HHS Public Access

Author manuscript

Obesity (Silver Spring). Author manuscript; available in PMC 2023 December 01.

Published in final edited form as:

Obesity (Silver Spring). 2022 December ; 30(12): 2338–2339. doi:10.1002/oby.23556.

Addressing Insurance-Related Barriers to Novel Anti-Obesity Medications: Lessons to be Learned from Bariatric Surgery

Hamlet Gasoyan, DMD, PhD, MPH[1], **David B. Sarwer, PhD**[2]

[1]Center for Value-Based Care Research, Cleveland Clinic, Cleveland, OH

[2]Center for Obesity Research and Education, College of Public Health, Temple University, Philadelphia, Pennsylvania

Abstract

The past decade has witnessed significant progress in the development of new anti-obesity medications, with several having greater efficacy than pharmacological agents previously approved by the Food and Drug Administration (FDA). Despite the potential of new medications to combat America's obesity crisis, access to these agents is severely limited. This paper presents the current coverage landscape for anti-obesity medications, including the recent requirement by the U.S. Office of Personnel Management for Federal Employees Health Benefits Program carriers to offer adequate coverage of FDA-approved anti-obesity medications, makes parallels with conditions that made expanded insurance coverage for bariatric surgery possible, as well as emphasizes the need for additional action by the legislature and the Centers for Medicare and Medicaid Services to expand coverage of evidence-based obesity treatments.

The past decade has witnessed significant progress in the development of new anti-obesity pharmacological agents. Several appear to have greater efficacy than medications previously approved by the Food and Drug Administration (FDA). The Semaglutide Treatment Effect in People with Obesity (STEP) 1 trial, for example, found that individuals who received 2.4 mg of semaglutide (a glucagon-like peptide-1 receptor agonist [GLP-1RA]) once weekly, plus a lifestyle modification intervention for 68 weeks, lost on average 14.9% of their body weight, compared to 2.4% of weight loss with placebo plus lifestyle modification.[1] Furthermore, individuals treated with semaglutide 2.4 mg were more likely to lose ≥10% and ≥15% body weight vs. placebo (61.8% vs 13.3% and 52.1% vs 7.0%) at 2 years.[2] Additionally, a recent report of phase 3 multicenter, double-blind, randomized, placebo-controlled trial indicates that 50% and 57% of individuals who received the investigational medicine tirzepatide (a novel glucose-dependent insulinotropic polypeptide and GLP-1RA) once weekly with 10-mg and 15-mg doses, respectively, had a reduction in body weight of 20% or more at week 72, as compared with 3% in the placebo group.[3] These weight losses were accompanied by a significant reduction in cardiovascular and metabolic risk factors.[1,3] Patients and providers alike are pleased with the larger weight losses compared to other medications currently approved by the FDA. However, like in the case of any

Corresponding author: Hamlet Gasoyan, DMD, PhD, MPH, Center for Value-Based Care Research, Cleveland Clinic, 9500 Euclid Avenue, G10, Cleveland, OH, 44195, USA, gasoyah@ccf.org.

other chronic disease management, anti-obesity pharmacological treatment discontinuation appears to result in a reduction of the achieved health benefits. A recent STEP 1 trial extension study, for example, found that one year after the withdrawal of once-weekly semaglutide 2.4 mg and lifestyle intervention, individuals regained two-thirds of their lost weight, with similar worsening of cardiometabolic parameters.[4] Thus, chronic use of these medications, as seen with many other classes of medications, will need to be the rule, not the exception, for most patients.

Despite the potential of these new medications to combat America's obesity crisis, access to FDA-approved anti-obesity medications is severely limited. Currently, most state Medicaid programs and Medicare Part D Prescription Drug Plans do not offer coverage for weight loss medications.[5] Private insurance coverage often is based on the insurance plan's or employer's decision to include the benefit; even if the coverage is offered, its initial and continued coverage is further restricted by stringent prior authorization criteria. Furthermore, list prices of novel GLP-1RA semaglutide and liraglutide are over $1,300 per month, making them unaffordable for uninsured or underinsured individuals. Given these circumstances, it is not surprising that utilization of anti-obesity medications among eligible individuals (adults with BMI ≥30 kg/m^2, or with a BMI 27–29.9 kg/m^2 and at least one obesity-related comorbidity) is low overall (0.5%). It is even lower among individuals from underserved groups (0.27%).[6]

Bariatric surgery, the most effective treatment for clinically severe obesity, is similarly underutilized in the United States, with only 1% of individuals who meet the weight criteria undergoing bariatric surgery annually.[7] A decade of evidence on the efficacy, safety, and cost-effectiveness of bariatric procedures, coupled with substantial advocacy, expanded insurance coverage. However, it has yet to profoundly impact utilization.[7] The slow nature of bariatric surgery coverage expansion may be a result of the perceived short-term financial consequences of offering the benefit by the third-party payers. It also may reflect the unwillingness to recognize the long-term individual and societal benefits of treatment for severe obesity, seeing it as a "lifestyle" condition and its treatment as "cosmetic." As of 2018, Medicare, 49 state Medicaid programs, individual and small-group insurance markets in 23 states, 43 state employee programs, and most private insurers offered coverage for bariatric surgery.[8,9] However, to date, health insurance plan features, including select prior authorization criteria, remain barriers to greater utilization.[8,10]

As in the case of bariatric surgery,[7] limited knowledge of the safety and efficacy of anti-obesity medications by both patients and providers are likely barriers to the use of obesity medications. For the GLP-1RAs, that are also used to treat type 2 diabetes, the cardiovascular benefits and safety profile has been well established in patients with diabetes.[11] Furthermore, combination oral agents phentermine/topiramate (2012) and bupropion/naltrexone (2014) have been available for over eight years without safety concerns.[12]

Long-term observational studies on the efficacy and safety of novel anti-obesity medications could help pave the path for expanded coverage. This is particularly important, given the troubling history of some earlier-approved anti-obesity medications that were withdrawn

due to serious adverse events. Real-world evidence regarding the economic value of novel chronic weight management medications in adults with obesity is critically needed to advocate effectively for greater utilization of these more efficacious medications.

On February 17, 2022, the U.S. Office of Personnel Management Healthcare and Insurance issued a Federal Employees Health Benefits (FEHB) Program Call Letter 2022–03 clarifying that FEHB carriers are not permitted to exclude anti-obesity medications from insurance plans based on a benefit exclusion or a carve-out. It further required FEHB Carriers to offer adequate coverage of FDA-approved anti-obesity medications on the formulary and include their exception process within their proposal. This is an encouraging step forward, particularly as the letter signals the policymakers' understanding that timely management of obesity can be cost-effective, lower comorbidity risks, and prevent disease progression.

However, more is needed to increase the utilization of anti-obesity medications. Like bariatric surgery, coverage for anti-obesity medications by state Medicaid programs and Medicare Part D Prescription Drug Plans is needed. Action by the legislature and the Centers for Medicare and Medicaid Services cannot happen soon enough. Such action would be a compelling signal to third-party payers that the time to expand coverage of evidence-based obesity treatments is now.

Conflicts of Interest and Source of Funding:

Dr. Hamlet Gasoyan received support from the Cancer Intervention and Surveillance Modeling Network's Junior Investigator Career Enhancement Research Award. Dr. David B. Sarwer discloses grant funding from the National Institute of Dental and Craniofacial Research (1R01DE026603-01A1) and Department of Defense. He has consulting relationships with Ethicon and Novo Nordisk.

References

1. Wilding JPH, Batterham RL, Calanna S, et al. Once-Weekly Semaglutide in Adults with Overweight or Obesity. N Engl J Med. 2021;384(11):989–1002. doi:10.1056/NEJMoa2032183 [PubMed: 33567185]
2. Garvey WT, Batterham RL, Bhatta M, et al. Two year Effect of Semaglutide 2.4 mg vs Placebo in Adults with Overweight or Obesity: STEP 5. In: Garvey WT, et Al. Presented at the 39 Th Annual Meeting of The Obesity Society (TOS) Held at ObesityWeek ®, Virtual Meeting.
3. Jastreboff AM, Aronne LJ, Ahmad NN, et al. Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med. Published online June 4, 2022. doi:10.1056/NEJMoa2206038
4. Wilding JP, Batterham RL, Davies M, et al. Weight regain and cardiometabolic effects after withdrawal of semaglutide: the STEP 1 trial extension. Diabetes, Obes Metab. Published online April 19, 2022. doi:10.1111/dom.14725
5. Gomez G, Stanford FC. US health policy and prescription drug coverage of FDA-approved medications for the treatment of obesity. Int J Obes. 2018;42(3):495–500. doi:10.1038/ijo.2017.287
6. Lyu B, Chang AR, Inker LA, Selvin E, Grams ME, Shin J-I. Socioeconomic status and use of obesogenic and anti-obesity medications in the United States: A population-based study. Lancet Reg Heal - Am. 2022;11:100249. doi:10.1016/j.lana.2022.100249
7. Gasoyan H, Tajeu G, Halpern MT, Sarwer DB. Reasons for underutilization of bariatric surgery: The role of insurance benefit design. Surg Obes Relat Dis. 2019;15(1):146–151. doi:10.1016/j.soard.2018.10.005 [PubMed: 30425002]
8. Gasoyan H, Soans R, Ibrahim JK, Aaronson WE, Sarwer DB. Do Insurance-mandated Precertification Criteria and Insurance Plan Type Determine the Utilization of Bariatric Surgery

Among Individuals With Private Insurance? Med Care. 2020;58(11):952–957. doi:10.1097/MLR.0000000000001358 [PubMed: 32868693]

9. Gebran SG, Knighton B, Ngaage LM, et al. Insurance Coverage Criteria for Bariatric Surgery: A Survey of Policies. Obes Surg. 2020;30(2):707–713. doi:10.1007/s11695-019-04243-2 [PubMed: 31749107]
10. Gasoyan H, Ibrahim JK, Aaronson WE, Sarwer DB. The role of health insurance characteristics in utilization of bariatric surgery. Surg Obes Relat Dis. 2021;17(5):860–868. doi:10.1016/j.soard.2021.01.024 [PubMed: 33664010]
11. Brunton SA, Wysham CH. GLP-1 receptor agonists in the treatment of type 2 diabetes: role and clinical experience to date. Postgrad Med. 2020;132(sup2):3–14. doi:10.1080/00325481.2020.1798099
12. Müller TD, Blüher M, Tschöp MH, DiMarchi RD. Anti-obesity drug discovery: advances and challenges. Nat Rev Drug Discov. 2022;21(3):201–223. doi:10.1038/s41573-021-00337-8 [PubMed: 34815532]