

Medicare Should Cover Weight Loss Drugs as Long as the Prices are Affordable

Health Policy Portal

Catherine S. Hwang¹,
Aaron S. Kesselheim¹,
and Benjamin N. Rome¹

1. DIVISION OF
PHARMACOEPIDEMIOLOGY
AND PHARMACOECONOMICS,
DEPARTMENT OF MEDICINE,
BRIGHAM AND WOMEN'S HOSPITAL
AND HARVARD MEDICAL SCHOOL,
BOSTON, MA

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Abstract: Glucagon-like peptide-1 receptor agonists are effective for treating obesity, but the high cost of these medications endangers the financial viability of our health care system. To ensure that these drugs are available to Medicare beneficiaries, pharmaceutical manufacturers must lower their prices.

Recent studies have demonstrated that glucagon-like peptide-1 (GLP-1) receptor agonists are effective for treating obesity. Clinical trials have shown that these medications can lead to an average of 15% reduction in weight and decrease cardiovascular complications associated with obesity.^{1,2} But regardless of their efficacy, medications indicated for obesity have not been covered by Medicare, the public health insurance program that serves millions of older adults in the US. Recently, in March 2024, semaglutide (Wegovy) became the first drug in this class to receive an expanded label indication for decreasing the risk of major cardiovascular events, such as heart attacks, strokes, and deaths, among patients with obesity and established cardiovascular disease.³ Given this updated label, the Centers for Medicare and Medicaid Services (CMS) announced that Part D plans would be allowed — but not required — to cover semaglutide. However, at hundreds of dollars per person per year of therapy, cover-

age of this class of medications could cost the government billions of dollars.⁴ To provide reasonable access to these drugs at a fair price, Medicare can look to price negotiation or existing government patent use authority.

Based on over a decade of publicly funded research, the first GLP-1 receptor agonist was introduced in 2005 for the management of type II diabetes mellitus.⁵ In the clinical trials, decreased appetite and weight loss were common, leading manufacturers to subsequently study the drugs in obese patients without diabetes. In December 2014, liraglutide (Saxenda) became the first GLP-1 receptor agonist to gain approval by the US Food and Drug Administration (FDA) for treating obesity, followed by semaglutide (Wegovy) in June 2021 and tirzepatide (Zepbound) in November 2023.

Yet almost two decades after this class of drugs reached the US market, they remain costly. By one estimate, if only 10% of eligible Medicare beneficiaries received one of these drugs for a year at current prices, it could cost the government \$27 billion a year, which would increase spending on prescription drugs by 18%.⁴ Such a dramatic surge in spending would need to be supported by higher premiums. For example, in response to the approval of a novel class of Alzheimer's medications and anticipated rise in Medicare spending, annual premiums increased by more than \$250 per person.⁶ In that case, the premiums fell again after CMS issued a national coverage determination limiting coverage to clinical trials, and overall use of the drug was far less than many anticipated due to poor efficacy data.⁷

About This Column

Aaron Kesselheim serves as the editor for Health Policy Portal. Dr. Kesselheim is the *JLME* editor-in-chief and director of the Program On Regulation, Therapeutics, and Law at Brigham and Women's Hospital/Harvard Medical School. This column features timely analyses and perspectives on issues at the intersection of medicine, law, and health policy that are directly relevant to patient care. If you would like to submit to this section of *JLME*, please contact Dr. Kesselheim at akesselheim@bwh.harvard.edu.

Catherine S. Hwang, M.D., M.S.P.H., Aaron S. Kesselheim, M.D., J.D., M.P.H., and Benjamin N. Rome, M.D., M.P.H. work in the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, at Brigham and Women's Hospital and Harvard Medical School.

By contrast, as more data emerges about the degree to which GLP-1 receptor agonists not only lead to weight loss, but also reduce downstream complications from obesity, demand will likely be high as Medicare decides the extent to which it will cover these medications. To help manage spending, Congress should ensure that Medicare coverage of GLP-1 receptor agonists for treating obesity and reducing cardiovascular risk is accompanied by negotiation of fair prices. The Inflation Reduction Act of 2022 laid a framework for such negotiation, and Medicare is already actively negotiating prices

In the meantime, existing law, codified at 28 U.S.C. §1498, authorizes the federal government to use patent-protected products for its own purposes, with the payment of a reasonable royalty to the manufacturer.¹⁰ In the case of prescription drugs, the federal government last publicly considered exercising this power during the post-September 11, 2001 anthrax bioterrorism scare, when it sought a stockpile of ciprofloxacin (Cipro), the only FDA-approved antibiotic to treat this infection at the time, and Bayer initially refused to increase production. Eventually, Bayer agreed to manufacture the necessary amount

of Wegovy and \$10.3 billion of Saxenda,¹² and Eli Lilly sold over \$175 million of Zepbound during the first quarter the drug was on the market.¹³ Given that GLP-1 receptor agonists have been generating substantial revenues for manufacturers for nearly 20 years, it is reasonable to pursue strategies that would lead to a more moderate price that can help ensure the ongoing fiscal sustainability of Medicare. And with negotiated prices or court-set royalties under 1498, the drugs would still be profitable to manufacturers. A recent study found that each patient's supply of Wegovy could be manufactured for less than \$5 per month.¹⁴

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The argument that seeking lower prices for these drugs would somehow stifle pharmaceutical negotiation is incorrect. For example, savings from the price negotiation system set up by the Inflation Reduction Act are expected to decrease new drug approvals by 1% over the next 30 years, but the new law is poised to promote better access to more patients for the drugs it affects.¹⁵ Another line of opposition to price negotiation is that manufacturers have charged that it infringes on their constitutional rights — violating their free speech and confiscating their property without proper compensation — but these legal contentions are flawed. Nothing about patent protection prevents the government from negotiating fair purchase prices, and the government has previously used 1498 outside the prescription drug context without constitutional challenge.

for the first 10 drugs under this new law.⁸ Medicare can negotiate drugs as soon as 7 years after initial FDA approval; this means that semaglutide, approved in December 2017, could be eligible for negotiation as early as 2025, although a negotiated price would not take effect until at least 2027. Tirzepatide, which was only approved in May 2022, would not be eligible for negotiation until 2029. To ensure that these medications are broadly accessible to Medicare beneficiaries sooner, Congress could expand the negotiation program to anti-obesity drugs, or President Biden could attempt to broaden the negotiation program by executive action. International experience proves that centralized price negotiations can effectively rein in prescription drug costs.⁹

of medication and make it available at an acceptable price.¹¹ If the government chose this route, it would pursue alternative forms of production of GLP-1 receptor agonists and seek FDA approval to make them available via Medicare; then, if current manufacturers sued the government for patent infringement, a court would determine a reasonable royalty for Medicare sales. Another advantage of this pathway is that it could help alleviate production shortages that have plagued manufacturers of this class of drugs, as more patients and prescribers have turned to them to address the worsening obesity epidemic in the US.

Even without Medicare coverage, manufacturers of GLP-1 receptor agonists have been accumulating billions of dollars. In 2023, Novo Nordisk sold \$31.3 billion dollars

As Medicare takes steps to cover effective anti-obesity drugs to improve the health of older adults, the government should use this opportunity to pursue strategies that will lead to lower prices. We must not permit the promise of these weight loss drugs to undermine the financial viability of our health care system.

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