Excelsior Solutions

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Evidence of Rapid, Widespread GLP-1 Weight Loss Medication Discontinuation: Why it Matters and What You Can Do

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The Rise of Gene Therapy Treatments and Key Considerations

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Evidence of Rapid, Widespread GLP-1 Weight Loss Medication Discontinuation: Why it Matters and What You Can Do

There is growing evidence of rapid and widespread early treatment discontinuation among patients who initiate treatment with a GLP-1 anti-obesity medication (AOM) such as Wegovy®. Several recent studies and reports, including our own internal data, illustrate the issue. In this article, we will: a) present evidence that continues to emerge surrounding this topic of concern, b) discuss the consequences of this pattern to your pharmacy benefit plan, and c) provide you with simple advice to help you determine if your plan is experiencing this issue and its consequences.

THE EVIDENCE

In 2020, the pharmaceutical company Merck published a study, "Real-World Adherence and Discontinuation of Glucagon-Like Peptide-1 Receptor Agonists Therapy in Type 2 Diabetes Mellitus Patients in the United States." While not related specifically to weight loss GLP-1s (Wegovy was not launched until June 2021), its conclusions were startling:

> **"Over half of [type 2 diabetes] patients initiating GLP-1 [drugs] were non-adherent and the majority (70.1%) discontinued therapy by 24 months. Reasons for non-adherence and discontinuation merit further research."**

In July 2023, Prime Therapeutics issued a release concerning work they had recently completed headlined, "Real-World Study Finds Low Patient Adherence for Weight Loss Drugs." This was the first study to include Wegovy and its less frequently prescribed "cousin," Saxenda®. Its conclusions were even more detailed than the Merck study, but no less startling:

> **"Among [Wegovy or Saxenda] new initiators without [diabetes] and with obesity, prediabetes, and/or BMI ≥ 30, there was no health care cost reduction in the first year. Instead, costs went up $7,727 per [Wegovy or Saxenda] treated member compared to the matched control group. [Wegovy or Saxenda] treatment persistency was poor with only one-third on therapy at one year. Among [Wegovy or Saxenda] adherent individuals, the increase in costs was even higher, double the prior year. These real-world findings are important to aid in the development of an evidence-based GLP-1a weight loss management program, pharmaceutical manufacturer value-based contracts, and health insurance benefit designs."**

In November 2023, our internal Data Sciences team reviewed a subset of our nationwide client database of combined pharmacy and medical claims data and produced the following findings:

- INCREASED SPEND: Usage of Wegovy or Saxenda for weight loss is observed to increase overall spend in the year of first usage as well as the subsequent year. Covering anti-obesity medication is expected to add $75,000 per 1,000 employees covered, without clear improvement to overall patient outcomes in the study period.
- LOW USER PERSISTENCY: Nearly two-thirds of claimants are observed to stop taking Wegovy or Saxenda before 12 months. Those who use the drugs longer are observed to drive more inflation and experience more frequent side effects.

Finally, in January 2024, a vendor partner of ours revealed that, on average, fully 80% of patients who initiated treatment with Wegovy or Saxenda discontinued such treatment within a year.

While the reasons for these early treatment discontinuation rates will require additional work to comb out, the consequences are clearly discernible today. The supply chain may be a factor, but it is likely not the root cause by itself.

THE CONSEQUENCES

One only has to turn to the respective product labeling information for Wegovy and its new competitor in the AOM weight loss space, Zepbound™, to understand why terminating treatment is such a concern.

In Table 8 on page 23 of the Wegovy product labeling, Wegovy's manufacturer reveals that, on average, in their "Study 4," patients who received Wegovy for 20 weeks lost 8% of their baseline weight. Upon discontinuation of Wegovy treatment, however, and within 48 weeks of discontinuation, a 7% weight gain occurred from the week 20 weight. In other words, within one year of discontinuing Wegovy, almost all of the weight lost while utilizing Wegovy was regained, rapidly reversing most of the time and money invested in the since-discontinued Wegovy treatment.

Similarly, Eli Lilly, manufacturer of Zepbound (tirzepatide, approved in November 2023), announced in an article in the Journal of the American Medical Association in December 2023, that,

> **"In participants with obesity or overweight, withdrawing tirzepatide led to substantial regain of lost weight (approximately 67%), whereas continued treatment maintained and augmented initial weight reduction."**

Clearly, the manufacturer's own data definitively establish that, for weight loss to be maintained, treatment must be sustained. However, a growing body of real-world experience shows that 66% to 80% of patients who initiate treatment with one of these medications walks away from such treatment, for whatever reason, within one year of starting treatment, leading to wasted time and money for both members and pharmacy benefit plans.

THE ADVICE

We suggest asking your PBM or carrier to tell you what percentage of patients who have started a GLP-1-containing AOM such as Wegovy, Saxenda, or Zepbound were still utilizing those medications upon their respective one-year anniversary date of treatment initiation. Once you receive that information, we will guide you in assessing its relevance in possibly altering

your plans for the ongoing coverage of these medications whose long-term benefits essentially and materially depend upon patients' long-term commitment to continuing treatment. Be wary of any vendor claiming de-prescribing GLP-1 medications as their big differentiator.

Robert Kordella, RPh, MBA
Chief Clinical Officer

Bob has more than 40 years of diverse experience in the pharmacy industry. Over the course of his career, Bob has led clinical and PBM operations teams in successfully managing more than $4 billion in annual drug spend. Additionally, his efforts have limited per-member-per-year spending growth to levels that have simultaneously drawn industry acclaim and consistently high levels of member and payer satisfaction.

The Rise of Gene Therapy Treatments and Key Considerations

Currently, over 20 significant cell and gene therapy products have been approved by the U.S. Food and Drug Administration (FDA), and they expect to approve 10 to 20 gene and cell therapies by 2025.[1, 2] Despite this rapid approval rate, there is great concern about the commercial market's ability to handle the expense of these therapies. The newest gene therapies approved for sickle cell disease and hemophilia have a market cost of over $3 million for a one-time dose. This price is for the drug alone and does not include any costs associated with the administration of the product to the patient (which often results in a month-long hospital stay for many patients).[3] By 2034, it is estimated that annual spending for gene therapy will increase to over $25 billion in the U.S.[4]

If these therapies are truly curative, then it could be argued that these price points are justified, considering that the cost to develop these therapies was around $5 billion[5] and the savings accrued from curing these diseases could be as much as $33 billion by 2029.[6] However, there is concern with the long-term safety and efficacy of these gene therapy products. For example, Lyfgenia™ (treatment for sickle cell disease) has a black box warning for blood cancer and carries the risk of infertility (due to treatment involving patients who receive high-dose chemotherapy). Clinical trials for Roctavian™ (treatment for hemophilia A), which costs $2.9 million per dose, have shown that, after three years, 46 of 134 patients studied had factor VIII levels classified as moderate or severe disease, and eight of them had resumed other treatments for their hemophilia.[7]

Gene therapy treatments are expected to be billed under medical benefits programs. With reports that current payment models are not equipped to handle such large payments, there is growing concern over how to pay for these treatments. Several payment options have been proposed, including installment plans, risk pools and reinsurance, price-volume and expenditure caps, and performance-based models based on individual patients.[8] However, payers will need to consider the potential benefits and drawbacks connected to these models. This is just one of many concerns regarding gene therapy that needs to be addressed before it can reach its full potential. For more information, CLICK HERE to read our white paper covering this topic.

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Pharmacy Intern, PharmD Candidate 2024

Sydney is a PharmD candidate at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences. She has a strong interest in managed care pharmacy and is currently in the application process for managed care PGY1 residencies. She has a particular interest in payer relations and has experience in specialty pharmacy, formulary management, and operational management through previous rotations.

Rebecca Lich, PharmD, MBA
Senior Vice President

As a doctor in pharmacy, Rebecca is an expert in contract development, pharmacy claim pricing, benefit design, rebate management programs, financial analysis, auditing, and adjudication of pharmacy claims. As a residency trained clinical executive, Rebecca has 15 years of managed care experience, including 10 years' experience with one of the largest pharmacy benefit management companies.

[1] Approved Cellular and Gene Therapy, U.S. Food and Drug Administration, Feb. 21, 2024.
[2] Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D, Director of the Center for Biologics Evaluation and Research on New Policies to Advance Development of Safe and Effective Cell and Gene Therapies, U.S. Food and Drug Administration, Jan. 15, 2019.
[3] US FDA Approves Two Gene Therapies for Sickle Cell Disease, Reuters, Dec. 8, 2023.
[4] Estimating the Financial Impact of Gene Therapy in the U.S., National Bureau of Economic Research, April 2021.
[5] Uncovering Behind-the-scenes Challenges in Bringing Gene Therapies to Market, Evernorth Health Services, May 18, 2022.
[6] Report Demonstrates Potential for Cell and Gene Therapies to Provide 10-year Cost Savings to the Healthcare System, Alliance for Regenerative Medicine, January 2020.
[7] Uptake of New Hemophilia Gene Therapies Slow as Field Assesses Options, Reuters, Dec. 15, 2023.
[8] They Cost Millions. How Payers Might Manage Those Astronomical Gene Therapy Bills, Managed Healthcare Executive, November 28, 2023.