innovative Rx STRATEGIES™

Pharmacy Benefits Briefing

GLP-1 and GLP-1/GIP for Obesity Management

What employers need to know in a landscape of innovation and cost inflation

Do You Have a Pharmacy Game Plan?

As the cost of providing pharmacy benefits continues to increase, employers must deploy strategies to contain costs. The pharmaceutical industry is complex and new drugs are flooding the market—and thorough understanding of the complete clinical landscape is vital to keeping your spending in check. This brief outlines what employers need to know about the GLP-1 class of medications for the treatment of obesity.

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Obesity is a common, serious and costly disease. If patients do not respond to lifestyle management, doctors can consider medication therapy, devices and surgery. Medications for weight loss are not new, however the effectiveness of newer weight loss medications has driven a new conversation on this topic.

Glucagon-like peptide-1 (GLP-1) receptor agonists are available as single agents and in combination with gastric inhibitory polypeptide (GIP) and are FDA approved for the treatment of type II diabetes and obesity/weight loss. The current wholesale acquisition cost (WAC) of weight loss GLP-1s and GLP-1/GIPs has made these medications budget-busters throughout the country. News reports are emerging of states, health systems and employers who previously provided coverage for weight loss agents but have had to pull back or stop coverage.

272%
Increase

The global GLP-1 and GLP-1/GIP market is projected to grow 272% by 2031.

It is estimated that the global GLP-1 and GLP-1/GIP market was $36.8 billion in 2023 with a projected growth to $138 billion by 2031 across diabetes and obesity indications. In 2023, the weight loss medications accounted for $9.3 billion (25%) of this cost, but this percentage split will continue to shift toward obesity if utilization trends continue.

GLP-1 and GLP-1/GIPs continue to be the focus of media and social media as well as conversations with plan sponsors around their spending. Wasteful spending due to high rates of discontinuation has been noted in studies and in the real world. Studies and real-world experience have also shown that once stopped, weight is regained, putting these agents in the category of chronic medications.

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FALL 2024 UPDATES

Adverse Drug Reactions

Like any prescription drug, these agents come with risk. While gastrointestinal side effects have been known, as these agents are used by a larger population and for a longer period of time, new concerns have arisen. While they may not impact everyone, consideration should be given to the more severe GI side effects such as intestinal blockage and gastroparesis. Additionally, the impact of these therapies and the ensuing weight loss on muscle and bone is of concern.

Additional safety concerns have been raised with the use of compounded medications. The risks are not centered on the actual agent. There have been issues with the prescription, compounding and patient use that have led to hepatizations.

Data

In late 2023, the results of the long-anticipated SELECT trial were released and showed some positive benefit to the use of GLP-1s in patients without diabetes. In this study, patients 45 years or older who had already experienced a cardiovascular event had a 1.5% lowering of additional events. The outcomes of the SELECT trial led to a new FDA approval for Wegovy in March of 2024. The medication received an indication for preventing cardiovascular disease in patients with obesity or for those who are overweight and also have existing cardiovascular disease.

It is important to truly assess what the information is saying. In the SELECT trial, the study population was those age 45 years and older who had previously had a cardiovascular event such as heart attack, stroke or symptomatic PAD with objective tests. This patient population is important to keep in mind as this cardiovascular impact cannot be expanded to those without these specific previous disease states.

When assessing studies like this, there is a key factor to consider: the number of people who require treatment. In this case, based on the number needed to treat, it would cost over $2 million, after rebates, to prevent one additional cardiovascular event. Contrasting that with GLP-1s in patients with diabetes, it costs around $650,000 to prevent one additional cardiovascular benefit.

$2,000,000

GLP-1 spending to prevent cardiovascular event in patients without diabetes

$650,000

GLP-1 spending to prevent cardiovascular event in patients with diabetes

Generic Pipeline

Victoza (liraglutide) generic first launched with an authorized generic in June 2024. While an authorized generic does not drive the price down significantly, there is the potential for 10 true generics, to the market starting in December 2024. This additional competition is anticipated to bring some pricing relief.

While pricing relief for liraglutide is a great outcome, it is anticipated to have little impact on the GLP-1 and GLP-1/GIP market. Due to its daily dosing and smaller impact, liraglutide is one of the least utilized GLP-1s for diabetes management with 4.6% of the market share. The same is true for obesity. Branded liraglutide, Saxenda, is not anticipated to have a generic approved until at least 2027, and off-label use of the current liraglutide is not anticipated to impact the obesity space as the weight loss is less than 50% of that with Wegovy and Zepbound. In addition, higher doses of generic liraglutide for diabetes would need to be used to achieve this impact, leading to doubling of the generic cost, which erases much of the savings.

Wegovy and Zepbound generics are not anticipated until at least 2035 or 2036, leaving the cost of brand names an issue for the foreseeable future. While the hope is that more GLP-1s and GLP-1/GIPs on the market will drive down cost through competition, the impact and timeline remain to be seen.

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Indication Pipeline

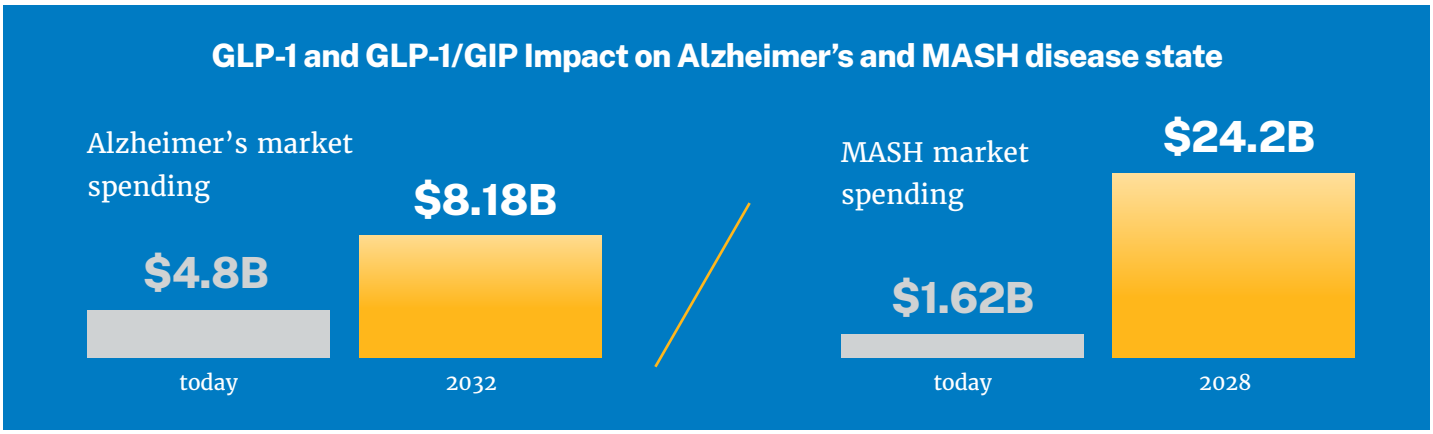
Due to the success of GLP-1 and GLP-1/GIP medications to date, the pipeline of future treatment is strong. Additional medications in the same classes today are close to approval, including oral semaglutide for obesity. Despite positive study results, the manufacturer has not yet commented on the timeline for approval. New agents are also being explored, including adding further agents to GLP-1/GIP and bringing triple-therapy medications to the market.

In addition to new agents, the use of GLP-1 and GLP-1/GIP medications is expected to expand past diabetes and weight loss in the coming years. Ongoing studies are looking at the use of these agents in other disease states. If GLP-1s and GLP-1/GIPs are approved for additional disease states, the impact of increased use of these medications will further impact pharmacy plan spending.

GLP-1s are being studied by manufacturers for a variety of disease states, including sleep apnea, metabolic dysfunction-associated steatohepatitis (MASH), kidney disease, heart failure, Alzheimer's disease, dementia and knee osteoarthritis. Sleep apnea is the closest to expansion with Eli Lilly submitting tirzepatide for FDA approval. This approval review is anticipated still in 2024. With the exception of Alzheimer's and dementia, these conditions have one thing in common — obesity tends to be a contributing factor. In regard to MASH, this is a disease state where GLP-1 and GLP-1/GIP medications can lead to cost savings. The currently approved treatment for MASH, Rezdiffra, has an annual WAC of $48,000.

In addition to manufacturer trials that can lead to expanded indications, data continues to be shared by others regarding additional disease states such as addiction, nicotine use, polycystic ovary syndrome and peripheral arterial disease.

Just as GLP-1s and GLP-1/GIPs have had a financial impact on diabetes and obesity, they are anticipated to grow spending once approved for other disease states. They are also expected to impact the Alzheimer's market with spending growth from $4.8 billion to $8.18 billion by 2032 and the MASH market with spending growth from $1.62 billion to $24.2 billion by 2028.



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Recommendations

Today, the majority of plan sponsors do not provide coverage for GLP-1s for weight loss. Not only that, but the reports of plan sponsors ending coverage because of the inability to afford the increase continue to hit the news. If a plan sponsor does elect to provide coverage, it is vital that they have controls for accountability in their approach.

Accountability actions can include the requirement to work with a health coach or behavioral specialist, the requirement for weight loss to continue to receive the medications and limits on refills. Prior authorization should be a given with adherence monitoring to ensure patients are taking as prescribed so the medication is not used in a wasteful manner.

Plan sponsors who do choose to cover these medications can also get creative in their coverage by offering them to a smaller population group in order to realize potential savings. One such example is covering those with a higher BMI, such as grade 3 obesity (BMI > 40 kg/m2). They may also choose to limit access to those enrolled in specific programs or working with specific providers. Some of these actions may impact rebates, in turn affecting the net cost of these agents. Regardless of decisions made, it is important to have an unbiased assessment done on the overall cost and/or savings of these decisions.

The expert team at Innovative Rx continues to monitor the GLP-1 and GLP-1/GIP market and its impact on health plans. **Contact us today for more information.**