay processes above this amount, so the member picks up some of the cost.

Step Therapy

If your plan is going to cover weight-loss medications, consider requiring members to try and fail lower-cost options before covering these higher-cost GLP-1 agonists. Drugs such as phentermine (generic) and Qsymia (brand)



have lower cash prices of \$7.50 to \$98 (manufacturer direct) per month. While infrequently covered by plans, these cheaper alternatives can be just as effective, and at a fraction of the price.

You may also consider programs like Scripta that provide member education, lower-cost alternatives, and decisionsupport tools to ensure your members are getting the right meds at the best price.

Prior Authorization

Wegovy is indicated for a BMI (Body Mass Index) of 27 or greater with at least one weight-related medical condition (i.e. hypertension, type 2 diabetes mellitus, elevated cholesterol/fats). If your plan is going to cover this medication, I would suggest strict documentation of the patient meeting the appropriate BMI and comorbidities.

This is not an unreasonable request for such a significant expense. Historically, weight-loss drugs have not been covered by plans. In plans with comprehensive weight-loss coverage, even weight-loss surgery would only be covered for the most at-risk populations, typically those with a very high BMI of 35, 40 or greater. Putting a prior authorization process in place can help ensure weight-loss medications are being used with medical necessity, not just for vanity.

Like weight-loss surgery, covering these weight-loss medications could also require proof of failing a program like Weight Watchers, six or more monthly clinician visits, as well as psychological and nutritional evaluations.





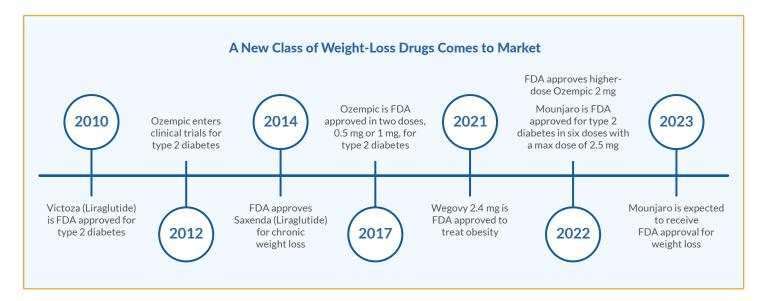
For Ozempic, I would want to see firm documentation of type 2 diabetes with an uncontrolled A1C (i.e. greater than 6.9). If the diabetes is already controlled and the goal is just weight loss, then maybe they need Wegovy. It's not just semantics if you don't plan on covering Wegovy.

Continuation of Therapy

If Wegovy is prescribed, I would require monthly visits with the medical provider at least until the goal weight is achieved. I see patients being given the starter dose with multiple refills and a six to 12 month follow up, when the drug is minimally effective unless the dose is increased each month. As a requirement for renewal, I would also like to see consistent and significant weight loss. I have had patients ask for a renewal prescription after just a one-pound weight loss. Think about this: a 19-pound weight loss in a year comes at a cost of \$1,000 a pound!

Weight-Loss Programs

If your plan does not choose to cover expensive weight-loss drugs, you may consider covering lower-cost weight-loss programs. For example, weight-loss surgery, which is mostly a onetime charge, averages between \$7,000 and \$33,000. Mail order meal plans that provide three meals a day range from Nutrisystem at \$300 a month to plans that deliver fresh meals at about \$800 per month. A monthly gym membership only costs \$10-200 a month. Weight-loss Medications are Not Going Away







Weight-Loss Medications are Not Going Away

The pharmaceutical pipeline is strong in this therapeutic class with multiple new anti-obesity drugs expected to enter the market over the next several years. Lilly's drug Mounjaro, which is currently only indicated for diabetes, is expected to be approved for weight loss in 2023. The weight-loss benefits appear to be even greater than Ozempic and Wegovy.

Competition will be good, as we will no doubt continue to see more players with better efficacy and tolerability. Unfortunately, in U.S. medicine, that rarely drives down the price. Self-funded health plans will need to establish their comprehensive strategy quickly by weighing the risks versus benefits of coverage. At Scripta, we're here to help guide you through that process.



Dr. Paul S. Bradley, M.D. Scripta Insights Co-Founder, Chief Medical Officer and Internist

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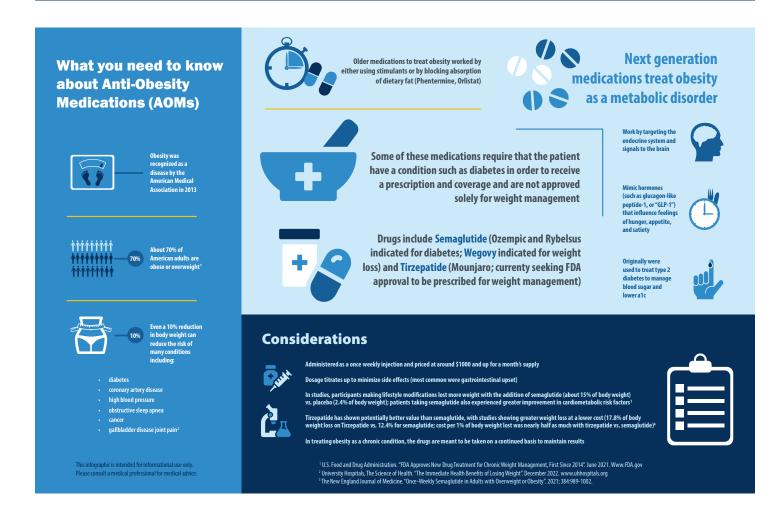
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Scripta Savings Strategies

Begin with your employee benefit goals and values to help guide your strategic decisions around weight-loss management. Scripta offers these cost-saving strategies for plan sponsors:

- Decide philosophically whether you want to cover weight-loss treatment and ensure alignment through your benefit offering, i.e. weight-loss surgery, meal plans
- Implement a cost-sharing approach for weight-loss drugs that accounts for coupons and other factors specific to your population's demographic
- Consult with Scripta for a deep dive into your pharmacy claims data to ensure your approach to weight-loss drug therapies aligns with your financial goals
- Address coverage controls like utilization management programs with your consultant/broker and PBM, i.e. step therapy and prior authorization



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