



## Medicare Part D Coverage of Antiobesity Medications — Challenges and Uncertainty Ahead

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**O**besity is highly prevalent in the United States — affecting more than 41% of adults, including a similar percentage of older adults — and is linked to myriad health problems, such as

type 2 diabetes, cardiovascular diseases, arthritic conditions, and some cancers. Obesity is associated with at least \$174 billion in annual excess health care spending, with the highest excess expenditures occurring once people reach their 60s (approximately \$1,500 to \$3,000 per person annually).<sup>1</sup> Recently, there has been growing public interest in “breakthrough” weight-loss medications, including several new medications that have been approved by the Food and Drug Administration, such as semaglutide (Wegovy), or are in the pipeline, such as tirzepatide and semaglutide–cagrilintide.

These new-generation antiobesity medications have produced weight loss of 15% to more than 20% in clinical trials — representing a clear advance from previous-generation medications (e.g., phentermine–topiramate, bupropion–naltrexone, and liraglutide).<sup>2</sup> But net prices can be more than 20 times as high for new antiobesity medications as for older ones,<sup>2</sup> and lifetime use might be required to prevent weight regain. Among these new medications, attention is currently focused on a once-

weekly semaglutide injection approved in 2021, which has been associated with a 13.7 percentage-point greater decrease in weight than that with placebo. The estimated U.S. price for semaglutide after rebates and discounts (the “net price”) of \$13,618 per year<sup>2</sup> has resulted in concerns that payers may not cover new antiobesity products and that patients won’t be able to afford them without coverage. Nevertheless, demand for effective antiobesity medications remains high and is expected to increase.

Although some state Medicaid programs and private payers cover antiobesity medications, the Medicare program — one of the largest payers in the United States, which provides prescription-drug coverage under Part D to more than 47 million beneficiaries — is prohibited by law from covering prescriptions for weight loss (though the same drug may be covered for other indications, such as diabetes). Concerns regarding medication use for cosmetic purposes, stigma against people with heavier bodies, and a long history of postmarketing withdrawals of weight-loss medications because of serious

side effects may have contributed to this prohibition. The Treat and Reduce Obesity Act, which is supported by antiobesity-medication manufacturers and several health associations, has gained momentum in recent years. It seeks to expand Part D coverage to include medications for obesity treatment and weight management for people who are overweight. Medicare may therefore soon be compelled to cover antiobesity medications, which intensifies the need to address questions of effectiveness and cost among its beneficiaries.

The budgetary effects of covering antiobesity medications under Medicare Part D are likely to be substantial. Using the Centers for Disease Control and Prevention’s estimated obesity prevalence for adults 60 years of age or older (41.5%) and a range of medication uptake between 1% and 100%, we calculated potential annual Part D spending on these medications (see table). At 10% uptake, total spending could be \$1.32 billion for generic versions of phentermine and topiramate (which have an annual combined net price of \$670 and have been associated with a 9.1 percentage-point greater decrease in weight in 1 year than that with placebo<sup>3</sup>) or \$26.80 billion for brand-name semaglutide. These amounts represent 0.91 to 18.48% of the \$145 billion in net

Potential Range of Medicare Costs for the Use of Antiobesity Medications.\*

Obesity Prevalence		Medication Users		Phentermine and Topiramate Cost		Semaglutide Cost	
Identification Method	People with Obesity (%)	People with Obesity Treated (%)	No. of Beneficiaries	Estimated Annual Total Cost (\$)	Percentage of Part D Net Spending	Estimated Annual Total Cost (\$)	Percentage of Part D Net Spending
Diagnosis in Medicare claims	21	1	99,568	66,710,261	0.05	1,355,910,952	0.94
		5	497,838	333,551,306	0.23	6,779,554,759	4.68
		10	995,676	667,102,612	0.46	13,559,109,517	9.35
		100	9,956,755	6,671,026,125	4.60	135,591,095,173	93.51
CDC estimate of adults 60 years of age or older	41.5	1	196,764	131,832,183	0.09	2,679,538,309	1.85
		5	983,822	659,160,915	0.45	13,397,691,547	9.24
		10	1,967,645	1,318,321,829	0.91	26,795,383,094	18.48
		100	19,676,445	13,183,218,294	9.09	267,953,830,938	184.80

\* Data are based on 2020 Medicare Part D enrollment of 47,413,121 persons. Data on obesity diagnoses are from the Centers for Medicare and Medicaid Services. The rate of obesity diagnosis is based on fee-for-service beneficiary claims in 2019; we conservatively assume an equal rate among beneficiaries enrolled in Medicare Advantage. Estimated annual net prices are \$670 for generic phentermine and topiramate and \$13,618 for brand-name semaglutide at a dose of 2.4 mg.<sup>2</sup> Net prices are after rebates and discounts; actual net costs to Medicare could differ. The estimated total costs don't account for use by beneficiaries who are overweight (body-mass index [the weight in kilograms divided by the square of the height in meters] of  $\geq 25$  to  $< 30$ ) and have at least one coexisting condition or those with current use of semaglutide for diabetes. The total costs also do not include offsets in pharmaceutical or medical spending. Part D net spending for 2019 was \$145 billion.<sup>3</sup> CDC denotes Centers for Disease Control and Prevention.

total 2019 Part D spending by beneficiaries and the Medicare program.<sup>3</sup> Even if projections are limited to people with obesity diagnoses that are identifiable in Medicare claims (21% of beneficiaries), which indicates cases in which a clinician may be more likely to employ obesity treatments, similar uptake could lead to annual costs of \$667 million for generic phentermine and topiramate or \$13.56 billion for brand-name semaglutide (0.46 to 9.35% of 2019 Part D spending). Under a hypothetical scenario in which all beneficiaries with obesity use semaglutide for weight loss (ignoring other indications for its use), the cost would exceed the entire Part D budget and would be greater than the total excess health care spending associated with obesity for people of all ages. These estimates exclude the costs associated with potential antiobesity-medication use by people who are overweight.


International health technology assessment agencies have made varied recommendations regarding reimbursement of antiobesity medications based on their long-term

cost-effectiveness. For example, the United Kingdom's National Institute for Health and Care Excellence recommended reimbursement of liraglutide for weight management, a decision restricted generally to people with a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of at least 35 and another cardiometabolic risk factor; it also recommended reimbursement of semaglutide but further limited reimbursement to a maximum of 2 years of use. In contrast, Canada's Drug and Health Technology Agency recommended against public reimbursement of liraglutide and semaglutide for weight management. In both countries, the prices of these medications are roughly one third the prices in the United States.

The Institute for Clinical and Economic Review (ICER), a non-profit health technology assessment organization based in the United States, recently evaluated the cost-effectiveness of lifetime use of semaglutide and three other antiobesity-medication regimens (brand-name liraglutide, phentermine-topir-

amate, and bupropion-naltrexone; including generic versions of phentermine and topiramate, and bupropion and naltrexone) for a 45-year-old patient as compared with lifestyle modification alone. ICER's evaluation concluded that semaglutide wasn't cost-effective, with an estimated cost of \$237,000 per quality-adjusted life-year gained.<sup>2</sup> This estimate reflects both changes in life expectancy and quality of life associated with improved daily functioning and a reduced risk of diabetes and cardiovascular outcomes; however, it is well above the \$100,000-to-\$150,000 range considered the upper bound for cost-effectiveness in the United States.<sup>2</sup> Under current U.S. thresholds, the annual \$13,618 price of semaglutide would need to decrease to \$7,500 to \$9,700 for the drug to be cost-effective as compared with lifestyle modification alone.<sup>2</sup> In that price range, however, it still wouldn't be cost-effective as compared with generic phentermine and topiramate.<sup>2</sup> Even with such discounted prices, the budgetary effects for Medicare could be substantial.

The balance of benefits and risks associated with antiobesity-medication use among older adults may be less favorable than was estimated for younger adults in the ICER report. Antiobesity medications have been shown to improve the surrogate end points of weight, glycated hemoglobin levels, systolic blood pressure, and waist circumference.<sup>2</sup> Long-term studies are needed, however, to clarify how medication-induced changes in these surrogate markers translate to health outcomes.<sup>2</sup> Such research will be especially important if antiobesity medications are used by older adults — who may have already incurred the health problems associated with long-term obesity — and not just the younger populations typically included in clinical trials. Previous research has shown that older adults with prediabetes are less likely to develop diabetes than younger adults with prediabetes,<sup>4</sup>

 An audio interview with Dr. Leech is available at NEJM.org

which would reduce the health benefits and cost savings associated with antiobesity-medication intervention in older populations. In addition, the relationship between high BMI and other adverse health outcomes weakens with age, and studies have shown that moderate obesity may even be protective against some cardiometabolic outcomes in adults 65 years of age or

older.<sup>5</sup> Side effects of antiobesity medications may also be more problematic in older adults. Because sarcopenia and obesity frequently co-occur in older adults,<sup>5</sup> the decreases in lean body mass that are often documented during antiobesity-medication use may be of greater concern in the Medicare population than among younger adults. In addition, the gastrointestinal side effects associated with antiobesity medications, such as nausea and diarrhea,<sup>2</sup> could be more serious in older adults.

The burden of obesity and obesity-related conditions is unquestionably high, but the value of Medicare coverage of antiobesity medications remains unclear. Depending on the types of medications used by beneficiaries and their rate of use, it's likely that Part D premiums would increase to accommodate spending on these products. To the extent that other payers follow Medicare's lead, such costs could be felt throughout the U.S. health care system. A thorough understanding of the health benefits and risks associated with antiobesity-medication use, particularly in the Medicare population, is needed to guide coverage and reimbursement decisions so that access is focused on the people most likely to benefit. Given the potential budgetary effects of antiobesity medications on Medicare

Part D and remaining questions about their benefits among older adults, it would be prudent for Congress and the Centers for Medicare and Medicaid Services to carefully consider the potential trade-offs associated with antiobesity-medication coverage and use for Medicare beneficiaries.

Disclosure forms provided by the authors are available at NEJM.org.

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## Eroding Judicial Deference to the FDA — Consequences for Public Health

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The legal foundation on which the authority of the Food and Drug Administration (FDA) rests is shifting. Since 1984, the FDA has conducted its oversight of prescription drugs, medical devices,

and other products with deference from courts enshrined by a landmark Supreme Court case, *Chevron U.S.A. v. Natural Resources Defense Council*. But mounting judicial skepticism of agency authority, which

reached a new height in the 2022 case *West Virginia v. Environmental Protection Agency* (EPA), has weakened this norm and now threatens to upend it. Congress and the FDA may have to adapt with more