

How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget?

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edicare beneficiaries who are overweight or who have the medical condition of obesity are more likely to have worse health outcomes and higher health care expenditures than beneficiaries in the healthy weight category. Among adults enrolled in randomized controlled trials, treatment with certain anti-obesity medications (AOMs) has been shown to lead to significant weight loss and improved health when recipients use the drugs consistently and at the prescribed time intervals. Those drugs include glucagon-like peptide 1 (GLP-1) receptor agonists, which were originally approved to treat diabetes.

The Medicare program covers some obesity-related services, including screening, behavioral counseling, and bariatric surgery (a procedure performed on the stomach or intestines to induce weight loss). It is prohibited by law from covering medications for weight management as part of the standard prescription drug benefit. Medicare covers GLP-1-based products only for beneficiaries who use them for medically accepted indications other than weight management. Currently, those accepted indications are diabetes and cardiovascular disease. Policymakers have introduced legislation to authorize Medicare to cover those medications more broadly.

In this report, the Congressional Budget Office estimates the budgetary effects of an illustrative policy that would authorize Medicare to cover AOMs starting in January 2026. The policy would apply to all beneficiaries with obesity, as well as certain beneficiaries who are classified as overweight. Adoption of such a policy would have these effects, in CBO's estimation:

 Federal Budgetary Cost. Authorizing coverage of AOMs in Medicare would increase federal spending, on net, by about \$35 billion from 2026 to 2034. Total direct federal costs of covering AOMs would increase from \$1.6 billion in 2026 to \$7.1 billion in 2034. Relative to the direct costs of the medications, total savings from beneficiaries' improved health would be small—less than \$50 million in 2026 and rising to \$1.0 billion in 2034.

- Cost and Savings per User. Weight loss is associated with reductions in health-related spending per user that are less than the estimated federal cost per user of covering AOMs throughout the 2026–2034 period. Per AOM user, the average direct federal cost would be roughly \$5,600 in 2026, decreasing to \$4,300 in 2034. And average offsetting federal savings would be about \$50 in 2026, reaching \$650 in 2034.
- Eligibility and Take-up. Over 12.5 million Medicare beneficiaries would newly qualify for AOMs in 2026 under the illustrative policy; 0.3 million, or 2 percent of the newly eligible population, would use an AOM in 2026. Despite growth in Medicare enrollment from 2026 to 2034, the number of newly qualified beneficiaries would fall to 11.9 million in 2034 as those drugs were approved to treat additional conditions under current law. In that year, about 1.6 million (or 14 percent) of the newly eligible beneficiaries would use an AOM.

Beyond 2034, the policy's net federal costs to the Medicare program would probably be lower on a peruser basis than in the first decade for two reasons. CBO expects that the cost of the drugs will fall over time and that the savings from improved health will grow over time. Nevertheless, the policy would still increase federal spending between 2026 and 2044.

The budgetary effects of authorizing AOM coverage in Medicare are highly uncertain. Estimates of costs and take-up rates are sensitive to the rapidly evolving

Table 1.

Share of Medicare Beneficiaries With and Without Diabetes and With Certain Other Chronic Conditions, by Category of Body Mass Index, 2021

Percent

Category	Share of Medicare population	Share with type 2 diabetes	Share without type 2 diabetes	Share with weight-related chronic conditions among beneficiaries without type 2 diabetes			
Underweight (BMI below 18.5)	2	8	92	72			
Normal weight (BMI from 18.5 to less than 25)	29	9	91	76			
Overweight (BMI from 25 to less than 30)	35	16	84	83			
Obesity (BMI of 30 or more)	34	28	72	87			

Data source: Congressional Budget Office, using data from the 2021 Medicare Current Beneficiary Survey. See www.cbo.gov/publication/60441#data. BMI = body mass index (a measure of body fat based on a person's height and weight).

evidence on the eligibility, use, price, and clinical benefits associated with those medications. Those factors are also sensitive to the scope of the policy, including who in the Medicare population would become eligible for treatment with AOMs.

Obesity Among Medicare Beneficiaries

Obesity is a common chronic disease among Medicare beneficiaries, and it is associated with adverse health effects and higher costs to Medicare, which are paid by the federal government and by beneficiaries through premiums and cost sharing. (Beneficiaries can obtain supplemental coverage—including federally subsidized coverage—for some or all of their costs.)

Prevalence of Obesity and Chronic Conditions

More than two-thirds of Medicare beneficiaries are classified as either obese or overweight, according to their body mass index, or BMI. (BMI is a measure of body fat based on height and weight; it is calculated by dividing a person's weight in kilograms by the square of their height in meters.)¹ In calendar year 2021, 34 percent of Medicare beneficiaries had a BMI of 30 or greater, placing them in the obesity category (see Table 1). An additional 35 percent of Medicare beneficiaries were classified as overweight, meaning they had a BMI of 25 to less than 30.²

Excess weight is associated with several chronic conditions. The prevalence of type 2 diabetes increases

with higher BMI, for example. In calendar year 2021, 16 percent of Medicare beneficiaries classified as overweight and 28 percent of beneficiaries with obesity had type 2 diabetes. Even among Medicare beneficiaries without type 2 diabetes, higher BMIs were associated with a greater prevalence of weight-related comorbidities (which are diseases or medical conditions that are simultaneously present in a patient). Among Medicare beneficiaries classified as overweight and without type 2 diabetes, 83 percent had weight-related chronic conditions (including different types of cancers and heart conditions). Among beneficiaries with obesity and without type 2 diabetes, 87 percent had at least one weight-related chronic condition.³

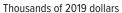
Association Between BMI and Health Care Spending

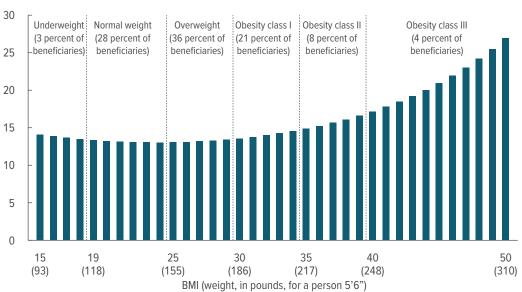
Body mass indexes are often grouped into four categories: underweight, normal weight, overweight, and obesity. The last category—obesity—can also be classified according to its severity: class I, low risk; class II, moderate risk; and class III, high risk. On average, health care spending for Medicare beneficiaries with obesity exceeds spending for people without obesity (see Figure 1). Among the three subcategories of obesity, differences in spending are larger for people with higher BMI. For example, average health care spending is considerably greater for people with a BMI of 40 or above (obesity class III) than for people with a BMI of 30 to less than 35 (obesity class I). In this analysis, health care spending includes spending by Medicare and by other payers.

a. Defined as ever having one or more of the following: hardening of the arteries, hypertension, a heart attack, angina pectoris or coronary heart disease, congestive heart failure, other heart conditions (for example, valve- or rhythm-related conditions), a stroke, high cholesterol, or certain types of cancer. Although other chronic conditions are associated with excess weight and obesity (such as fatty liver diseases), those are not included in the survey's questionnaire.

Figure 1.

Average Annual Health Care Spending per Person Among Medicare Beneficiaries, by Body Mass Index, 2015 to 2019





Health care spending among beneficiaries with obesity exceeds spending among people with normal weight, on average. Within the three categories of obesity, spending is higher for people with a higher BMI, in part because of their greater likelihood of having other chronic conditions.

Data source: Congressional Budget Office, using data from the Medicare Current Beneficiary Survey for selected years (2015 to 2019). See www.cbo.gov/publication/60441#data.

BMI is a measure of a person's body fat based on height and weight. The bars shown apply to all people with a given BMI, including people of various height and weight combinations, even though this graphic, for illustrative purposes, shows the body weight for a person of a certain height.

Obesity can be classified according to its severity: class I, low risk; class II, moderate risk; and class III, high risk.

To increase the precision of the estimates shown here, CBO pooled data from several years of the survey. The share of Medicare beneficiaries in each BMI category in this figure differs slightly from the values shown in Table 1, which are based on analysis of only the 2021 Medicare Current Beneficiary Survey.

BMI = body mass index.

That observed relationship between spending and BMI at a point in time does not necessarily imply that health care spending would decrease if a Medicare enrollee with obesity lost weight, however. Estimating the budgetary effects of weight loss by comparing health care spending among people at a single point in time is potentially misleading for two reasons. First, it is uncertain whether weight alone causes the differences in average health care spending for people in various BMI categories. Differences among people in health risks and behavior can persist even after weight loss. Second, the extent to which the adverse health effects associated with excess weight are reversible through weight loss is also uncertain. Ascertaining the direct effects of weight loss on spending for health care services requires a different type of analysis.

Recent Innovations in AOMs and Coverage of Those Drugs in Medicare Under Current Law

GLP-1-based medications have recently been approved for weight management in a targeted population, and sales of those products have increased rapidly since 2021. Under current law, Medicare is prohibited from covering AOMs as part of the standard prescription drug benefit. Policymakers have considered lifting that prohibition, however, and have introduced legislation that would newly authorize Medicare to cover those medications.

Recent Innovations in AOMs

Prescription medications for weight management have been available for over a decade (see Table 2). Certain AOMs, originally approved to treat type 2 diabetes, have

Table 2.

Selected Prescription Medications Currently Approved and Marketed for Weight Management

Molecule	Medication	FDA approval date for weight management	Type 2 diabetes medication with same molecule and FDA approval date for type 2 diabetes							
GLP-1-based products										
Liraglutide	Saxenda	December 2014	Victoza; January 2010							
Semaglutide	Wegovy ^a	June 2021	Ozempic; December 2017							
Tirzepatide	Zepbound	November 2023	Mounjaro; May 2022							
	Othe	r weight-loss medications								
Orlistat ^b	Xenical	April 1999	n.a.							
Phentermine/Topiramate	Qsymia	July 2012	n.a.							
Bupropion/Naltrexone	Contrave	September 2014	n.a.							

Data source: Congressional Budget Office, using information from the Food and Drug Administration. See www.cbo.gov/publication/60441#data.

The approval date for weight management indications applies to people who have obesity or are classified as overweight (having a body mass index from 27 to 30 and a weight-related chronic condition).

FDA = Food and Drug Administration; GLP-1 = glucagon-like peptide 1; n.a. = not applicable.

- a. Also approved to treat cardiovascular disease.
- b. Also available in a lower-dose over-the-counter formulation (marketed as Alli).

recently been shown to lead to more significant weight loss than older medications.⁵ The products, including GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) receptor agonists, have been approved for chronic weight management in adults with obesity and certain people classified as overweight (those with a BMI of 27 to 30 and at least one weight-related comorbidity). As of September 2024, marketed GLP-1-based products approved for weight management are Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide).⁶ Zepbound is the newest product, having entered the market in the fourth quarter of 2023. Older non-GLP-1-based medications for weight management include Xenical (orlistat), Qsymia (phentermine/topiramate), and Contrave (bupropion/naltrexone).

Clinical trials have shown that the GLP-1-based medications most recently approved for weight loss among people without type 2 diabetes—Wegovy and Zepbound—are associated with larger reductions in body weight than are older weight loss medications, including Saxenda. Many additional AOMs are under development, and some are in late-stage clinical trials. Those drugs could prove even more effective for weight loss than the AOMs now on the market.

Total sales of GLP-1-based AOMs, net of manufacturer discounts, have increased dramatically over the past two

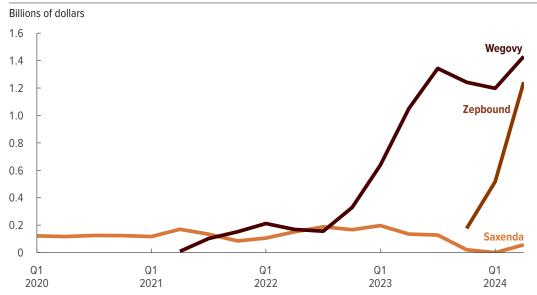
years (see Figure 2). That growth reflects demand for AOMs among patients without diabetes who meet the BMI thresholds for weight-loss treatment. In the second quarter of 2024, sales of brand-name GLP-1-based products approved for weight loss in the United States amounted to \$2.7 billion, which was more than five times the sales in the fourth quarter of 2022, when they totaled \$0.5 billion. Most sales in the second quarter of 2024 were for either Wegovy (52 percent) or Zepbound (46 percent); the remaining sales were for Saxenda. CBO expects that sales of GLP-1-based products will continue to rapidly increase as more people gain access to those drugs.

Coverage of Obesity Treatments in Medicare Under Current Law

Medicare covers some treatments for obesity under Parts A and B of the program. Under Part A (Hospital Insurance), Medicare covers bariatric surgery. That surgery is restricted to certain beneficiaries, following rules issued by the Centers for Medicare & Medicaid Services (CMS). To qualify for bariatric surgery, beneficiaries must have a BMI equal to or greater than 35 and at least one obesity-related comorbidity. In addition, they need to have tried a prior medical treatment for obesity (such as medical nutrition therapy) that was unsuccessful. ¹⁰ Under Part B (Medical Insurance, which covers physicians' services, outpatient care, and other medical

Figure 2.

Sales of Brand-Name GLP-1-Based Anti-Obesity Medications Across All Payers, Net of Manufacturer Discounts, 2020 to 2024



Total sales of GLP-1-based anti-obesity medications have increased over the past two years because of greater use of GLP-1-based products. That growth reflects strong demand among patients for weightloss treatment.

Data source: Congressional Budget Office, using sales information from SSR Health. See www.cbo.gov/publication/60441#data.

The figure shows total sales for Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide). It does not include sales for products with the same molecule but for different indications (such as type 2 diabetes).

GLP-1 = glucagon-like peptide 1; Q1 = first quarter.

services), Medicare covers behavioral counseling by primary care providers. Also, as part of preventive coverage, Medicare pays for obesity screenings and intensive behavioral therapy (IBT), such as nutritional evaluation and counseling, for beneficiaries with a BMI equal to or greater than 30.

Part D plans, which administer Medicare's outpatient prescription drug program, are prohibited from covering AOMs as part of the standard prescription drug benefit under the terms of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹¹ Those plans can cover such drugs as a supplemental benefit, but that coverage is not subsidized by the federal government and must be funded entirely by beneficiaries through additional premiums. The volume of prescriptions issued that way remains low. Beneficiaries can also elect to pay for the medications entirely out of pocket.

Although AOMs are not covered as part of Medicare's standard prescription drug benefit, some beneficiaries who

have obesity or are classified as overweight are eligible for those treatments if they also have type 2 diabetes or certain cardiovascular conditions. As the number of indications for AOMs expands, CBO expects that many beneficiaries will newly qualify for coverage of those medications under current law and that spending for GLP-1-based products will continue growing quickly. The expected additional spending for that class of drugs is reflected in CBO's 10-year baseline budget projections.¹²

Currently, insurers in other (non-Medicare) markets cover AOMs to different extents. Novo Nordisk reports that more than half of people with obesity who are eligible for coverage in the commercial market had access to Wegovy as of the second quarter of 2024, for example.¹³ In Medicaid, coverage of drugs for weight management is optional.¹⁴ According to one study, of the 47 states with publicly available lists of preferred drugs, nine had Medicaid programs that covered Wegovy in the first quarter of 2023.¹⁵ Coverage provided through the Affordable Care Act's marketplaces largely excludes

Table 3.

Budgetary Effects of a Policy That Would Cover Anti-Obesity Medications in Medicare, by Fiscal Year

Billions of dollars										
	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Direct costs of covering AOMs	1.6	1.8	2.9	3.8	4.3	5.1	5.8	6.5	7.1	38.8
Savings from improved health	*	*	-0.1	-0.2	-0.3	-0.4	-0.6	-0.8	-1.0	-3.4
Net effect on the deficit	1.5	1.8	2.8	3.7	4.0	4.7	5.2	5.7	6.1	35.5

Data source: Congressional Budget Office. See www.cbo.gov/publication/60441#data.

The policy would take effect in January 2026. Estimates were calculated relative to CBO's February 2024 baseline budget projections.

AOM = anti-obesity medication; * = between -\$50 million and zero.

GLP-1-based drugs for weight management: As of June 2024, 1 percent of prescription drug plans covered Wegovy, and no plans covered Zepbound. ¹⁶ People taking those drugs who are not yet eligible for Medicare or who are eligible but have not yet enrolled in the program could experience treatment interruptions upon enrollment.

Recent Legislation Addressing Obesity Treatments in Medicare

Given the high rates of obesity in the United States and the associated detrimental effects on health, policymakers have considered and introduced legislation to expand access to AOMs in Medicare. For example, the Treat and Reduce Obesity Act (TROA) of 2023 (H.R. 4818 and S. 2407) would authorize Medicare Part D to cover drugs for weight management.¹⁷

As introduced, TROA would expand coverage to Medicare beneficiaries with obesity and to certain beneficiaries classified as overweight—those with a BMI of 25 to 30 and one or more related chronic conditions. ¹⁸ The bill also would permit additional health care providers and counseling programs to be reimbursed for the IBT services they provide to beneficiaries to treat their obesity. (That reimbursement is currently limited to primary care providers.) ¹⁹ In June 2024, the House Committee on Ways and Means ordered the bill reported with an amendment that would include AOMs as covered Part D drugs for new Medicare beneficiaries with prior continuous use of AOMs. ²⁰

Budgetary Effects of Authorizing Medicare to Cover Anti-Obesity Medications

CBO analyzed an illustrative policy that would authorize Medicare to cover AOMs for weight management beginning in January 2026. The policy, which is broadly similar to TROA, would apply to Medicare beneficiaries with obesity (in other words, those having a BMI equal to or greater than 30), as well as certain beneficiaries who are classified as overweight (having a BMI of 27 to 30) and with a weight-related chronic condition.²¹

The policy would increase federal spending by \$35.5 billion, on net, from 2026 to 2034, in CBO's estimation (see Table 3). Spending on AOMs would amount to \$38.8 billion over that period but would be partially offset by reductions of \$3.4 billion in other health care spending because of beneficiaries' improved health. Beyond 2034, the policy's net federal costs to the Medicare program would probably be lower on a peruser basis than in the first decade, CBO estimates, but the policy would still increase federal spending between 2035 and 2044.

Total Federal Costs

CBO estimates that the illustrative policy would increase federal costs by \$1.5 billion in 2026 and by \$6.1 billion in 2034 (see Table 4). Those estimates reflect several factors: the number of newly eligible beneficiaries who are projected to use a prescription AOM; the average duration of that use; and the direct federal cost per user after accounting for manufacturers' rebates and discounts, the low-income subsidy in Part D, and added income from increased Part D premiums.²² In addition, CBO's projections of the costs of AOM coverage reflect

Table 4.

Federal Medicare Costs of Anti-Obesity Medications, in Total and per User, by Fiscal Year

2026 2027 2028 2029 2030 2031 2032 2033 2034 5,900 4,000 4,200 4,300 4,500 4,700 4,900 5,100 5,300 Average net price of AOMs^a Minus: Beneficiaries' cost-sharing amounts, adjusted to reflect the share of people who receive the low-income subsidy^b -300 -300 -300 -300 -300 -400 -400 -400 -400 Minus: Increase in premium income 0 0 0 0 -400 -400 -400 -500 -500 Average annual federal cost per user 5,600 3,700 3,800 4,000 3,700 3,900 4,000 4,200 4,300 0.5 Number of AOM users (millions of people) 0.3 0.7 1.0 1.2 1.5 1.6 1.3 1.4 Direct annual federal cost (billions of dollars) 1.5 1.8 2.8 3.7 4.0 4.7 5.2 5.7 6.1

Data source: Congressional Budget Office. See www.cbo.gov/publication/60441#data.

This table presents the budgetary effects of an illustrative policy that would authorize Medicare to cover AOMs starting in January 2026. The policy would apply to all beneficiaries with obesity, as well as certain beneficiaries who are classified as overweight.

AOM = anti-obesity medication.

- a. The average net price equals the list price of AOMs after subtracting manufacturers' rebates and statutory discounts. CBO expects average net prices for AOMs to fall in 2027 because of Medicare drug price negotiations.
- b. Estimates of the out-of-pocket cost are adjusted for the average annual spending on prescription drugs by Part D beneficiaries without diabetes. Estimates of the average federal cost include the low-income subsidy, an additional benefit for some beneficiaries. Eligibility and the amount of that subsidy depend on a beneficiary's income and assets.
- c. An increase in spending on prescription drugs would lead to higher Part D premiums in later years, which would reduce the federal costs of covering AOMs.

the prevalence of obesity in the Medicare population, substantial demand for weight loss treatments among beneficiaries, and the price of the medications.

Number of Newly Eligible Beneficiaries. Owing to the expanded coverage under the illustrative policy, 12.5 million beneficiaries would become eligible for AOMs in 2026, CBO projects; that number would fall slightly, to 11.9 million, in 2034 (see Figure 3). The size of the newly eligible population under the illustrative policy would decrease over the period as more beneficiaries became eligible to receive AOMs under current law. Those figures are in accord with CBO's baseline projections of growth in Medicare enrollment.

To calculate the number of beneficiaries who would newly qualify for coverage of AOMs, CBO did the following:

- Determined the number of people satisfying the criteria in the illustrative policy,
- Subtracted the number of people with type 2 diabetes or cardiovascular disease who will already be eligible for coverage of GLP-1-based medications in Medicare, and

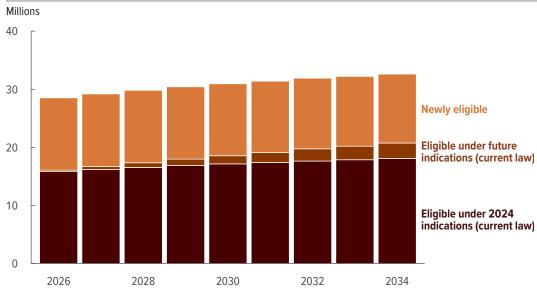
 Subtracted the number of people expected to be eligible for coverage of AOMs in Medicare under future FDA-approved indications.

In 2026, in CBO's estimation, 29 million beneficiaries would qualify for coverage under the illustrative policy. About half of that group, or 16 million people, would have access to those medications under current law for indications such as diabetes, cardiovascular coverage, and other indications approved by the FDA in the interim.²³ By the end of the projection period, in 2034, 33 million people would be eligible, 21 million of whom would qualify for coverage on the basis of non-weight-related indications that are currently approved or expected to be approved by that year.

Take-up and Continuation of AOMs. Under the illustrative policy, an additional 0.3 million newly eligible Medicare beneficiaries would begin treatment with an AOM in 2026, CBO estimates, which is about 2 percent of that population (see Table 5). By 2034, use of AOMs among newly eligible Medicare beneficiaries is projected to rise to 1.6 million, or 14 percent of that population.²⁴ Those numbers imply that 3 percent to 5 percent of the eligible population would initiate treatment in each year of the budget period.

Figure 3.

Medicare Beneficiaries Who Would Be Eligible for Treatment With Anti-Obesity Medications, by Fiscal Year, 2026 to 2034



If Medicare covered anti-obesity medications more broadly, roughly 30 million beneficiaries would be eligible for treatment each year from 2026 to 2034. In the absence of any policy changes, CBO estimates that a growing number of Medicare beneficiaries would qualify for treatment over that period as the products are approved for additional indications.

Data source: Congressional Budget Office. See www.cbo.gov/publication/60441#data.

Those estimates of take-up reflect CBO's assessment of two factors: how many beneficiaries would initiate treatment with AOMs in each year and how long beneficiaries would continue that treatment. CBO expects that the percentage of eligible beneficiaries who used AOMs would grow over time because of increases in take-up and continuation. The percentage of first-time users who remained on AOMs for one continuous year would increase from 35 percent among new users in 2026 to 50 percent among new users in 2034, CBO projects. Conversely, those figures imply that 65 percent of new users in 2026 and 50 percent of new users in 2034 would complete less than one year of treatment.²⁵ To make those estimates, CBO analyzed rates of first-year use of AOMs and observed changes in continuation rates for GLP-1 receptor agonist products among Medicare beneficiaries with diabetes.²⁶

Among beneficiaries with at least one year of continuous treatment with AOMs, 80 to 85 percent of those who use such treatment at the beginning of a subsequent year are projected to remain on that treatment at the end of that year. Together, those adherence estimates imply that about 30 percent of new users in 2026 will continue treatment for at least two years, and 15 to 20 percent of those new users will continue treatment for at least five

years. Those estimated continuation rates—which hold for each additional year of use of AOMs among Medicare beneficiaries with at least one year of continuous treatment—are based on CBO's analysis of historical claims data for GLP-1 receptor agonist products in Part D.

CBO's projections of take-up of AOMs among Medicare beneficiaries are consistent with three factors. First, AOM use has grown rapidly in market segments (such as the commercial market) that already cover those medications.²⁷ Second, CBO's estimate of AOM take-up is smaller than observed take-up rates for other medications that treat chronic conditions (such as statins, which lower cholesterol). Classes of medications with higher take-up rates typically have lower-cost generic alternatives and few limitations from payers on the medications' uses.²⁸ Third, take-up of AOMs is likely to be limited by a share of the indicated population that for various reasons would neither seek out nor begin treatment with those medications. Reasons for that reluctance might include stigmas around receiving treatment, concerns about side effects, or coverage decisions among Part D plans.²⁹

Annual Federal Costs per User. The average annual federal cost of treatment for each AOM user in Medicare, excluding the increase in Part D premiums, would be

Table 5.

Savings to Medicare From Improved Health, in Total and per User, by Fiscal Year

	2026	2027	2028	2029	2030	2031	2032	2033	2034
Number of AOM users (millions of people)	0.3	0.5	0.7	1.0	1.2	1.3	1.4	1.5	1.6
Savings per user (dollars)	50	50	100	200	250	350	450	550	650
Total savings (billions of dollars)	*	*	-0.1	-0.2	-0.3	-0.4	-0.6	-0.8	-1.0
Savings as a percentage of total Medicare spending per capita among AOM users (percent) ^a	0.2	0.4	0.6	1.0	1.4	1.8	2.1	2.5	2.8

Data source: Congressional Budget Office. See www.cbo.gov/publication/60441#data.

AOM = anti-obesity medication; * = between -\$500 million and zero.

a. Includes spending on Parts A (Hospital Insurance), B (Medical Insurance, which covers doctors' services, outpatient care, and other medical services), and D (which covers outpatient prescription drugs).

\$5,600 in 2026 and \$4,300 in 2034, CBO estimates (see Table 4). Those amounts represent total payments to Part D plans, after subtracting rebates, statutory discounts, and beneficiaries' cost-sharing amounts and adjusting for federal subsidies for people who receive the low-income subsidy. The net prices reflect CBO's analysis of the current list prices of marketed AOM products covered under Part D, as well as estimated manufacturers' rebates and statutory discounts.

CBO's estimates of average annual federal costs per user also are based on the agency's projection of spending on AOM products over the 2026–2034 budget period. For each product, CBO estimates the federal cost and weighs that amount by the drug's projected market share.

One factor that will affect the price of AOMs beginning in 2027 is the drug price negotiation program put in place as part of the 2022 reconciliation act. That law enables Medicare to negotiate directly with drug companies to lower prices for some of the costliest single-source brand-name drugs. CBO expects semaglutide to be selected by the Secretary of the Department of Health and Human Services for price negotiation in 2025 because of its high cost to the Medicare Part D program and its duration on the market.³¹

Consistent with CBO's expectations of the effect of those drug price negotiations—expectations that are based on federal guidance about the scope of affected products—the agency projects that the net price of semaglutide products will fall substantially beginning in 2027.³² That price reduction will affect all forms of semaglutide, including Ozempic, Wegovy, and Rybelsus.³³

Furthermore, CBO expects that the reduction in the price of semaglutide will affect the prices of other AOMs, such as Zepbound (tirzepatide for weight loss). As a result, average federal Part D spending per user of AOMs will decrease by roughly one-third, in CBO's estimation. For years after 2027, CBO projects that the list prices of AOMs will rise at the rate of inflation.

Budgetary Savings From Use of AOMs

The expanded use of AOMs under the illustrative policy is projected to improve beneficiaries' health, mainly by reducing the incidence of obesity-related chronic diseases, such as diabetes and cardiovascular conditions. On average, per capita Medicare spending (for Parts A, B, and D of the program) among AOM users is projected to decline by 0.2 percent in 2026 and by 2.8 percent in 2034 because of reduced prevalence of those conditions (see Table 5). In each year, the estimated savings reflect a weighted average of savings for people with different durations of treatment. The estimated savings for a given duration of treatment reflect an average of evidence from bariatric surgery experiences and microsimulation modeling.

Research about the effects of newer AOMs on health care spending is not yet available, given the recent approval of those drugs for weight-management indications. Therefore, to estimate the savings from improved health stemming from AOM use, CBO reviewed two types of comparable research.

 First, the agency examined evidence from observational studies that looked at the effects of bariatric surgery on health care related spending. In those studies, researchers compared actual spending outcomes among people who did or did not undergo surgery. Because

- the decision to undergo surgery is not random, researchers used statistical methods to account for other differences between people who did or did not undergo surgery that can affect spending outcomes.
- Second, the agency reviewed evidence of health care savings from AOM use by looking at microsimulation studies that have linked BMI and health care spending. Those studies estimated how changes in weight for a given sample of people would affect the prevalence and severity of various weight-related conditions and then estimated how those changes in health would alter spending on health care services.

CBO synthesized its findings from the research literature, made certain adjustments to the findings, and weighed the adjusted evidence from the observational and microsimulation studies equally. Using that information, CBO estimated the percentage reduction in medical spending associated with AOM use, which varied depending on how long users stayed on the treatment—from less than one year to 10 years. Separately, the agency tracked the distribution of treatment duration for each year of the illustrative policy (2026 to 2034) among all AOM users who would begin treatment. Then, for each year of the projection period, CBO averaged health care savings as a percentage of costs across all AOM users, weighting that average by the distribution of treatment duration.

Evidence From Observational Studies of Bariatric Surgery. Evidence about the effects of bariatric surgery on health care spending is mixed. Some observational studies showed lower health care spending after surgery, and others showed no change or higher health care spending.³⁴ On the basis of the bariatric surgery studies it reviewed, CBO calculated changes in health-related spending for the 10 years after surgery in four steps:

- CBO adjusted the findings from those studies to reflect the prices that Medicare pays for health care services.
- CBO assigned a weight to each study to reflect its quality and calculated the weighted difference in average spending for each of the first five years after surgery. Studies received higher weights if they had lower attrition, better matching of observable characteristics between the cohort that underwent surgery and the one that did not, longer follow-up periods, and more-recent study periods. Studies received lower weights if they had the opposite factors.

- CBO estimated that savings would be zero in years for which that weighted average showed costs, because the agency expects that increases in health care spending after bariatric surgery are likely a result of surgical complications and thus would not apply to the use of medications.
- CBO estimated that annual savings would continue to increase from six to 10 years after surgery at the same average rate at which they increased over the first five years.

Altogether, the agency estimated no savings in the first year and savings that steadily rise to an average of about \$1,000 per person (in 2022 dollars) in the 10th year. CBO used those estimates to project the effects for a given person according to how long they took the AOM. A person who took the drug for one year would have no savings in that year. (In that case, federal spending on AOMs would increase, however.) A person who took the drug continuously for 10 years would have no savings for the first year and savings that increased in subsequent years. When applying that evidence to each year of the policy, CBO adjusted it to account for the growth of Medicare spending.

One limitation of the evidence from observational studies is that AOMs and bariatric surgery may have different effects on health. For example, although bariatric surgery patients can receive significant health benefits, they can also develop both short- and long-term (even lifelong) complications that may affect their health care costs. Furthermore, the results from observational studies could be biased in either direction (indicating savings that were too low or too high) if the statistical methods used by researchers did not fully account for the differences between surgical and nonsurgical patients that affect health care spending.

Evidence From Microsimulation Models. CBO drew on evidence from two similar microsimulation models to estimate how AOM use affects health care spending (excluding the direct costs of the medications).

The Institute for Clinical and Economic Review's (ICER's) microsimulation model used estimates from the literature to examine the effects of semaglutide use on health care costs.³⁵ ICER's study found that, compared with lifestyle modifications, semaglutide use increased overall health care spending, on net. The estimated reductions in nondrug costs amounted to about

one-fourth of ICER's estimate of the net cost of the drugs. 36

The microsimulation model at the University of Southern California's (USC's) Schaeffer Center also analyzed health care savings from AOM use.³⁷ That study reported that AOMs could generate at least \$175 billion in savings for Medicare over 10 years, but only if the entire indicated population took the drugs, maintained perfect compliance, and did not discontinue use over their lifetime—conditions that are not achievable in practice.

Using those microsimulation studies, CBO estimated savings in each year from continuous use of semaglutide and extrapolated those savings to tirzepatide use, taking into account its larger average weight reduction.³⁸ (CBO incorporated additional analyses of ICER's simulated health care savings so as to be able to include that organization's findings, estimating health care spending separately for different lengths of continuous use and adjusting for differences in prices for health care services between the commercial and Medicare markets.) CBO calculated a weighted average of those two streams of savings using weights that reflect the projected share of the market for each drug. On the basis of that information, CBO projected that health care costs for a beneficiary who continuously took an AOM for 10 years would fall by an average of \$250 during the first two years. Savings would then rise by an average of about \$175 in each subsequent year, reaching about \$1,600 in the last year. (All numbers are expressed in 2022 dollars.) CBO adjusted those values to account for growth in Medicare spending in each year of the policy period.

One limitation of the estimates from microsimulation studies is that those studies generally do not rely on demonstrated effects of AOMs or weight loss on health conditions (aside from obesity). Instead, they rely on correlations between BMI and health conditions and between health conditions and health care spending, which may or may not be driven by a causal relationship.

A second limitation is that the composition of the population that would use AOMs under the illustrative policy is uncertain. In CBO's estimation, savings from AOM use could be about 50 percent higher or lower than estimated, depending on whether beneficiaries newly using AOMs had a BMI at the upper or lower ends of the eligible range. If beneficiaries had a BMI at the upper end of the range, the estimated savings would be 50 percent

higher and the total budgetary cost would be 5 percent less than CBO estimates. (The opposite effects would occur if beneficiaries had a BMI at the lower end of the range.) The impact of weight loss associated with AOM use on health and health care spending may ultimately differ from those simulated results.³⁹

Direct Evidence. CBO is not aware of any direct evidence showing that treatment of obesity with GLP-1-based products reduces spending on other medical services. One randomized controlled trial found that the use of Wegovy lowered the incidence of major adverse cardiovascular events, compared with the incidence of such events among a control group. ⁴⁰ That finding suggests that medical spending would fall among beneficiaries with obesity who achieved weight loss using AOMs—an offset to the cost of the medications. An observational analysis, however, found no evidence of any medical savings among people with private health insurance who took GLP-1 agonists for a full year. ⁴¹

Budgetary Effects in the Second Decade

An illustrative policy that made AOMs more widely available to Medicare beneficiaries for weight-loss treatment would continue to affect the federal budget beyond 2034. From 2035 to 2044, the costs of the drugs per user would be smaller and the savings from improved health would be larger than they would be from 2026 to 2034, in CBO's estimation, but the policy would still increase net federal costs in the second decade.

To estimate those second-decade effects, CBO accounted for three factors: AOMs' prices, use, and savings from improved health. CBO expects that AOMs' prices would continue to fall and the average effectiveness of new AOMs would improve, both of which would lower spending and reduce the impact of the policy on the budget deficit. CBO also expects that take-up and continuation rates would rise, boosting spending on AOMs and increasing average savings from improved health.

Prices. Average prices for AOMs are projected to fall by increasing amounts in the second decade because of the entry of generic drugs into the market. The introduction of generic versions would shift use to those lower-priced versions and thus place downward pressure on average prices for AOMs. Partially offsetting that effect is the expected market entry of new, more effective AOMs—some in other formulations—which would raise prices. For example, additional oral medications, which have

lower manufacturing costs and easier storage requirements than injectable drugs, are expected to become available.

Use. The rates at which AOMs are taken up and continued are projected to increase over time, placing upward pressure on both the direct costs of medication use and the average health care savings per user. More people may be able to take future drugs (and take them for longer) because of fewer side effects, less frequent dosing schedules, or preferable routes of administration. Other factors contributing to more widespread use of the medications are greater access to clinical programs and services that offer the drugs (such as obesity clinics), patient monitoring, and telehealth services.

Savings From Improved Health. As more users begin and remain on treatment with AOMs, CBO expects average annual savings from improved health (both in total and per user) to increase over time. Those increases would be even larger if future AOMs were more effective than current versions. In addition, savings would be larger if beneficiaries who began treatment before enrolling in Medicare were further along in their treatment cycle. Even though net federal savings per user are projected to be larger over the longer term, they would still be less than the cost of the medications.

Sources of Uncertainty

The budgetary effects of the illustrative policy are highly uncertain and sensitive to the rapidly evolving, real-world data on use, savings from improved health, prices, eligibility for treatment, and other factors associated with the newer class of AOMs. Additional evidence about any of those factors could make future estimates differ from those in this report. CBO will continue to monitor new evidence as it emerges and update its estimates accordingly.

Use of AOMs

How many people would use AOMs and for how long are significant sources of uncertainty in CBO's estimates. Take-up of AOMs might be greater than CBO expects if new products were more effective or better tolerated than existing products. However, take-up might be less than expected if Part D plans implemented stronger utilization management (limiting access to those drugs) or if supply shortages persisted beyond 2026. (CBO expects those shortages to be resolved before then.)

Similarly, continuation rates might differ from CBO's estimates, which are based on observed data for the diabetes GLP-1 market. Individuals using those medications for weight loss might remain on them longer than CBO estimates, or their duration of use might be shorter than CBO estimates.

Take-up and continuation rates also might vary from CBO's projections for other reasons. Clinical guidelines from medical associations and specialty societies could recommend uses of AOMs that differ from current recommended uses, which would affect demand for those medications. And demand might be affected by the risk of complications from long-term treatment with GLP-1 agonists. Furthermore, CBO's estimates consider the portion of the eligible population that can access those drugs under current law by paying for them out of pocket. If more people (or fewer people) paid out of pocket for AOMs, then take-up rates might vary from CBO's projections.

Savings From Improved Health

The health care savings resulting from use of AOMs are another significant source of uncertainty about the budgetary effects of the illustrative policy, mainly because CBO's estimates of savings are based on indirect evidence. Savings could be larger than CBO estimates if research found that use of AOMs generated sizable savings in health care costs. Savings also could be larger if greater-than-expected AOM use among the current non-Medicare population resulted in lower obesity rates and less spending to treat health complications for those people as they aged, became eligible for Medicare, and enrolled in the program.

Average savings in health care costs could be smaller than CBO estimates if Medicare beneficiaries lost less weight than has been reported in clinical trials. ⁴³ Additionally, savings could be smaller if research found that weight loss among AOM users did not translate into reduced spending on health care services. Furthermore, if weight loss led beneficiaries to seek or receive additional medical services—perhaps as a result of being on AOMs or from qualifying for certain medical treatments after weight loss—health care savings could be smaller.

Prices

Prices for AOMs are a source of moderate uncertainty. On the one hand, increased competition might lead manufacturers to offer larger-than-expected discounts, which would decrease the direct federal costs of those drugs. On the other hand, newer products could be launched at higher prices because of their greater efficacy, fewer side effects, or higher production costs. Higher prices would, in turn, put upward pressure on federal costs, especially if adoption of the new medications was widespread.

Generic versions would put downward pressure on average prices, although the timing of generic entry into the market could be sooner or later than CBO expects. Exclusive sales rights for semaglutide and tirzepatide are expected to expire in 2032 and 2036, respectively, but manufacturers' efforts to delay competition from generic entry make predicting the launch and rollout of any generic versions difficult.⁴⁴

Lastly, prices are likely to be affected by Medicare's drug price negotiations. CBO expects semaglutide to be subjected to negotiated prices in 2027, and its negotiated price could be more or less than CBO estimates, potentially changing the resulting federal costs. The negotiated price could also spur competition among manufacturers of AOMs already on the market or products in development that later come to the market.

Eligibility

Another source of moderate uncertainty in CBO's estimates is eligibility for treatment with AOMs. If additional indications for GLP-1-based drugs were approved, the size of the population newly eligible to receive treatment with AOMs under the illustrative policy would decline because more of those people would receive treatment without a change in law. Expanded access to those medications under current law would boost Part D

outlays in CBO's baseline projections, and the net budgetary effects of the policy would diminish.

Mortality

A final source of uncertainty is the degree to which AOM use could affect mortality rates and, in turn, federal spending. If AOM use reduced mortality rates—extending people's life expectancy, on average—then it could boost spending on Medicare and Social Security because people would receive benefits through those programs for more years than they would if mortality rates remained unchanged.

Evidence about the effects of weight loss on mortality lacks consensus, however. Recent analyses found that weight loss from use of GLP-1 receptor agonists reduced mortality from all causes among patients with type 2 diabetes and reduced cardiovascular-related mortality among patients without type 2 diabetes. For other types of weight-loss interventions, the evidence is mixed: Some studies have shown reductions in mortality, whereas others found no association between weight loss and mortality. Furthermore, randomized controlled trials that examined dietary interventions alone or in combination with physical activity generally found no changes in mortality. Together, the evidence suggests caution about inferring mortality effects from AOM use.

Because evidence about the effects of weight loss on mortality is evolving, CBO's estimates of the illustrative policy's effects do not consider that factor. If new evidence about the effects of weight loss on mortality rates emerged, CBO's budgetary estimates of the policy would differ.

- 1. For more information, see Centers for Disease Control and Prevention, "BMI Frequently Asked Questions" (June 28, 2024), www.cdc.gov/bmi/faq/index.html. Despite its widespread use for assessing health, many clinicians consider BMI to be an imperfect measure that does not directly approximate body fat. For more information, see Sara Berg, "AMA: Use of BMI Alone Is an Imperfect Clinical Measure," *American Medical Association* (June 14, 2023), https://tinyurl.com/2rt99w4s.
- 2. To estimate those shares, CBO used data from the 2021 Medicare Current Beneficiary Survey.
- 3. CBO estimated those shares using data from the 2021 Medicare Current Beneficiary Survey. People were considered to have a weight-related chronic condition if they indicated in the survey that they had ever had hardening of the arteries, hypertension, a heart attack, angina pectoris or coronary heart disease, congestive heart failure, other heart conditions (for example, valve- or rhythm-related conditions), a stroke, high cholesterol, or certain types of cancer. Although other chronic conditions are associated with excess weight and obesity (such as fatty liver diseases), those are not included in the survey's questionnaire. Even beneficiaries who have a normal weight (categorized as a BMI of 18.5 to less than 25) and do not have type 2 diabetes have a high prevalence (76 percent) of weight-related chronic conditions.
- 4. Those statistics are based on CBO's analysis of data from several years (2015 to 2019) of the Medicare Current Beneficiary Survey. By pooling those data, CBO was able to increase the precision of its estimates. CBO did not use more recently available data, to avoid capturing the effects of the coronavirus pandemic. Estimates of average health care spending per person represent health care spending for people with different BMIs based on regression analysis that accounts for certain observable characteristics, including age, sex, race and ethnicity, education, and marital status. For other estimates of health care spending among people with obesity, see John Cawley and others, "Direct Medical Costs of Obesity in the United States and the Most Populous States," *Journal of Managed Care and Specialty Pharmacy*, vol. 27, no. 3 (March 2021), pp. 354–366, https://doi.org/10.18553/jmcp.2021.20410; and David D. Kim and Anirban Basu, "Estimating the Medical Care Costs of Obesity in the United States: Systematic Review, Meta-Analysis, and Empirical Analysis," *Value in Health*, vol. 19, no. 5 (July 2016), pp. 602–613, https://doi.org/10.1016/j.jval.2016.02.008.
- 5. Institute for Clinical and Economic Review, *Medications for Obesity Management: Effectiveness and Value* (August 2022), Tables 3.11 and 3.12, https://tinyurl.com/3a7vbnum; Christophe De Block and others, "Tirzepatide for the Treatment of Adults With Type 2 Diabetes: An Endocrine Perspective," *Diabetes, Obesity and Metabolism*, vol. 25, no. 1 (August 2022), pp. 3–17, https://doi.org/10.1111/dom.14831; and Ania M. Jastreboff and others, "Tirzepatide Once Weekly for the Treatment of Obesity," *New England Journal of Medicine*, vol. 387, no. 3 (July 2022), pp. 205–216, https://doi.org/10.1056/NEJMoa2206038.
- 6. In March 2024, the FDA approved Wegovy to treat cardiovascular events (incidents that can damage the heart muscle by interrupting blood flow or heart function) in adults with cardiovascular disease and excess weight or obesity. CMS subsequently issued guidance to Part D plans allowing coverage of Wegovy for those events. See Centers for Medicare & Medicaid Services, "Part D Coverage of Anti-Obesity Medications With Medically Accepted Indications" (memorandum, March 20, 2024), https://tinyurl.com/2jw2tm45.
- 7. Institute for Clinical and Economic Review, *Medications for Obesity Management: Effectiveness and Value* (August 2022), Table 3.11, https://tinyurl.com/3a7vbnum.
- 8. According to one report, more than 110 AOM products are under development. See Elaine Chen, Allison DeAngelis, and J. Emory Parker, "Here Are the Dozens of Weight Loss Drugs in Development to Catch a Booming Market," Stat+ Obesity Drug Tracker (September 12, 2023), https://tinyurl.com/4esyehzf.
- 9. Those statistics are based on CBO's analysis of sales data for AOMs from SSR Health. Those data exclude sales of products that report insufficient volume, generic products, and products manufactured by companies that are not publicly traded. CBO's analysis excludes products with the same molecule but for different indications (such as type 2 diabetes).
- Centers for Medicare & Medicaid Services, "Part D Coverage of Anti-Obesity Medications With Medically Accepted Indications" (memorandum, March 20, 2024), https://tinyurl.com/2jw2tm45.
- 11. That statutory restriction extends to weight management agents used for anorexia or weight gain and agents used for cosmetic purposes. See Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual* (January 2016), Chapter 6, p. 51, https://tinyurl.com/mwav2fkw.
- 12. As additional indications receive FDA approval, access to those medications under current law increases Part D outlays in CBO's baseline. For more information on the effects of newly covered indications of AOMs on CBO's most recent 10-year budget projections of Medicare spending, see Congressional Budget Office, *An Update to the Budget and Economic Outlook: 2024 to 2034* (June 2024), p. 46, www.cbo.gov/publication/60039.
- 13. Novo Nordisk, "Novo Nordisk—A Focused Healthcare Company" (Investor presentation, 2024), https://tinyurl.com/bdxpea6s.
- 14. Elizabeth Williams, Alice Burns, and Robin Rudowitz, "Medicaid Utilization and Spending on New Drugs Used for Weight Loss" (KFF, September 2023), https://tinyurl.com/yfe8nayc.

- 15. Benjamin Y. Liu and Benjamin N. Rome, "State Coverage and Reimbursement of Antiobesity Medications in Medicaid," *JAMA*, vol. 331, no. 14 (March 14, 2024), pp. 1230–1232, https://doi.org/10.1001/jama.2024.30733.
- 16. KFF, "Costly GLP-1 Drugs Are Rarely Covered for Weight Loss by Marketplace Plans" (June 12, 2024), https://tinyurl.com/cupb3keh.
- 17. Treat and Reduce Obesity Act of 2023, H.R. 4818, 118th Cong., https://tinyurl.com/5y3r9tpn; and Treat and Reduce Obesity Act of 2023, S. 2407, 118th Cong., https://tinyurl.com/mr4ecepa.
- 18. As defined in sections 1861(yy)(2)(C) and 1861(yy)(2)(F)(i).
- 19. Centers for Medicare & Medicaid Services, "National Coverage Determination: Intensive Behavioral Therapy for Obesity" (updated November 2011), https://tinyurl.com/yc6pwhxm.
- 20. The bill considered in the House is H.R. 4818. See House Committee on Ways and Means, "Markup of H.R. 1691, H R. 2407, H.R. 8816, and H.R. 4818" (June 27, 2024), https://tinyurl.com/5fuuurbn.
- 21. Those eligibility parameters differ slightly from those of TROA and are consistent with the FDA's approved indications for AOMs.
- 22. In addition to the standard Part D benefit offered to all Medicare beneficiaries, the federal government provides a low-income subsidy to some beneficiaries. Eligibility for that additional benefit and its amount depend on a beneficiary's income and assets.
- 23. More trials are being conducted to assess the effects of GLP-1 agonist use on a broader range of cardiovascular conditions. For example, see National Library of Medicine, ClinicalTrials.gov, "A Study of Tirzepatide (LY3298176) on the Reduction on Morbidity and Mortality in Adults With Obesity (SURMOUNT-MMO)" (updated September 4, 2024), https://tinyurl.com/mrurtdpn.
- 24. CBO expects current supply shortages of AOMs to be resolved by the start of calendar year 2026, the policy's assumed date of implementation.
- 25. Estimated drop-off rates incorporate patients' responses to cost-sharing amounts and utilization management for the medications, as well as their side effects. See Ana Palanca and others, "Real-World Evaluation of GLP-1 Receptor Agonist Therapy Persistence, Adherence and Therapeutic Inertia Among Obese Adults With Type 2 Diabetes," *Diabetes Therapy*, vol. 14 (February 2023), pp. 723–736, https://doi.org/10.1007/s13300-023-01382-9.
- 26. Hamlet Gasoyan and others, "Early- and Later-Stage Persistence With Antiobesity Medications: A Retrospective Cohort Study," *Obesity*, vol. 32, no. 3 (December 2023), pp. 486–493, https://doi.org/10.1002/oby.23952; and Prime Therapeutics, "Real-World Analysis of GLP-1a Drugs for Weight Loss Finds Low Adherence and Increased Cost in First Year" (July 11, 2023), https://tinyurl.com/7z59z5bu.
- 27. Katie Palmer, "Where Are Patients Getting Their Prescriptions for GLP-1 Drugs Like Wegovy and Ozempic?" Stat+ Health Tracker (August 10, 2023), https://tinyurl.com/hrpjpzut.
- 28. Research shows that the average cost per day of brand-name statin use is generally less than \$10. That price is the result of robust competition among statin manufacturers, including makers of generic versions. See, for example, Jonathan T. Davies and others, "Current and Emerging Uses of Statins in Clinical Therapeutics: A Review," *Lipid Insights*, vol. 9 (2016), pp. 13–29, https://doi.org/10.4137/LPI.S37450. According to one report, roughly 60 percent of prescriptions for GLP-1 receptor agonists went unfilled in the first half of 2023, in part because of limitations that payers put in place to prevent off-label use (that is, use that is contrary to the FDA's approved indications) of those medications. See Ruthy Glass and Eric Foster, "New Demand in an Old Market: How the Launch of Mounjaro Transformed the GLP-1 Market," *IQVIA Blog* (September 5, 2023), https://tinyurl.com/2s4e4kuc.
- 29. To manage the prescription drug benefit, Part D plans may apply utilization criteria—such as prior authorization, step therapies, and other tools—that affect access to certain medications. Plans are most likely to apply those types of restrictions and exclusions to high-cost medications, as well as newly approved medications with a shorter history of demonstrated therapeutic effectiveness. Many Medicare Advantage plans already restrict weight-related surgical operations (such as bariatric surgery), as well as use of GLP-1 receptor agonist products indicated for diabetes. See Obesity Coverage, "Humana—Insurance Requirements for Weight Loss Surgery" (accessed April 12, 2024), https://tinyurl.com/yykf62ez; and Anthem, "Bariatric Surgery and Other Treatments for Clinically Severe Obesity" (December 28, 2023), https://tinyurl.com/bdd8tuvy.
- 30. CBO's analysis of Medicare beneficiary survey data suggests that 28 percent of the indicated AOM population qualified for that subsidy in 2021.
- 31. Under the drug price negotiation program, small molecule products without competition from generic versions must be FDA-approved for at least 7 years before being selected by CMS for negotiation. The threshold for biologic therapies (treatments that use substances derived from living organisms to treat disease) is at least 11 years.

- 32. The price that results from negotiations, called the maximum fair price, or MFP, applies to all products with the same active ingredient as the negotiated product. See Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026 (June 30, 2023), https://tinyurl.com/65bs2x5c, and Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024), https://tinyurl.com/2am8cyew.
- 33. To estimate the average share of postsale rebates and discounts paid from drug manufacturers to Part D plans for AOM products in years before drug price negotiations take effect, CBO used public estimates of rebate shares and the average discount for endocrine metabolic agents, which include GLP-1-based products. See Inmaculada Hernandez and Sean D. Sullivan, "Net Prices of New Antiobesity Medications," *Obesity*, vol. 32, no. 3 (March 2024), pp. 472–475, https://doi.org/10.1002/oby.23973. For more information, see Government Accountability Office, *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending*, GAO-23-105270 (September 5, 2023), www.gao.gov/products/gao-23-105270.
- 34. Valerie A. Smith and others, "Health Expenditures After Bariatric Surgery: A Retrospective Cohort Study," *Annals of Surgery* (May 10, 2024), https://doi.org/10.1097/SLA.000000000000006333; Sonali Shambhu and others, "Long Term Cost Outcomes Among Commercially Insured Patients Undergoing Bariatric Surgical Procedures," *Obesity Science and Practice*, vol. 10, no. 1 (February 2024), https://doi.org/10.1002/osp4.727; Andrew Canakis and others, "Type 2 Diabetes Remission After Bariatric Surgery and Its Impact on Healthcare Costs," *Obesity Surgery*, vol. 33 (2023), pp. 3806–3813, https://doi.org/10.1007/s11695-023-06856-0; Jean-Eric Tarride and others, "Association of Roux-en-Y Gastric Bypass With Postoperative Health Care Use and Expenditures in Canada," *JAMA Surgery*, vol. 155, no. 9 (July 2020), https://doi.org/10.1001/jamasurg.2020.1985; Qing Xia and others, "Bariatric Surgery Is a Cost-Saving Treatment for Obesity—A Comprehensive Meta-Analysis and Updated Systematic Review of Health Economic Evaluations of Bariatric Surgery," *Obesity Reviews*, vol. 21, no. 1 (January 2020), https://doi.org/10.1111/obr.12932; Valerie A. Smith and others, "Association Between Bariatric Surgery and Long-Term Health Care Expenditures Among Veterans With Severe Obesity," *JAMA Surgery*, vol. 154, no. 12 (October 2019), https://doi.org/10.1001/jamasurg.2019.3732; and Jonathan P. Weiner and others, "Impact of Bariatric Surgery on Health Care Costs of Obese Persons: A 6-Year Follow-up of Surgical and Comparison Cohorts Using Health Plan Data," *JAMA Surgery*, vol. 148, no. 6 (June 2013), pp. 555–561, https://doi.org/10.1001/jamasurg.2013.1504.
- 35. Institute for Clinical and Economic Review, *Medications for Obesity Management: Effectiveness and Value* (August 2022), https://tinyurl.com/3a7vbnum.
- 36. Ibid., Table E7.
- 37. Alison Sexton Ward and others, "Benefits of Medicare Coverage for Weight Loss Drugs" (white paper, USC Schaeffer Center, April 18, 2023), https://tinyurl.com/5543bw84.
- 38. Patricia J. Rodriguez and others, "Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity," *JAMA Internal Medicine* (July 8, 2024), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2821080.
- 39. The issue of presumed causation probably generalizes to other assumptions made by ICER and USC about the relationship between BMI and health status.
- 40. A. Michael Lincoff and others, "Semaglutide and Cardiovascular Outcomes in Obesity Without Diabetes," *New England Journal of Medicine*, vol. 389, no. 24 (December 14, 2023), pp. 2221–2232, https://doi.org/10.1056/NEJMoa2307563.
- 41. That finding is based on a non-peer-reviewed article. The analysis has at least two limitations: It does not control for multiple factors affecting adherence (such as cost and availability of medication), and it analyzes use over a short period that does not completely capture all potential cost savings. See Joseph Leach and others, "Real-World Analysis of Glucagon-Like Peptide-1 Agonist (GLP-1a) Obesity Treatment One Year Cost-Effectiveness and Therapy Adherence" (Prime Therapeutics and MagellanRx, July 11, 2023), https://tinyurl.com/7z59z5bu.
- 42. Julien Bezin and others, "GLP-1 Receptor Agonists and the Risk of Thyroid Cancer," *Diabetes Care*, vol. 46, no. 2 (February 2023), pp. 384–390, https://doi.org/10.2337/dc22-1148; and Björn Pasternak and others, "Glucagon-Like Peptide 1 Receptor Agonist Use and Risk of Thyroid Cancer: Scandinavian Cohort Study," *BMJ*, vol. 385 (April 10, 2024), https://doi.org/10.1136/bmj-2023-078225.
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- 44. Novo Nordisk, "Form 20-F 2023," https://tinyurl.com/2a72r8ud; and Eli Lilly and Company, "Form 10-K," https://tinyurl.com/4ee8w82u. The injection mechanisms that deliver GLP-1s are heavily patented. See Rasha Alhiary and others, "Delivery Device Patents on GLP-1 Receptor Agonists," *JAMA*, vol. 331, no. 9 (February 5, 2024), pp. 794–796, https://doi.org/10.1001/jama.2024.0919.

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CBO seeks feedback to make its work as useful as possible. Please send comments to communications@cbo.gov.

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