

A CAUTIONARY TALE: THE RISE OF GLP-1s

From television and magazine ads to widely shared content on social media, drugs treating diabetes and obesity have hit craze status. And for good reason. The drugs, known as GLP-1s, first received FDA approval in 2005 and have excelled in treating diabetes. However, in recent years, the drugs have gained notoriety for their weight-loss use.

The dramatic increase in popularity underscores unanswered clinical questions and presents a need for commonsense policies addressing which patients are suited for the drugs and at what cost. **GLP-1s (Glucagon-like peptide-1 receptor agents) are proven to effectively control blood sugar, or glucose, to help treat diabetes.** It's their ability to accelerate weight loss, however, that has sparked the rise in consumer demand and concerns from policymakers.

A major issue surrounding GLP-1 utilization for weight loss purposes relates to the clinical appropriateness of the drugs, ranging from side effects to the unknown implications of long-term use. For instance, patients must remain on the drug in perpetuity – most commonly with weekly injections – or risk regaining weight. A recent *Journal of the American Medical Association* study¹ found that while obese or overweight adults lost an average of 21 percent of total weight after 36 weeks of treatment, they regained 14 percent within one year of switching to a placebo. The findings fail to account for the emotional stress significant weight loss and gain has on patients.

The other key challenge is the egregious price tag of the drugs. The average GLP-1 costs approximately \$1,000 per month, per patient², and the drugs are generating massive amounts of revenue for their manufacturers. **In 2023, the global market for these drugs reached \$6 billion. By 2030, it could grow to \$100 billion, according to Goldman Sachs Research.**³ The high cost creates challenges for patients, clinicians, policymakers and state and federal budgets. For example, in January 2024, North Carolina officials halted coverage of GLP-1s⁴ for state employees noting it had spent \$100 million in 2023 and projected \$1.5 billion by 2030. Health plans have seen their prescription drug spending accelerate in recent years due to increased demand for GLP-1s. Unfortunately, there are no generic alternatives on the near horizon, underscoring the need for policymakers to act.

Bringing down the price of GLP-1s is critical before any conversation about expanding coverage. Congress must take action, starting with increasing competition with generic alternatives. To do so, patent reforms are essential. **The current batch of GLP-1s enjoys a median of 19.5 patents filed and 18.3 years of exclusivity after FDA approval.**⁵ This lucrative tangle of regulatory gimmicks, dubbed “patent thickets,” are used for the sole purpose of blocking affordable generics and ensuring market dominance for higher-priced brand products.

GLP-1s are drugs proven to treat diabetes. But with high costs, increased use for other purposes and clinical uncertainty, GLP-1s are not without controversy.

To address pharmaceutical companies' gaming of the patent system, ACHP calls for passage of H.R. 6986/S. 3583 to curb manufacturer abuses of patents, making it easier for competitors to enter the market and lower the costs of GLP-1s.

A CAUTIONARY TALE: THE RISE OF GLP-1s



For more information contact Josh Jorgensen at jjorgensen@achp.org.

POLICY CONSIDERATIONS FOR COVERAGE AND UTILIZATION OF GLP-1S

To ensure the right patients are receiving the right drugs at the right time, ACHP calls on policymakers to consider the **Three Cs**:

- ▶ Reasonable price must come before **COVERAGE**. *The price is unsustainable. Coverage expansion without addressing the underlying price and considering the impact to the American health care system is dangerous.*
- ▶ **CLINICAL** flexibility is critical and **CLINICAL** evidence is paramount. *Clinicians need tools to ensure GLP-1s are in the best interest of each patient. Further, studies are needed to determine who should be prescribed the drugs and for how long.*
- ▶ **COMPETITION** is vital. *Manufacturers are gaming the system. Less expensive generic options are years away. Policymakers must change the drug supply chain to ensure robust competition that decreases the price tag of GLP-1s and other prescription drugs.*

FREQUENTLY ASKED QUESTIONS

What is a GLP-1?

GLP-1s are medications used to treat diabetes and obesity. Twelve percent of Americans are diagnosed with diabetes⁶ and 42 percent of American adults live with obesity.⁷

What drugs are classified as a GLP-1?

Commonly prescribed examples include semaglutide (Ozempic, Wegovy, Rybelsus), dulaglutide (Trulicity) and tirzepatide (Mounjaro).

How much does a GLP-1 cost?

On average, GLP-1s cost more than \$1,000 per month, per patient.

How long do patients utilize GLP-1s?

Typical utilization of GLP-1s is long-term. Current studies have not shown effective wind-down in coverage for individuals using these drugs.

Citations

1. Louis J. Arnone, MD, et al. "Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity," JAMA. December 11, 2023. <https://achp.pub/JAMA-Arnone>
2. Constantino, Annika Kim, "Weight-loss drugs are priced substantially higher in the U.S. than in other countries, analysis says," CNBC. August 17, 2023. <https://achp.pub/CNBC-Drug-Prices>
3. "Why the anti-obesity drug market could grow to \$100 billion by 2030," Goldman Sachs. October 30, 2023. <https://achp.pub/Goldman-Anti-Obesity>
4. Castronuevo, Celine, "Ozempic, Wegovy Strain State Budgets in Battle Against Obesity," Bloomberg Law, February 2, 2024. <https://achp.pub/BL-State-Budgets>
5. Rasha Alhiary, et al. "Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists," National Library of Medicine. August 15, 2023. <https://achp.pub/NLM-GLP1>
6. "Statistics About Diabetes," American Diabetes Association. Accessed February 20, 2023. <https://achp.pub/Diabetes-Stats>
7. "State of Obesity 2023: Better Policies for a Healthier America," Trust for America's Health. September 21, 2023. <https://achp.pub/TFAH-Obesity>