White Paper

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Journal of **Comparative Effectiveness Research**

Affordable access to GLP-1 obesity medications: strategies to guide market action and policy solutions in the US

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Glucagon-like peptide 1 receptor agonists and glucagon-like peptide 1/gastric inhibitory polypeptide receptor agonists offer weight reduction and associated health benefits that, if sustained over time, have the potential to markedly improve population health. However, over 40% of US adults have obesity, translating into more than 100 million potential new users of obesity medications. Standing in the way of the major opportunity to improve health for these individuals is the massive and likely ongoing cost of treating such a large segment of the population, even though use of the treatments is estimated to be cost–effective over a lifetime. This paper analyzes the range of emerging market approaches and policy reforms that have the potential to help the broader US health system achieve affordable and equitable access to these medications, and the relative advantages, barriers and possible unintended consequences of each approach. We seek to present policymakers and industry leaders with insights and lessons learned from experts while offering a menu of options for the future that will help all stakeholders play an active part in an innovative future of pricing, coverage and payment for new obesity medications.

Shareable abstract: New policy analysis from the Institute for Clinical and Economic Review (ICER) provides clear policy and market solutions to help the US health system achieve affordable and equitable access to glucagon-like peptide 1 obesity medications.

First draft submitted: 23 May 2025; Accepted for publication: 24 June 2025; Published online: 11 July 2025

Keywords: affordable access • budget impact • GLP-1/gastric inhibitory polypeptide (GIP) receptor agonists • glucagon-like peptide 1 (GLP-1) receptor agonists • obesity management

Glucagon-like peptide 1 (GLP-1) receptor agonists and GLP-1/gastric inhibitory polypeptide (GIP) receptor agonists are among the most noteworthy and widely known medical innovations of the past few decades. These new obesity medications (OMs), currently exemplified by semaglutide (Wegovy®, Novo Nordisk) and tirzepatide (Zepbound®, Eli Lilly and Company), offer weight reduction and associated health benefits that, if sustained over time, have the potential to markedly improve population health. However, over 40% of US adults have obesity, translating into more than 100 million potential new users of OMs. Standing in the way of the major opportunity to improve health for these individuals is the massive and likely ongoing cost of treating such a large segment of the population. Although the Institute for Clinical and Economic Review (ICER) has judged the net price for semaglutide, and by extension for tirzepatide, as meeting reasonable cost–effectiveness levels in the US market [1], the number of potential users creates a scale of spending on a single drug class that some analysts have estimated will reach over $100 billion annually within the next 5 years [2,3].

Although the new OMs cast in high relief the tension between the scale of the opportunity for improved health and the magnitude of the financial implications, the tension is far from unique. Among other diseases affecting more than 10 million Americans are major depression, high cholesterol, Type 2 diabetes and dementia [4]. Gene therapies and other major advances in the care for these conditions are in development. The prospect of a new transformative therapy for any of these conditions would raise major opportunities for public health improvement with attendant budgetary concerns, as was demonstrated by the tense debates over the financial implications for Medicare should new amyloid-reducing drugs for Alzheimer's disease be widely adopted [5].

The purpose of this white paper is to analyze the range of emerging market approaches and possible policy reforms that have the potential to help achieve this goal. There are stark differences between approaches, which range from relatively 'open door' coverage and payment to denial of coverage for any treatment of obesity. Within this paper, we analyze the relative advantages, the barriers and the potential unintended consequences for each market or policy option, and explore the pros and cons of combining strategies either internally within an insurance system or externally through stand-alone obesity management providers. None of the market actions or policy reforms we will discuss are 'silver bullets' that can singlehandedly solve all the barriers and tensions inherent in trying to maximize affordable access while retaining incentives for future innovation. Still, we seek to present policymakers and industry leaders with insights and lessons learned from experts while offering a menu of options for the future that will help all stakeholders play an active part in an innovative future of pricing, coverage and payment for new OMs.

Materials & methods

Information to inform this paper was gathered in two ways: a targeted literature review, and interviews with key content experts, policymakers and representatives from organizations that participate in ICER's Policy Leadership Forum.

The targeted literature review included keyword and hand searches for peer-reviewed and gray literature articles focusing on the use of OMs in the US. Additional information was gathered from relevant clinical guidelines, publications from professional medical societies, purchaser coalition white papers and patient advocacy group materials.

Guided by perspectives gathered through this literature review, we then conducted fourteen 45 min interviews with key policy experts, including pharmacy benefit managers, manufacturers, patient advocacy groups, purchasers, benefit consultants and state and Medicaid experts, to explore their experience in the OM landscape and their views on potential new market or policy options for the future, including, but not limited to, the menu of options developed as a starting point by the ICER team. We targeted experts in the policy issues surrounding pricing and access for GLP-1s who have been featured in the media and at conferences, and leveraged our own networks and the networks of the interviewees to identify additional experts.

In December 2024, senior policy leaders from 26 payer and life science companies were joined by patient advocacy, employer, state and Medicaid experts at a 2 day meeting to deliberate on the potential market strategies and federal policy interventions and provide suggestions for revisions to a draft version of this paper. The participants in this meeting are shown in Appendix A. None of these participants or their organizations should be considered as approving of any element of this paper. The perspectives and recommendations presented here are those of the editorial team at ICER and Brown University alone.

Background

Obesity is one of most significant public health crises in the USA. Using a threshold of BMI $\geq$ 30 (weight in kilograms/height in m^2) as the diagnostic criterion, the proportion of adults with obesity in the US has increased from 13% in 1960 to over 40% today [6]. The proportion of Americans who meet the broader criteria for overweight, or BMI $\geq$ 27, rises to over 70% [7]. Numerous studies link obesity to increased risks for diabetes, cardiovascular disease, cancer and overall mortality. Obesity also drives increased healthcare costs, with the direct costs of obesity now estimated at between $170 and $260 billion per year in the U.S [8,9]. Broader economic and societal costs are undoubtedly far higher [10].

All these negative health and economic effects are not borne equally, with nonwhite and lower-income populations having notably higher rates of obesity [11]. People living with obesity are also subject to widespread stigma that has always overshadowed care for this chronic condition [12,13]. Because obesity can start in childhood, the stigma can affect social interactions, educational development, relationships and work. The net effect is that obesity can have a profound impact on all aspects of patients' lives and those of their families.

Obesity medications

For people who do not achieve desired weight loss with lifestyle changes alone, various pharmacotherapy options, such as earlier generations of OMs, can support weight loss when combined with calorie reduction and physical activity. OMs approved by the US FDA prior to the new generation of GLP-1 therapies include phen-

Table 1. Current glucagon-like peptide 1 obesity medications.

Drug	Manufacturer	FDA approval indication(s)	FDA approval date	Annual list price†	Annual net price‡
Liraglutide (Saxenda®) GLP-1 receptor agonist Daily subcutaneous injection	Novo Nordisk	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: 1) Adult patients with an initial body mass index (BMI) of 30 kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition; 2) Pediatric patients aged 12 years and older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cutoffs	23 December 2014	$16,188	$9191
Semaglutide (Wegovy®) GLP-1 receptor agonist Weekly subcutaneous injection	Novo Nordisk	GLP-1 receptor agonist indicated in combination with a reduced calorie diet and increased physical activity: •To reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight • To reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity; adults with overweight in the presence of at least one weight-related comorbid condition	4 June 2021	$16,188	$7401
Tirzepatide (Zepbound®) Combined GLP-1/GIP receptor agonist Weekly subcutaneous injection	Eli Lilly	GIP receptor and GLP-1 receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in indicated in combination with a reduced-calorie diet and increased physical activity: • To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition • To treat moderate to severe obstructive sleep apnea in adults with obesity	8 November 2023	$12,720	$8700

† Sources: novopricing.com and pricinginfo.lilly.com.
‡ Net pricing data from SSR Health, Inc., obtained March 2025.

termine (1959), orlistat (Xenical®, H2 Pharma, 2007), phentermine/topiramate (Qysmia®, Vivus, 2012) and bupropion/naltrexone (Contrave®, Currax Pharmaceuticals, 2014).

These earlier OMs are oral drugs taken daily. Because orlistat causes intestinal side effects and results in only modest weight loss, it is less commonly used for initial medication management. Phentermine is an amphetamine-like medication that suppresses appetite and is approved for short-term use (less than 12 weeks). It is also available in combination with topiramate, a carbonic anhydrase inhibitor used to treat seizures. Another treatment option combines bupropion, an inhibitor of norepinephrine and dopamine approved as a treatment for depression and anxiety, with naltrexone, an opioid antagonist that blocks the effect of opioid pain medications. Since phentermine, topiramate, bupropion and naltrexone are all available as single agents, clinicians may also use them off label alone and in various combinations for weight loss.

The cost of earlier OMs, even in their combination branded forms, is much less than that for currently available brand GLP-1 medications. For example, the annual cost of phentermine/topiramate (Qsymia) is approximately $1465, while buproprion/naltrexone (Contrave) costs $2095 [1]. Due to their relatively low cost and the lack of alternative treatment options, these medications have been commonly used for many years by obesity specialists. The role of these earlier OMs within current obesity management platforms being offered to purchasers and insurers will be discussed later in this paper.

The advent of GLP-1 receptor agonists

The arrival of the new generation of OMs came after almost two decades of the use of GLP-1 medications in the care of patients with Type 2 diabetes [14]. The first GLP-1 receptor agonist in the US approved for treatment of obesity was liraglutide (Saxenda®, Novo Nordisk), in 2014. Seven years later, semaglutide, first developed by Novo Nordisk under the trade name Ozempic®, which had been used for diabetes since 2017, received a new FDA approval for obesity as Wegovy® in 2021. Tirzepatide, a combination GLP-1/GIP receptor agonist that also had an earlier life as a treatment for diabetes under the trade name Mounjaro®, received approval for the treatment of obesity as Zepbound® in November 2023 [15]. An overview of each new OM, including its current FDA label and pricing for obesity treatment, is shown in Table 1.

10.57264/cer-2025-0083

Clinical trials of GLP-1s for obesity have consistently demonstrated substantial average weight loss and, in some cases, broader health benefits such as reduced cardiovascular events and improvements in obstructive sleep apnea. The full ICER report details these benefits [1]. However, there are important remaining uncertainties that should not be overlooked. Whether individuals sustain weight loss over longer time periods is a major question given that any reduction in long-term cardiovascular or other benefits may require ongoing adherence to treatment. High rates of discontinuation of treatment with GLP-1 drugs have been noted in observational analyses. In a study from Prime Therapeutics of over 16 million commercially insured people in 2021 who did not have diabetes but were treated with GLP-1 drugs, adherence to treatment over 1 year was only 36% for patients who initiated treatment with Wegovy, and 47% with Ozempic [16]. This report should be viewed cautiously given that in 2021 patients without diabetes treated with Ozempic were being treated off-label, GLP-1 products were in shortage, and patients may have faced new cost sharing and insurance restrictions that curtailed ongoing use. A follow-on study presented in April 2025 showed that only 14.3% of patients were still on therapy at the end of 2 years [17].

Uncertainties also remain about how many patients will decide to discontinue use after achieving target weight loss, and whether cardiac or other benefits are sustained following discontinuation of GLP-1s. In addition, while GLP-1s have a nearly 20-year history of relatively safe use for diabetes treatment, a recent large retrospective cohort study found that the use of GLP-1s among patients with diabetes was associated with a twofold higher risk of incident neovascular age-related macular degeneration development compared with similar patients with diabetes who did not receive a GLP-1 [18]. In addition, all GLP-1s have FDA black box warnings for a potential association with thyroid cancer and long-term data on the safety of the higher doses used for obesity treatment are not yet available [19].

As shown in Table 1, current estimated annual net prices for GLP-1s used for obesity in the US commercial market range from approximately $8000 to $9000. Prices charged by GLP-1 drugmakers in their own direct-to-consumer offerings outside of insurance are lower, approximately $499 per month, or $5988 annually [20,21]. Net prices have fallen substantially from the $12,000–14,000 cited in ICER's 2022 evaluation of OMs [1]. As noted earlier, ICER's cost–effectiveness modeling at that time suggests that today's lower prices for GLP-1 drugs, net of all rebates and discounts, fall solidly within the general range considered reasonable long-term value for money in the US context. However, whether current net prices for GLP-1s are 'fair' remains a topic of vigorous debate. Those critical of current pricing have raised multiple considerations that they feel trump a pure cost–effectiveness paradigm [22]. These critics raise several perspectives in arguing that current prices are too high:

- The cost impact of current pricing across such a large patient population will heighten inequities in access to effective treatment for obesity.
- Even at lower prices drugmakers would make significant profits, far outstripping usual returns on investment for most blockbuster agents, suggesting that lower prices would not harm future innovation.
- Pricing in the US market is far higher than in high-income European nations [23]. For example, at a Congressional hearing, legislators highlighted that net prices for Wegovy in the US are approximately $8000–9000 per year, whereas the approximate annual cost for the same product is $2232 in Denmark, $1680 in Germany and $1104 in the UK.
- Net unit pricing of semaglutide and tirzepatide in the obesity-labeled Wegovy and Zepbound are approximately 1.5–2.8-times higher than the price for the same molecules in the brands Ozempic and Mounjaro, labeled for the treatment of diabetes.
- Current pricing levels are buttressed by a system that unreasonably delays generic competition. Research has shown that brand-name GLP-1 manufacturers have obtained a median of 19.5 patents per GLP-1 receptor agonist and secured a median of 18.3 years of expected protection, with more than half of all patents obtained on the delivery devices rather than active ingredients [24].

ICER does not disavow the importance of considering long-term cost–effectiveness as the most appropriate foundation of fair pricing for innovative drugs. However, shorter-term budget impact and other considerations should always play a role in broader policy judgments, especially for products meant to serve such a large population of patients. Given the immense scale of potential use of GLP-1s, lower prices might not solve affordability concerns for all payers, but lower prices will remain an important element in the debate over potential solutions through both market actions and policy reforms.

Compounded versions of GLP-1 drugs

Compounded drugs are intended to be custom-made medications produced by licensed pharmacists working from the active ingredients of an FDA approved drug. These compounded versions are produced outside the control of the licensed drugmaker and are intended for use only when the specific dose or dosage form needed by an individual patient is not available or when the FDA determines that a drug is in short supply on a national basis. Once an approved drug is removed from the FDA's drug shortage list, compounded drugs may no longer be identical or nearly identical to the drug.

Throughout 2023 and much of 2024, both semaglutide and tirzepatide were deemed by the FDA to be in shortage due to unprecedented demand. During this time, the high demand for GLP-1 medications created a booming market for compounded versions, especially since many direct-to-consumer telehealth companies and medical spas and clinics have been able to sell compounded versions for a fraction of the price of their name-brand counterparts [25,26]. Many telehealth companies ship compounded GLP-1 drugs after a quick questionnaire, with or without a tele-health clinician visit, with no lab work, lifestyle management, or in-person doctor visit required. One report estimated that as of October 2024 over 2 million Americans had received treatment with compounded versions of GLP-1 drugs [27].

The FDA has made it clear that it does not recommend taking compounded versions of GLP-1 medications and has prominently shared its concerns over potential dosing errors and adverse effects brought about by inadequately controlled compounding processes [28]. The American Diabetes Association and a variety of obesity advocacy organizations, representing both clinicians and patients, have also warned against taking compounded GLP-1 drugs, citing the lack of regulatory oversight of both compounded formulations and prescribers of compounded products [29,30].

The legal and regulatory landscape for compounding of GLP-1 drugs has shifted notably in recent months. The FDA removed tirzepatide from its shortage list in October 2024, and in a 21 February 2025 declaratory order, the agency did the same for semaglutide [31]. These actions have heightened scrutiny of the appropriateness of producing and distributing compounded versions of semaglutide or tirzepatide [32]. Nonetheless, litigation challenging these determinations was filed by the Outsourcing Facilities Association and others, and is still ongoing. Meanwhile, the FDA has said it will exercise enforcement discretion until May 2025 given the very large number of patients who may need to be switched over to approved brand drug formulations [33].

Current coverage patterns & financial impact of GLP-1s

Insurance coverage

Coverage of new OMs by commercial insurers, state Medicaid programs, and Medicare varies widely and is evolving rapidly. In its last few months, the Biden Administration formally proposed that Medicare and Medicaid provide coverage for weight loss medications starting in 2026, potentially expanding access to several million US seniors [34]. The implementation of this rule was left at the discretion of the incoming Trump Administration, which announced in early April 2025 that it would not be included in a final update to parts of Medicare's Part D drug benefits and Medicare Advantage [35]. A spokeswoman for Centers for Medicare and Medicaid Services (CMS) said in an email to the New York Times that the agency believed that expanding coverage "*is not appropriate at this time*" [36]. But she said the agency had not ruled out coverage and "*may consider future policy options*" for the drugs.

State Medicaid programs are not required to provide coverage for weight loss medications, but 13 programs were providing coverage of GLP-1s for obesity as of October 2024, with additional programs expressing potential interest in expanding coverage in the near term [37–39]. The majority of Affordable Care Act (ACA) marketplace plans cover GLP-1 drugs approved for diabetes, though a June 2024 analysis from KFF shows that fewer than 1% of plan formularies include drugs solely approved to treat obesity [40].

For commercial plans, coverage decisions are even more varied. One survey of employers by the Pharmaceutical Strategies Group, published in July 2024, found that 33% of health plans and employers were providing coverage for GLP-1 medications for obesity, while an additional 19% of respondents said they were considering coverage [41]. An August 2024 survey from the Business Group on Health, which surveyed 125 large businesses with a total of 17.1 million employees, found that 67% of these larger employers were covering GLP-1s as a treatment for obesity [42].

Several commercial insurers and employer purchasers have announced decisions to rescind coverage of GLP-1 drugs for weight loss after having initially provided such coverage [43,44]. At least 17 state employee health plans

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do cover the drugs for weight loss, according to the Leverage Obesity Coverage Nexus [45]. But state employee health plans have been among the most visible purchasers to drop or reconsider coverage. News reports have highlighted Colorado, New Mexico and Delaware as states with employee health plans reconsidering coverage in light of higher than anticipated costs, while West Virginia and North Carolina have already formally rescinded coverage [46].

Financial impact

Given the shifting tides of coverage, variable adherence, the rapid acceleration in the interest in GLP-1 drugs, and the substantial confidential rebates that are given by manufacturers for these drugs, it is difficult to estimate with any precision current uptake and net spending on new OMs from publicly available data. Peer-reviewed evidence is currently lacking. In justifying its decision to rescind coverage for GLP-1s for obesity, the North Carolina state employee health plan reported that it would have needed to double its insurance premium to continue to pay for the increase in overall costs it experienced after initially providing GLP-1 coverage [47]. Colorado's spending on OMs for state workers more than quadrupled from 2023 to 2024 – and costs have been doubling every 6 months [46]. The large pharmacy benefit manager (PBM) Prime Therapeutics has reported that the average healthcare costs of commercially insured people with obesity in their system rose approximately $7000 in the first year after beginning GLP-1 use despite only a third of patients being able to use the treatment consistently [48]. No medical cost offsets were seen. Separately, Prime Therapeutics provided examples of several self-insured employer clients offering coverage for GLP-1s for obesity, all of whom saw more than a tenfold increase in per-member, per-month (PMPM) costs for GLP-1s from January 2023 to December 2024. And at a company level, a dramatic example of the cost impact of rising GLP-1 use came from Blue Cross Blue Shield of Massachusetts, which ended 2024 with a staggering $400 million operating loss – its worst financial performance on record [49]. The health plan cited GLP-1 drugs as the single largest driver of increased costs, accounting for more than $300 million in 2024, 20% of the insurer's total pharmacy costs, and double the amount spent in the prior year.

Large swings in estimated costs also complicate efforts by purchasers and payers to plan financially for GLP-1 spending. For example, the California Public Employees' Retirement System (CalPERS) notes that estimates of GLP-1 costs increased from $3 per-member per-month, to $20, and then to $16. These fluctuating estimates hinder the ability of purchasers to adequately plan for the financial impact of GLP-1s. Despite not covering GLP-1s for obesity, overall CalPERS pharmaceutical spending increased by 25% between 2021 and 2023 [50].

Analysts have had difficulty calculating a precise estimate of the financial impact for Medicare of extending coverage of GLP-1 drugs to obesity. One academic group estimated that expanding Medicare coverage could cost $3 billion to $6 billion [51]. The CMS estimated additional spending of $24.9 billion over 10 years for Medicare, and $14.8 billion for Medicaid [52], figures close to estimates from the Congressional Budget Office of $35 billion in additional federal spending over 8 years. The Congressional Budget Office analyses assumed that 12.5 million Medicare beneficiaries would be eligible for obesity treatment with GLP-1s in 2026, but that only two percent would use the drugs in the first year [53]. Under these assumptions, the analysis found that drug costs would increase, as expected, and that "*Total savings from beneficiaries' improved health would be small – less than $50 million in 2026 and rising to $1.0 billion in 2034.*" All efforts to estimate the financial impact within Medicare and Medicaid of GLP-1 coverage for obesity are very sensitive to these underlying assumptions about uptake, persistence and cost offsets, setting the stage for continued vigorous debate among policymakers.

Potential market strategies

Temporary coverage denial

Some purchasers have estimated that they do not have the budgetary flexibility, or 'elasticity', to provide coverage for GLP-1s for treatment of obesity at current prices. The same is true for certain lines of insurance within some insurers, including nonprofit community health plans, whose profit margins are generally lower than larger for-profit national insurers. The story of the North Carolina state employee health plan, described earlier, demonstrates how forecasted or experienced higher spending can be at a scale that would require increases in insurance premiums and/or budgetary cuts in other areas of healthcare spending that purchasers view as infeasible. With questions also swirling regarding whether patients are likely to persist with treatment long enough to accrue significant health benefits, it is not unreasonable for some purchasers to decide that they should wait to provide coverage.

We also heard in interviews that some purchasers are confident that, within another year or two, providers will be more efficient and effective, more will be known about how to maintain long-term use of all OMs, and competition may bring lower pricing. For purchasers with high employee turnover and limited resources, this perspective can provide a compelling argument for holding off on providing coverage until the landscape changes.

There is one additional reason that noncoverage, on a broad scale, although it creates obvious access problems, may conversely support market options that can, with adequate scale, provide affordable access to GLP-1s outside of insurance. The past year has already shown that many individuals are able and willing to bear the cost of GLP-1 drugs outside of insurance, although much of that access was made possible through far less expensive, and less reliable, compounded versions. Today, there is already one company selling the idea that employers should exclude GLP-1s from their formal drug benefit while moving instead to subsidize employees who want to use cash-pay options [54]. There are also recent efforts from the drugmakers themselves to work with telehealth clinicians in order to provide access to consumers outside of insurance. Lilly is the most advanced in this 'pharm-to-table' [55] model. Its LillyDirect program has been active for a year making Zepbound available for a cash price, offering patients access to telehealth and then connecting them into an online pharmacy [56]. In February 2025 LillyDirect began offering a wider range of doses and brought prices down to approximately $499 per month, far below the net price for many payers [21]. In March 2025 Novo Nordisk joined in by launching NovoCare Pharmacy, which is offering a cash-only version of Wegovy at the same $499 price per month [20].

Purchasers may see in this evolving market landscape options through which their employees or members can find affordable treatment outside of insurance, creating an ethical outlet for the access concerns created by noncoverage. But $499 per month is not affordable for many people, and with obesity more common in people with lower financial resources, this price does nothing to reduce existing disparities in access that have serious equity implications. There is also an inescapable equity concern about requiring people with one particular medical condition to bear the financial burden alone when most costs of other conditions are covered by insurance. Therefore, although the current lack of coverage for millions of Americans may support less expensive options outside of insurance, equity considerations argue strongly against viewing noncoverage as an ethical long-term position.

Other arguments can also be made against even temporary noncoverage. Clinical trials have demonstrated relatively rapid reductions in cardiac events among patients with existing cardiac conditions after treatment initiation. As noted earlier, it is also reasonable to assume that annual costs for GLP-1 treatment drugs will come down, at least somewhat, over the next several years as new competitive entrants are approved and when semaglutide becomes subject to Medicare price negotiation. Financial forecasts figuring in some level of price reduction might change the perceived affordability of beginning coverage now for some purchasers. All purchasers should also take seriously their part in the broader societal goal of reducing disparities in access to effective treatments for obesity across socioeconomic and racial categories. Purchasers cannot be condemned if they are transparent in their justification of the financial barriers they face in offering GLP-1 coverage for obesity in the short term, but they should be vigilant in seeking opportunities to apply strategies such as those detailed in this paper to bring OMs within the normal range of insured services as soon as possible.

Enhanced prior authorization & formulary management

For purchasers and insurers seeking to develop an affordable approach to coverage for expensive drugs, it is common to apply enhanced utilization and formulary management to ensure that coverage is framed along evidence-based lines that may narrow use to those patients for whom the benefits of treatment are best established. Although the current GLP-1 landscape has given drugmakers significant leverage to use rebates to avoid limited coverage terms, given the substantial aggregate costs of GLP-1 drugs, along with uncertainties about longer-term adherence and outcomes, purchasers and payers have explored a variety of coverage policy approaches to target treatment to a narrower set of patients. Any evidence-based approach to narrowing coverage may help patients by avoiding use where the safety and benefits of treatment are less well known. Patients and all health plan members also benefit from measures that help keep insurance premiums more affordable. But the risks of targeting coverage are that some patients who merit treatment will face delays or other barriers to effective care. In a previous white paper, ICER addressed this tension by developing guidelines for appropriate use of prior authorization and step therapy [57]. Working from this framework, we analyze the role of various options potentially available to purchasers to manage GLP-1 benefits below, and in Table 2 we present a summary of some of the key potential advantages and limitations of each strategy.

10.57264/cer-2025-0083

Table 2. Strategies to manage appropriate use and costs of obesity medications through enhanced prior authorization and formulary management.

Strategy	Benefits	Disadvantages
Narrow coverage through BMI and clinical comorbidity restrictions	Direct limited financial resources to patients with the greatest need FDA label updates give greater latitude for purchasers and payers to define BMI thresholds Other payers and nations have set examples of narrowing coverage using BMI $\geq$ 35 or even BMI $\geq$ 40, with cardiac comorbidities	Higher thresholds for BMI can be viewed as arbitrary Restrictions beyond FDA label language may lead to loss of rebates, negating the financial goal of narrowing coverage With expanding indications beyond obesity, may be difficult to reduce budget impact significantly
Require lifestyle management as a prerequisite or concomitant part of medication treatment	Create a more holistic care plan for patients that may be more sustainable and cost-effective than medication management alone May help some patients reduce dosages or discontinue GLP-1s	Most patients have tried lifestyle interventions without success These programs often lack any evidence that they enhance weight loss beyond that gained with medication management
Limit duration of coverage for GLP-1 treatment	Limit financial impact on purchasers Anecdotal experience in England and claims by obesity management companies suggest that some patients can maintain weight loss after discontinuing GLP-1s	Rigorous evidence not available on patient outcomes with mandatory discontinuation of GLP-1s Risk of alienating patients, losing clinical benefits of sustained weight loss, and ultimately restarting GLP-1 treatment
Step therapy through non-GLP-1 obesity medications	Evidence suggests some patients can meet weight targets with less expensive medications If structured appropriately, patients can quickly shift to GLP-1s if first line drugs are inadequate	Earlier obesity medications are believed to have higher rates of gastrointestinal and other side effects Patients and clinicians are highly motivated to use GLP-1s
Negotiate lower prices by covering only a single GLP-1 drug	Weight loss and side effect differences between current GLP-1 drugs not viewed as requiring coverage of both drugs on clinical grounds	No evidence on outcomes of switching between GLP-1 drugs Burden of switching GLP-1 drugs may create pushback or loss of rebates for patients granted an exception

Coverage criteria

BMI & clinical comorbidities

Specifying clinical criteria for coverage through a prior authorization process is a common approach within insurance policies to assure that only appropriate patients receive the treatment. When the FDA label includes generalized terms, or when the underlying clinical evidence comes from a narrower spectrum of the condition, insurers can consider whether to construct coverage policies with more precise evidence-based criteria based on clinical guidelines or clinical trial eligibility criteria.

When semaglutide and tirzepatide were first approved for the treatment of obesity, their FDA labels included a specific BMI threshold of 30, or of 27 among patients with an obesity-related comorbidity [58]. Subsequently, in part because of concern that specific BMI thresholds might not be appropriate for different races and ethnicities, the FDA updated its labels in March 2024 for semaglutide and in October 2024 for tirzepatide to remove any mention of BMI thresholds, leaving the approval for both drugs as for the treatment of 'adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition' [59].

Given the broad language in the updated FDA labels, purchasers and payers seeking to create a more affordable coverage policy can consider adding clinical eligibility criteria that will narrow the eligible pool of patients. Even before the labels were made less specific, ICER and other analysts had noted that most patients treated in the pivotal trials for both drugs had a BMI $>$ 35 and at least one weight-related comorbid condition. Some insurers and purchasers therefore have decided to use BMI $\geq$ 35 in their coverage criteria [60,61], and some have also included a requirement for one or more comorbid conditions, such as hypertension. For example, Blue Cross Blue Shield of Michigan recently raised BMI coverage thresholds to 35, and, for some plan members, Blue Shield of California recently changed its coverage to require a BMI of $\geq$40 unless there are cardiac comorbidities [43,62]. Overseas, at least one national health system, the NHS in England, has done the same in its funding decision for semaglutide [63], whereas for its planned initial phase of the rollout of funding for tirzepatide it has selected the even more restrictive level of BMI $\geq$ 40 plus three cardiac comorbidities [64].

Using more restrictive BMI and comorbidity thresholds for coverage can be seen as a principled, evidence-based approach to targeting coverage to those individuals at highest risk for short-term adverse events and who therefore

stand to benefit most from treatment. However, there are several important limitations. First, as GLP-1 drugs obtain new indications for patients with obesity, such as the treatment of obstructive sleep apnea and reducing the of risk of cardiac adverse events in adults with established cardiovascular disease, using BMI thresholds to narrow use will become less feasible. In addition, coverage criteria narrower than the FDA label language can be criticized by clinicians and patients as being inappropriately restrictive. For example, BMI, the main patient characteristic being used for limiting coverage eligibility, is an imperfect measure of obesity-related health risks [65]. Furthermore, as noted earlier, attempts to apply coverage criteria that limit eligibility are likely to be met with resistance from drugmakers and perhaps even from some payers whose revenues are tied to rebates. If more coverage criteria are countered by reduced rebates, the overall effect may not improve affordability.

Additional clinical or genetic factors

The intense competition among weight management carve-out companies has led to the application of additional, often proprietary measures to help craft 'personalized' weight management programs. As one company suggests, they will use screening tools to "*develop your personalized weight loss plan based on your goals, preferences and unique biology*" [66]. In our interviews with benefit design consultants and purchasers, we were told that these screening tools are often presented as a way to help patients achieve their goals while narrowing the number of patients started directly on GLP-1s. Psychological screening tests and even genetic screening tests are being touted as helping to improve the matching of patients with their ideal weight management approach [67]. No well-conducted studies of these screening techniques have been published.

Lifestyle management

The FDA labels for semaglutide, tirzepatide and all former OMs stipulate that they are approved for treatment 'in combination with a reduced calorie diet and increased physical activity.' The pivotal trials of GLP-1 drugs for obesity do not demonstrate a major difference in the magnitude of weight loss depending on the degree to which patients followed diet and exercise guidance, but exercise is an important complement to GLP-1 use, particularly among the elderly, because of the potential for muscle-wasting and bone mineral density side effects [68,69]. It is therefore very reasonable for purchasers to include in coverage policy some form of requirement that patients engage with a lifestyle management program. Doing so can be seen as ensuring that patients are fully committed to a broader approach to weight loss than may help them sustain benefits of drug treatment.

There are two key questions regarding the inclusion of lifestyle management requirements within coverage policies. The first is whether lifestyle management is set up as a preliminary requirement that patients must complete prior to beginning GLP-1 treatment. This approach makes lifestyle management a first step in 'step therapy' [57], a coverage policy approach that requires that patients try a less expensive first-line therapy and demonstrate lack of adequate benefit before moving on to receive coverage for other treatments.

Although requiring a formal course of lifestyle management before allowing GLP-1 coverage would narrow the population receiving GLP-1 drugs, this approach ignores the reality that most people living with obesity have already tried multiple diet and exercise programs before considering drug therapy. Setting yet another attempt at lifestyle management as a first step would likely only delay treatment unnecessarily for most patients, potentially driving up overall costs of a broader approach to weight loss. Requiring that patients participate in a lifestyle management program during treatment with GLP-1 drugs is more likely to serve the needs of patients and maximize the longer-term benefits that purchasers also seek.

The second key question regarding lifestyle management is which version to use in clinical practice and coverage policy. A comparison of all the various forms of lifestyle management is beyond the scope of this paper. Nearly all include ways to encourage increased physical activity and seek to modify patients' diets. Some programs apply principles of psychology of change and other techniques to weave mental health into a broader approach to long term weight loss. Some programs involve in-person counselling, some use virtual counselling and many today rely on online programs that do not require any personal interaction at all. In addition to addressing overall wellbeing, in interviews with purchasers and benefit design consultants, we heard that lifestyle management programs are being presented by many providers as a way to allow patients to eventually taper down on GLP-1 dosing or even shift entirely off medication after reaching target weight. A recent media report of company presentations at the 2025 J.P. Morgan HealthCare conference highlighted lifestyle management companies touting positive results after tapering patients off of GLP-1 medicines [70]. For example, a company that launched in 2019, Calibrate, recently released data showing that 42 patients maintained weight loss (average 22%) a year after ending GLP-1 use [71].

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The number of patients involved in these reports is very small, and many aspects of their outcomes after tapering off GLP-1s remain unknown, but interest in exploring this approach, should further evidence demonstrate its effectiveness, is high across purchasers and payers we interviewed.

Duration of coverage

Although our interviews did not suggest that any purchaser or payer has formally restricted the duration of coverage, this approach has been suggested by academics in the US and has been implemented by the NHS in England [63,72]. The general idea is to set either a weight target or a time target, after which patients would be expected to move off GLP-1s to a weight loss regimen using either less expensive options or purely based on lifestyle management.

Clinical experts and others we interviewed in the US expressed keen interest in a time-limited approach to GLP-1 treatment, but only if well-conducted clinical trials were first to establish the effectiveness of this approach. Both purchasers and patient advocates expressed concern that the clinical evidence is currently not robust enough to know whether patients would regain weight or lose any cardiovascular risk benefit after coverage expiration. Purchasers who had contracted with weight loss management companies said that these companies explicitly mentioned the prospect of moving people off GLP-1 treatment over the course of time, but without firm evidence backing this approach, there was no support for formal caps on the duration of coverage.

Formulary management

Covering only a single GLP-1 drug

As part of a comprehensive approach to coverage, purchasers and insurers can consider various formulary management approaches to seek lower prices for GLP-1 drugs and lower costs for overall medication management of weight loss. When supported by the clinical evidence, payers routinely seek to negotiate lower prices for brand drugs by offering preferential placement in the formulary that is linked to lower cost sharing for patients and/or less requirement for step therapy through less expensive treatment options. In cases where two or more drugs are considered functionally equivalent in their safety and effectiveness, payers can also consider negotiating to cover only one drug in a particular class, excluding others in a search for the deepest price concessions from a single drugmaker.

Up until recently, the shortage of GLP-1s across markets in the US has made it impossible for payers to consider covering only semaglutide or tirzepatide. It has been very difficult for clinicians and patients to find an adequate and consistent supply of either drug, so in our interviews with payers we heard that this approach would be considered only after supplies improved. However, the potential benefit of single-drug coverage of GLP-1s is the ability to negotiate a significantly lower price. We are aware of a single example of single-drug coverage in the current market. The Massachusetts state Medicaid program, MassHealth, has decided to prefer a single obesity GLP-1 drug, and has made it clear to manufacturers that the preferred product will change, if necessary, to secure the best value to the Commonwealth.

There are no publicly available data on the outcomes of patients who switch from one GLP-1 drug to another. Another concern about this approach is that it will require switching patients from one treatment to another to retain rebates. It is rarely easy to administer a switching process, and it may be even more difficult in commercial insurance, where new health plan members may have more flexibility to shift plans, and providers have more robust exception procedures. In addition, even with formal shortages ending, patients and clinicians may also struggle to find adequate supply. Single-drug coverage could force patients onto nonrebated drugs if the covered drug is not available. Nonetheless, for Medicaid programs and other payers who feel they are unable to provide coverage without further price reductions, single-drug coverage offers one approach that may help meet budgetary targets.

Step therapy through earlier OMs

Prior to the advent of GLP-1 drugs, obesity specialists had become skilled in helping many people reach their weight loss goals with a combination of lifestyle management and tailored use of earlier OMs. Today, it is widely accepted that GLP-1 drugs provide greater average weight loss and have equal or lower rates of side effects than earlier options. In our discussions with clinical experts, they confirmed that it is clinically reasonable to start many patients on drugs other than GLP-1s, especially when the weight loss goals are relatively modest. We also heard from purchaser consultants that many, if not most, independent weight loss management companies use their clinical networks of obesity specialists to apply this approach, often leading to more than 50% of patients using no medication or less-expensive earlier OMs. For example, the state employee health plan of the state of Connecticut

contracts with Flyte for its weight management program. Early results presented in March 2024 showed that 50% of participants were prescribed an OM other than a GLP-1 drug [73]. Patients prescribed non-GLP-1 options lost an average of 5% of baseline weight, and it is unknown what proportion of patients met their weight loss goals. Further evidence is needed on the clinical outcomes of step therapy approaches, but cost savings from helping patients reach weight loss goals without using brand GLP-1s can be significant and is one of the primary ways that weight loss specialty companies are creating savings for purchasers.

The downsides of step therapy are well known [57]. As ICER documented in its earlier report on fair access, patients may be frustrated and feel they are being offered second-class care [74]. For those patients who do not obtain desired outcomes, delay receiving the treatment that is ultimately needed may increase the risk of unnecessary side effects and may, in some cases, lead to higher overall costs. And there are not enough obesity specialists in the US with experience with earlier OMs to come close to matching the size of the population eligible for GLP-1 drugs. But if patients are in a system in which they are receiving excellent, personalized care from a clinician who can guide the selection of appropriate earlier OMs for suitable patients, and manage those patients closely so that they can be switched to a GLP-1 drug without significant delay if needed, a step therapy approach may offer important advantages for purchasers seeking a more affordable way to provide broad coverage for their employees/members.

Provider network management

Managing the network of clinical providers engaged in managing obesity and prescribing OMs is an important element in seeking to improve outcomes while controlling costs. There are three basic approaches for purchasers and insurers to consider:

Open prescribing with attendant tighter utilization management

One option is to allow all primary care providers to prescribe GLP-1 drugs as part of their practice. This approach maximizes access to the most effective obesity treatment, thereby reducing disparities in access across socioeconomic, racial and other categories. In addition, integrating GLP-1 prescribing into primary care helps keep medication use coordinated across other clinical conditions, such as diabetes and hypertension. If rapid weight loss is achieved, other medications may need to be adjusted accordingly.

The drawbacks of open prescribing begin with the likelihood that a certain proportion of GLP-1 drugs will be prescribed for patients who could do well with other, less expensive OMs. Combining open prescribing with tight utilization management criteria is one way to try to provide wide access without producing high rates of inappropriate use. In our interviews with clinical experts and others, they argued that most primary care clinicians are not yet expert in prescribing the broad range of earlier OMs as well as GLP-1s, nor are they versed in working with lifestyle management options and psychological support often needed for optimal care. Clinical guidelines integrating all these features of care have not been widely disseminated in primary care. With this backdrop, some experts and purchasers believe that keeping prescribing limited to a narrower network of obesity specialists is a better approach for the short-term until clinical expertise in obesity medicine can be more widely embedded in primary care. In contrast, we heard from other experts that they believe that the extensive experience primary care physicians have had prescribing GLP-1s for diabetes over the previous 20 years makes them well-suited to prescribe the drugs for obesity management.

Limited prescribing by a curated expert network with lighter or no utilization management

This approach has the opposite advantages and drawbacks of an open prescribing model. Setting up a 'Centers of Excellence' approach to obesity medication prescribing maximizes the likelihood of appropriate comprehensive care for patients with obesity, including the use of GLP-1 drugs. Even in the broadest clinician networks, however, there are nowhere near enough obesity specialists to manage the number of people seeking GLP-1 treatment. Long waiting lists would result. On the other hand, a curated group of obesity specialists could be allowed to prescribe GLP-1 drugs with light or no prior authorization and other elements of utilization management. How these contrasting benefits and disadvantages balance out could be very different across varying health systems.

Carve-out clinical care & prescribing to external weight loss management firm

Instead of trying to cobble together an internal set of obesity specialists into a network of Centers of Excellence, many purchasers and health systems are currently 'carving out' the care for obesity to external obesity management companies. There are many dozens of these companies now competing for the obesity care market, largely based

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on PMPM contracts with self-insured purchasers and insurers. Some of the largest PBMs have organized their own obesity carve-out programs for clients, including Evernorth's EncircleRx℠ and CVS Caremark's program to transform metabolic health. We will discuss independent obesity carve-out companies later in this paper.

One element in common across all these carve-out programs is that they offer a curated obesity expert network. These providers generally have virtual visits with patients, offering greater convenience and more rapid access. Some clinical experts and purchasers expressed concern, however, that some of these 'experts' do not have true clinical experience with obesity and are included in these virtual networks after receiving minimum training. As noted earlier, some of these programs seek to start many patients on less expensive medications, increasing the importance that clinicians be adequately skilled to provide appropriate, tailored individual care.

Innovative payment arrangements

Performance agreements

It is appealing to think of designing payment for GLP-1 drugs to provide a warranty or deeper rebates when patients are not able to achieve their desired weight loss. Agreements could be made to link rebates to achieving a desired weight goal, to a particular percentage weight loss target, or to adherence to treatment. However, there are many reasons that patients might not reach their goal, whether from lack of drug availability, ineffectiveness of the drug, side effects or financial barriers. In the current landscape, with demand exceeding the supply of medication, drugmakers have little incentive to even consider any form of performance agreement. However, when further new OMs enter the market there may be adequate supply and competition to drive some drugmakers to be open to considering performance-based agreements linked to clinical outcomes.

In the short term, we heard in interviews that even carve-out obesity management companies are not commonly offering performance-based guarantees. Purchasers are also wary that performance-based agreements with carve-out companies could be 'gamed' given that weight measurement is commonly done virtually (i.e., in the patient's home) and cannot be verified. However, as opposed to clinical performance agreements, we heard in interviews that many carve-out companies are offering financial guarantees on the total cost of care. Documents from some carve-out companies claim a 3-to-1 return on investment, but we were unable to determine specific contractual financial guarantees being offered in the marketplace.

Performance agreements sometimes include aligned patient incentives to maintain adherence or to achieve particular clinical goals. With GLP-1s, however, outside the question of drug availability, adherence is likely driven far more by the tolerability of side effects than any other factor. On the other hand, neither purchasers, payers, nor drugmakers want people taking GLP-1s to cycle on and off them in a fashion that may undercut any long-term health benefits. Still, stakeholders at the Policy Leadership Forum expressed little interest in pursuing the idea of creating a financial incentive for patients to adhere to a GLP-1 therapy.

Subscription models

A subscription model for drug coverage is a payment arrangement between a payer and a drug manufacturer that involves a fixed amount paid in exchange for access to a specific drug or drugs for a specific patient population over a set period of time [75]. These models guarantee financial certainty for purchasers, but also guarantee recurring revenue for manufacturers. We heard in interviews that some large purchasers had explored a subscription model in discussions with drugmakers, but there was little interest given the current supply/demand context and the acknowledged administrative burden of setting up a subscription model. Moreover, the prospect in coming years of lower prices with additional competition and/or governmental price negotiation removes part of the incentive for a subscription model for purchasers. Equally, for GLP-1 drugmakers, it is not clear that subscription models offer any advantages and may not be a feasible consideration for drugs that must be taken for many years, if not a lifetime.

Volume-based rebates

Volume-based rebate agreements set one or more thresholds of utilization such that greater use of a drug results in greater rebates to the payer. These arrangements help give some sense of financial protection to payers and are often used when there is substantial uncertainty about the uptake of a new drug within a population. GLP-1 volume-based rebates could also be framed as per-member per-month payment caps to help give more budgetary certainty to purchasers and payers.

In our interviews we did not hear of any volume-based agreements in the market today. The administrative burdens of these agreements are relatively low, but, as noted, the GLP-1 drugmakers are in a strong position in negotiating coverage terms given the balance of supply and demand of their products, and so it is not surprising that no volume-based agreements have been struck to date. Another reason that these agreements are challenging in the US context is the linkage of any rebate in the commercial market to the requirement for drugmakers to offer their 'best price' for any customer to all state Medicaid programs under the Medicaid Best Price statute [76]. Nonetheless, as with other market strategies, if greater competition ensues in coming years with the approval of additional OMs, purchasers and payers may find more openness to consideration of volume-based rebate agreements.

Carve-out programs for obesity management services

This paper has already described that many purchasers and payers are delegating obesity management to a comprehensive program offered by a PBM or to an independent obesity management company. One purchaser that has contracted with this type of 'carve-out' program is the state employee health plan for the state of Connecticut. The Connecticut plan paired GLP-1 coverage with engagement with an obesity management carve-out company, Flyte Health [77]. Like many obesity management programs, Flyte combines GLP-1 coverage with lifestyle management programs. Flyte also uses clinical criteria to narrow the set of patients who take GLP-1s and attempts to ensure appropriate GLP-1 use.

In initial nonpeer-reviewed findings on a small number of patients after launch, Connecticut has reported meaningful reductions in weight loss among participants [78]. Among patients enrolled in Flyte for at least 6 months, weight decreased by an average of 10% overall. Approximately 50% of patients were prescribed an OM other than a GLP-1 drug. Average weight loss was 12% on patients treated with GLP-1s and 4% among others, although it is unknown what proportion of patients met their weight loss goal across groups. Overall, in addition to weight loss, Flyte also reported improvements in other clinical metrics, including blood pressure. These carve-out programs come in many different flavors, and, unfortunately, there are no publicly available data with which to assess which programs, or which elements of programs, are more effective than others. Nonetheless, there are many common features of these programs, and, in our interviews, we heard of several important best practices that all purchasers and payers should be aware of when considering whether to adopt this approach to obesity care.

The common elements of obesity carve-out programs are as follows:

- National network of clinical experts who engage with patients virtually.
- Clinical algorithms that help identify patients for whom less expensive treatment options are appropriate.
- Integration of interventions on diet and activity as part of lifestyle management.
- PMPM payment model, often with guarantees on adherence to medication use and overall cost reductions [79].

In addition, we heard in interviews with benefit design consultants and purchasers that many, if not most obesity carve-out companies have been using compounded versions of GLP-1 drugs as another way to achieve lower overall costs of care.

As noted earlier, some clinical experts and purchasers believe that carve-out companies are the best option because the primary care provider community is not yet prepared to handle obesity care, and carve-out companies can bring not only clinical expertise but a more comprehensive approach to ensuring that all patients receive individualized care, including appropriate lifestyle management interventions. For example, we heard from one purchaser that they work with the company FORM, which determines the most appropriate care for an individual using a staging model based on clinical comorbidities and psychologically validated 'readiness to change' criteria [66]. To our knowledge, there are no data available from a rigorous trial of this or other components of carve-out programs, but they reflect years of experience working with patients with obesity and other chronic conditions.

There are several important potential drawbacks of carve-out programs depending on how they are structured. One challenge is the distribution of rebate dollars. If obesity management is fully carved out, then rebates from GLP-1 manufacturers in many cases go directly to the carve-out program and not to the purchaser. Purchasers should therefore consider setting up an agreement with their carve-out partner to share the rebates. Carving out obesity care also runs the risk of creating a lack of coordination with the care for other conditions. It is essential that carve-out programs have a formal mechanism for communicating with primary care clinicians so that all medications and other facets of care can be clearly understood by all clinicians caring for the patient.

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Another potential concern, noted earlier, is that carve-out programs may not offer clinicians who are truly qualified to serve as obesity specialists. We heard in interviews that some carve-out obesity companies have been found to qualify their 'experts' through a one-time seminar and then give them a script to use in their interactions with patients. Purchasers should examine whether clinicians have formal credentials from the American Board of Obesity Medicine or other relevant training.

Since most carve-out programs use earlier OMs as well as GLP-1 drugs, clinical experts interviewed suggested that purchasers should ensure that any step therapy approach uses a reasonable 3 to 4 month period to determine whether less expensive options are working adequately before allowing patients to begin GLP-1 treatment. Some carve-out companies use a 6-month trial period, but clinical experts advised that this was far longer than necessary to determine whether less expensive OMs would be effective for an individual patient.

A final challenge with these programs is their wide variability in efficacy and transparency into outcomes. Due to patient self-selection, access to data, and transparency of approaches, evaluating these programs is challenging. There currently is not a rigorous evaluation of these programs, making them difficult to compare. This evidence limitation is particularly relevant for expanded use of carve-out programs. Expanded use of carve-out programs will likely require Medicare and other purchasers to design criteria for covering lifestyle management programs and ensuring adequate quality of these programs.

Potential federal policy interventions

In addition to the potential market actions that purchasers, payers and drugmakers can implement, there are also potential policy reforms that the federal government could enact to address access to GLP-1 medications and the overall costs of obesity treatment. As with market actions, no single policy reform alone can solve the short-term tension between the opportunities GLP-1 drugs offer to improve health on a broad scale and the challenges of managing the corresponding high costs.

Improve access by offering coverage for obesity drugs in medicare

For more than two decades, federal law has prevented Medicare from providing coverage for drugs that treat obesity. For almost as long, advocates and some legislators have sought without success to change that by advancing a bill known as the Treat and Reduce Obesity Act (TROA) [80]. The recognition of obesity as a chronic disease in 2013 and advent of GLP-1 drugs has completely changed this dynamic. GLP-1s have accelerated interest in opening up coverage for OMs in Medicare, while also stimulating questions about the financial impact on the program. As noted earlier, in November 2024, shortly after the federal election, the Biden Administration proposed expanding Medicare and Medicaid coverage to GLP-1s for people with obesity, but the Trump Administration decided in April 2025 not to move forward with expanded coverage, although statements suggested that CMS had not ruled out considering future options for expanded coverage [36].

Months before the Biden Administration announcement of its proposal to cover GLP-1s for obesity, federal policymakers were searching for a way to extend coverage without this scale of added costs. On 27 June 2024, the House Ways and Means Committee voted to approve an amended version of the TROA and send it to the full House. This revised version of the TROA would limit coverage to people who had been taking an OM for a year prior to enrolling in Medicare [81].

The idea of limiting coverage for OMs to only those patients already taking them at entry into Medicare helps address worries over the potential financial impact, and also would eliminate the problem of having patients with successful weight loss on treatment suddenly face high out of pocket costs that may not be affordable, leading them to stop treatment, regain weight and increase their risks for adverse health outcomes. On the other hand, letting new entrants to Medicare get OM coverage while those already in the program cannot raise important equity considerations within the Medicare program. Some legislators have already indicated that they view other measures to bring down the prices of OMs to be better policy approaches to allowing Medicare to cover OMs in a financially prudent manner [82].

Now that the Trump Administration has decided not to move forward with the Biden proposal at this time, it is unclear which mechanisms may be considered in the future to expand coverage in other ways. One possibility would be to expand coverage through an evaluation managed by the Center for Medicare and Medicaid Innovation. The Center for Medicare and Medicaid Innovation would likely not have the authority to create its own version of narrower clinical eligibility criteria, but in principle it could design a model in which expanded coverage is linked to evaluation of longer-term clinical and economic outcomes, or to evaluation of combinations of drug treatment with

different versions of lifestyle management. The advantage of expanding coverage through some form of evaluation model is that it could be the most effective way to generate evidence on longer-term outcomes in the Medicare and Medicaid populations that could help guide future practice. However, trying to launch a coverage model for GLP-1s for obesity with an evaluation component might create unanticipated constraints on access, with unknown effects on existing disparities in access and outcomes. Conversely, an evaluation model alone might not address concerns regarding the budgetary impact on the Medicare and Medicaid system, and by extension, on coverage among private insurers that might feel obligated to follow suit and expand coverage to their members.

Improve access in private insurance through action by the USPSTF

At a federal level, in lieu of Medicare coverage of GLP-1s for obesity, another way to broaden coverage would be to ask the United States Preventive Services Task Force (USPSTF) to evaluate GLP-1s and deem them as preventive treatments worthy of a rating of 'A' or 'B' that creates a mandate for coverage by all private insurers with no patient cost sharing [83].

One advantage of mandated coverage across all insurers would be that the disparities in access across different types of purchasers would be eliminated, improving equity and possibly accelerating the ability of the US to benefit from a positive shift in public health.

The corresponding concern about this approach is its impact on the budgets of all purchasers, with the greatest liability for smaller and less financially flexible purchasers. In our interviews we heard from some stakeholders that mandated coverage at current prices would drive up premiums for all participants in private insurance markets so much that many individuals and organizations would not be able to afford insurance. Mandated coverage also creates the risk of limiting the ability of purchasers to use prior authorization, tiered formularies, step therapy or other utilization management strategies discussed in this report, potentially leading to even greater premium increases for all members. Lastly, a legal challenge to the Affordable Care Act provision that mandates coverage without cost-sharing is due to be heard by the Supreme Court in the summer of 2025, casting further doubt over whether USPSTF action could affect coverage for OMs.

Reduce costs through aggressive federal drug price negotiation

Although tirzepatide likely will not be eligible for Medicare price negotiation until 2030, with implementation of negotiated pricing in 2033, semaglutide is at the top of the list of the set of drugs for Medicare price negotiation for implementation in 2027 [84], with total Part D gross spending surpassing the second drug on the list by more than $9 billion from November 2023 to October 2024 [85]. The incoming Trump administration has not commented on its approach to taking over the drug price negotiation process, but since there is no lower price, or price 'floor' set by statute, it is possible that Medicare will be more aggressive in price negotiation on semaglutide than it was in its first round of negotiated drug prices [86], seeking far further discounts than those minimum discounts required under the Inflation Reduction Act (IRA).

Lower prices on brand versions of semaglutide in the Medicare system would seem most likely to lead to lower prices in the commercial market as well, but the negotiated prices on the first round of drugs have not even been fully implemented yet, so there is no experience from which to draw lessons. If negotiation achieves a price for semaglutide lower than its current net price, it remains unclear how payers and purchasers will manage their formularies. Prices negotiated under the IRA process are list prices, and since GLP-1s are heavily rebated, this means that a lower Medicare price for semaglutide will reduce the rebates available to purchasers, payers and others in the drug delivery system. This could lead purchasers and payers to prefer GLP-1 drugs other than semaglutide that have higher list prices but that continue to offer substantial rebates. Medicare may choose to monitor formulary management of semaglutide closely to ensure that patients gain the benefits of having a lower list price option, but how semaglutide will be managed in commercial insurance formularies is an open question. Although it can be argued that a lower list price option should be preferred since it leads to lower cost barriers for patients, an alternative argument can be made that payers should always prefer the option that is clinically equivalent (or superior) with the lowest net cost to the purchaser, who should 'share' the benefits of this lower net cost with patients through benefit design and through keeping employee insurance premiums as low as possible.

Reduce costs by providing federal subsidies for private insurance coverage of obesity treatments

If the private insurance market cannot create affordable options for coverage of OMs, leading to significant disparities in access, some of the stakeholders we interviewed believed that the federal government should step in to

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provide subsidies to private insurers to support a broad requirement that all purchasers provide coverage for OMs. It was also suggested that, in return for federal subsidies, the federal government could negotiate significant price concessions not just on semaglutide but on all GLP-1s, along the lines of the affordable prices that were negotiated for COVID vaccines and treatments during the pandemic [58].

Some stakeholders we interviewed favored subsidies, believing that they could be set to expire over a short number of years, and that such an approach might be the only way to guarantee that the US achieves the broad public health benefits of GLP-1 drugs. Others we interviewed thought federal subsidies would be an overreaction and highly unworkable across the wide variety of purchasers and payer types. How to phase out subsidies over a long time frame would also be highly contentious. Federal subsidies would also create a difficult precedent, raising questions of why coverage for treatments of other chronic conditions cannot be subsidized as well.

Reduce costs by licensing GLP-1 products from drugmakers

Along with negotiating lower prices through the IRA process, another governmental action that has been proposed to address the costs of GLP-1 drugs is to require that drugmakers license GLP-1 drugs to generic manufacturers for the express purpose of providing more affordable versions for public payers, including state Medicaid programs and state employee health plans [87]. In return, the federal government could 'reasonably' compensate the companies by offering royalties.

Any such move by the federal government to pressure drugmakers to license their intellectual property is extremely unlikely and was not even seen during the height of the COVID pandemic. The drug industry and many analysts fear that this kind of governmental action would send a shock wave through the ecosystem required for investment and risk-taking to bring new innovative treatments forward. Nonetheless, the fact that this idea is being discussed is a testament to the frustration of some public health officials as they wrestle with their inability to provide affordable coverage for treatments that they believe should be available to all Americans.

Conclusion

Obesity is one of the most significant public health challenges faced by the US. As a class of drugs, GLP-1s offer a promise of a revolutionary treatment option, one emerging from over 20 years of clinical experience in diabetes that has created strong evidence of sustained weight loss and a seemingly ever-expanding list of additional ways they can improve health.

After so many years of concern and futile efforts, the opportunity to be able to finally address obesity and its health and social effects on a national level is palpable. It is also complicated. The opportunity is clouded by remaining unknowns about whether patients can maintain treatment over many years and about the long-term outcomes of patients taking GLP-1s for indications other than diabetes. Optimism must also be balanced by uncertainties about how best to integrate these treatments with other approaches to obesity, how the fragmented US healthcare system can adopt treatment without adding to entrenched disparities in access, and by what could be a staggering potential cost to government, private purchasers, insurers and patients.

This paper has traced the outlines of current attempts to manage the tension between the opportunity, the uncertainties and the cost of the new generation of OMs. It has also used a broad scan of the literature and insights gained from experts and stakeholders from all perspectives to weigh the potential advantages and disadvantages of market actions and policy solutions to managing GLP-1s. From this effort, several themes have emerged. First, in part because of the pluralistic nature of the US healthcare system, not only is no single approach able to achieve a perfect balance, but also there remains vigorous debate about what the perfect outcome looks like. Should the US be seeking the broadest possible rapid uptake of GLP-1s, recognizing their landmark effectiveness by shifting huge resources to fund a population-wide campaign to reduce obesity and improve health? Or is a better outcome one of prudent delay, in which uncertainties are explored, price competition and governmental negotiation is awaited, and clinical experience enhanced before a more measured, less costly, and perhaps more targeted and effective approach to GLP-1s and obesity is adopted?

A second theme that has emerged is that, lurking behind this choice, are deeply held views about the root causes of obesity and the priorities of public health, about the level of incentives needed for pharmaceutical innovation, and about the ability of the health system to absorb new costs without creating secondary harms to access and to the overall quality of healthcare. But we have found that most experts and stakeholders do expect that GLP-1s will rapidly gain broader use and that there are market actions and policy solutions that provide options for finding some kind of 'middle ground.' Many purchasers and payers today are combining new approaches to applying

evidence-based coverage criteria, working with providers or carve-out companies to integrate lifestyle management into a personalized treatment plan, and exploring ways to negotiate lower pricing through formulary management or innovative payment arrangements.

Multilayered approaches can be designed in myriad ways, and none can completely address the tensions between broad access and costs. As of today, for many purchasers and insurers, there appears to be no combination of market actions that would enable them to provide affordable broad coverage for GLP-1s for obesity. Drugmakers and others may feel that budgetary concerns are overblown, and that purchasers and payers can and should marshal the financial elasticity to absorb the costs of these treatments that are, by standard definition, cost–effective. But the experience of purchasers such as the North Carolina and West Virginia state employee health plans, of private payers such as the Blue Cross Blue Shield plans of Massachusetts and Michigan, and that of a growing number of employers, demonstrate that many purchasers and payers will struggle in the short-term to manage the financial impact of covering GLP-1 treatment for obesity at current pricing, particularly in light of the many uncertainties about longer-term adherence and outcomes. Change is needed, but there is no easy script for all to follow.

If the market is unable by itself to deliver needed outcomes, could federal policy reform help? Another theme we discovered in our interviews was the ambivalence toward federal policy action to help 'solve' the private insurance market tensions around GLP-1 coverage. Although many stakeholders realize the positive potential for federal policy to intervene when private insurance markets are unable to provide equitable and affordable access, the landscape is changing so fast, and the uncertainties remain so high regarding future competition and pricing, that most stakeholders seem interested in letting these dynamics play out, at least for a while longer, before seeking aggressive federal action.

And it is this sense of rapid change and uncertainty that is the last major theme of this paper. We have sought to provide perspectives on the potential advantages and the potential limitations or disadvantages of different market actions and policy solutions. But these perspectives are presented within an environment of such rapid change – in emerging new agents, pricing, clinical evidence, federal policy, drug availability and patient demand – that approaches that may appear the best at one point of time may fade from relevance or even be detrimental at a future time. Drugmakers, purchasers, payers, clinicians, patient advocates and governmental policy makers will need to remain flexible and ready to adapt their approaches as circumstances change.

One important goal of this paper has therefore been to embed a recognition of uncertainty and the corresponding need for flexibility into our analysis of options for managing GLP-1s. ICER will provide ongoing reviews of the evolving evidence on current and future GLP-1s to inform future market actions and policy considerations. We have also been privileged to work with outstanding leaders and experts who have shared their perspectives with us for this paper. We hope that the product will guide stakeholders in their efforts to achieve the best possible outcomes, both in effectiveness and in affordability, for patients and for the US health system.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: https://becarispublishing.com/doi/epdf/10.57264/cer-2025-0083

Author contributions

All authors were responsible for the conception and design of this project. All authors participated in the drafting and review of this manuscript and are responsible for its contents.

Acknowledgments

The full ICER White Paper is available on the ICER website at https://icer.org/assessment/strategies-affordable-access-for-obesity-medications-2025/

The authors thank Amanda Mehlman for her contributions to the research and development of the white paper on which this work is based. The authors also thank the stakeholders who participated in the structured interviews, the member organizations of the ICER Policy Leadership Forum, and AT&T, MassHealth, National Academy for State Health Policy (NASHP), North Carolina State Health Plan and Obesity Action Coalition for their participation at the ICER Policy Summit and their thoughtful comments on the white paper draft.

No assertion, judgment or recommendation included in this manuscript should be viewed as representing the opinion of any participant or their company. ICER alone is ultimately responsible for the final content.

Financial disclosure

This work was supported by the 2024–2025 members of the ICER Policy Leadership Forum: Abbott, AHIP, Alliance of Community Health Plans (ACHP), Alnylam Pharmaceuticals, AstraZeneca, Bayer Healthcare LLC, Blue Shield of CA, Boehringer Ingelheim, California Public Employees' Retirement System (CalPERS), Centene Pharmacy Services, Chiesi USA, Inc., CVS Caremark, Eisai, Inc, Elevance Health, Express Scripts, GSK, Health Care Service Corporation (HCSC), Humana, Kaiser Permanente, LEO Pharma, Mallinckrodt Pharmaceuticals, Merck & Co., National Pharmaceutical Council (NPC), Novo Nordisk, Otsuka Pharmaceutical, Point32Health, Premera Blue Cross, Prime Therapeutics, Regeneron Pharmaceuticals, Inc., Sanofi and UnitedHealthcare. ICER also receives funding from nonprofit foundations including Arnold Ventures, The California Health Care Foundation, The Patrick and Catherine Weldon Donaghue Medical Research Foundation and the Peterson Center on Healthcare, LLC.

No assertion, judgment or recommendation included in this manuscript should be viewed as representing the opinion of any participant or their company. ICER is ultimately responsible for the final content.

Competing interests disclosure

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Writing disclosure

No funded writing assistance was utilized in the production of this manuscript.

Summary points

- Glucagon-like peptide 1 (GLP-1) receptor agonists and GLP-1/gastric inhibitory polypeptide receptor agonists offer weight reduction and associated health benefits that, if sustained over time, have the potential to markedly improve population health.
- However, over 40% of US adults have obesity, translating into more than 100 million potential new users of obesity medications.
- Standing in the way of the major opportunity to improve health for these individuals is the massive and likely ongoing cost of treating such a large segment of the population.
- Although the Institute for Clinical and Economic Review has judged the net price for semaglutide, and by extension for tirzepatide, as meeting reasonable cost–effectiveness levels in the US market, the number of potential users creates a scale of spending on a single drug class that some analysts have estimated will reach over $100 billion annually within the next 5 years.
- This paper analyzes the range of emerging market approaches and possible policy reforms that have the potential to help achieve affordable access to these medications.
- The potential market strategies explored in the paper include temporary coverage denial, enhanced prior authorization and formulary management, provider network management, innovative payment arrangements and carve-out programs for obesity management services.
- The potential federal policy interventions explored in the paper include offering coverage for obesity drugs in Medicare, action by the United States Preventative Services Task Force, aggressive federal drug price negotiation, providing federal subsidies for private insurance coverage of obesity treatments and licensing GLP-1 products from drugmakers.
- The authors analyze the relative advantages, the barriers and the potential unintended consequences for each market or policy option, and explore the pros and cons of combining strategies either internally within an insurance system or externally through stand-alone obesity management providers.
- None of the market actions or policy reforms discussed are 'silver bullets' that can singlehandedly solve all the barriers and tensions inherent in trying to maximize affordable access while retaining incentives for future innovation.
- Still, the authors seek to present policymakers and industry leaders with insights and lessons learned from experts while offering a menu of options for the future that will help all stakeholders play an active part in an innovative future of pricing, coverage and payment for new obesity medications.

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