

January 27, 2025

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4208-P  
7500 Security Blvd.  
Baltimore, MD 21244

**Re: Part D Coverage of Anti-Obesity Medications (§ 423.100) and Application to the Medicaid Program (CMS-4208-P)**

Dear Dr. Dorothy Fink:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS)'s proposed rule that would reinterpret section 1927(d)(2)(A) of the Social Security Act to include Part D coverage of anti-obesity medications (AOMs) when used to treat obesity.

For more than a decade, researchers at the University of Southern California (USC) Schaeffer Center for Health Policy & Economics have studied the burden of obesity and projected future health and economic impacts of the obesity epidemic.<sup>1</sup> We have modeled the value of obesity treatments, and we have measured the social value and social returns to investments for expanding access to patients. Based on our research, we support the proposed reinterpretation that would allow broader coverage of AOMs for Medicare and Medicaid patients. Our research finds that expanding access will increase life expectancy and reduce years spent living with chronic diseases. We organize this comment around four broad themes:

- **New policy interventions are needed:** The societal burden of obesity is large and the status quo programs promoting diet and exercise alone have failed to impact rising prevalence rates. New policy interventions are needed to reverse obesity trends and to begin address the soaring rates of chronic disease in the U.S.
- **Treating obesity offers compelling returns on investment:** Forthcoming research from USC Schaeffer Center estimates the lifetime social returns to broader AOM treatment for various age and health-risk groups. We find that, after accounting for treatment costs, total lifetime net social value is positive for all patients with obesity and the estimated social returns from investing in AOMs exceed other private and public uses of capital recognized as valuable.
- **Cost-offsets from Medicare coverage of AOMs may exceed current estimates:** AOM policies adopted by CMS could influence coverage decisions in the private insurance

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<sup>1</sup> The opinions expressed in this document are solely those of the authors and do not necessarily reflect the views of the University of Southern California or the USC Schaeffer Center for Health Policy & Economics. The Schaeffer Center receives funding from foundations, government agencies, individuals, and corporations — including Eli Lilly & Company and other companies that may have interests in obesity treatments.

market which would generate future cost offsets for Medicare by improving the health of cohorts entering Medicare. Several prominent budget impact estimates, such as the CBO's, abstract away from these potential effects. Broad coverage of AOMs for patients before they enter Medicare would prevent or delay chronic conditions like diabetes, heart disease, and cancer where the costs largely accumulate later in life.

- **Broad access to AOMs will shrink existing health disparities:** Obesity disproportionately impacts Black and Hispanic beneficiaries, as well as individuals with lower income and education. Additionally, research shows that these under-represented minority communities lose less weight with behavioral interventions. At the same time, economically disadvantaged individuals receive less access to behavioral weight-loss interventions. This means that the status quo – limited access to AOMs – coupled with continued focus on behavioral interventions will likely widen existing disparities in obesity and related comorbid diseases like diabetes, hypertension, heart disease, lung disease, cancer and stroke.

In what follows, we elaborate on these four critical considerations.

### **New policy interventions are needed**

Since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 was passed, advances in science and medicine have helped us to understand that obesity is a chronic, progressive and relapsing disease that can give rise to more than 200 other chronic conditions. In 2013, the American Medical Association recognized obesity as a disease and sought to raise awareness about the link between obesity and its many serious comorbidities including diabetes, heart disease, hypertension, stroke, and cancer.<sup>1</sup> The AMA's hope was that discussing obesity as a disease might change the perception that obesity is a lifestyle choice and that medical treatments were unnecessary. Just this year, the FDA issued draft guidance that would categorize obesity as a chronic disease instead of a health risk.<sup>2</sup>

Perhaps as a result of an insufficient policy response, obesity is widely recognized as a public health crisis in the United States, with Americans still lacking access to effective treatments and obesity rates among adults rising to approximately 42%.<sup>3</sup>

An estimated 300,000 Americans die from obesity-related conditions each year, and a 2024 report from the Joint Economic Committee predicts that obesity will cost the U.S. between \$8.2–\$9.1 trillion in excess medical expenses over the next decade.<sup>4,5</sup> Yet some policymakers still argue that obesity should be treated with diet and lifestyle interventions alone.<sup>6</sup> This reluctance to invest in treatments for obesity are reminiscent of the treatment paradigm for hypertension before the introduction of beta blockers. Prior to the 1950s, the only effective way to treat high blood pressure was through exercise and reduced salt consumption. However, the commercial availability of treatments like hydrochlorothiazide, a diuretic, and later oral agents like beta blockers, calcium channel blockers, ACE inhibitors, and others revolutionized treatment and shrank health disparities among people with hypertension.<sup>7</sup> Yet, 20 years later, “significant resistance to clinical acceptance of antihypertensive therapy still existed.”<sup>8</sup> It was only through intervention by the federal government (at the behest of then-President Nixon) that these blockbuster drugs gained acceptance and coverage. Like unmanaged hypertension before it,

obesity is also a grave threat to public health and well-being, calling for federal leadership in bringing effective treatments to patients in need.

### **Treating obesity offers impressive returns on investment**

The introduction of a new class of AOMs has reinvigorated the policy conversation around treating obesity and offers hope for millions of Americans living with the disease. In clinical trials, newer GLP-1 therapies have helped patients lose 15% or more of their body weight,<sup>9</sup> and there is growing evidence around the additional health benefits of GLP-1 therapies. Yet, insurance coverage remains low with many companies citing budgetary concerns for their restrictions.<sup>10</sup>

Prior work from the Schaeffer Center addressed some of the financial concerns by demonstrating that treating obesity at current efficacy rates would generate substantial benefits to society and that the cumulative gross social benefits could exceed \$1.2 trillion over the next 10-years.<sup>11</sup> The research also estimates that Medicare coverage of weight-loss therapies would generate \$245 billion in gross cost offsets for federal taxpayers in the first 10 years of coverage alone. Yet Medicare and many commercial insurers have only extended coverage for AOMs to patients with obesity who also have diabetes or heart disease – the additional FDA-approved indications considered “medically acceptable” for GLP-1s.

In a new project, the USC Schaeffer Center estimates the net lifetime benefits of treating obesity such as life years gained, reduction in years spent with chronic conditions, medical cost offsets, net social value, and the internal rate of return on investment in expanded treatment access. *After accounting for treatment costs*, we find that *total lifetime net social value from AOM treatment is positive* for all patients with obesity. Additionally, we show that investing in broad access to AOMs would generate positive social returns on investment that exceed returns on the stock market and on early childhood education, both of which stand as valuable uses of capital. In other words, expanding access to AOMs would generate significant benefits to society that are worth the required investment.

### **Cost-offsets from Medicare coverage of AOMs may exceed current estimates**

Some analysts and experts believe private insurers will follow Medicare’s lead on AOMs.<sup>12</sup> And, although most private insurers do not currently provide coverage for new GLP-1 therapies when they are prescribed to treat obesity, a broader coverage decision by CMS may lead to broader coverage in the private market.<sup>13</sup> This possible connection between private and public coverage policies is important to consider when estimating the costs of expanding Medicare access for AOMs because increased access in the private market will lead to a healthier Medicare population in the future. Our research shows that broad access to AOMs among patients with both private and public insurance will reduce the incidence of many obesity-related diseases in the Medicare population.<sup>11</sup> For example, we estimate that the prevalence of diabetes in the Medicare population would fall by 24% over 30 years; which would lead to 4.4 million fewer beneficiaries living with diabetes in 2055. Additionally, broad access to AOMs would save the Medicare population 45 million person-years spent with diabetes.

Budget impact estimates offered by the Congressional Budget Office (CBO) and by CMS Office of the Actuary (OACT) suggest that broad access to AOMs in Medicare would cost the government \$25-\$35 billion over the next 10 years, but they do not consider any cost offsets that

could be generated through follow-on coverage in the private insurance market. Research at the USC Schaeffer Center finds that, combining private insurance coverage of AOMs with Medicare coverage would generate much greater cost-offsets to Medicare, than would Medicare coverage alone.<sup>11</sup> For example, we find that after 10 years, combined coverage could generate up to \$245 billion in cost offsets compared to \$176 billion from Medicare coverage alone. Our analysis also shows that the Medicare cost offsets from private coverage for AOMs will grow over time as the average 65-year-old entering Medicare becomes healthier. After 30 years of coverage for both Medicare and private insurance patients, Medicare could save almost \$1.5 trillion.

The available budget estimates for expanding Medicare coverage also fail to consider how treatment costs will change over time given the robust pipeline for weight-loss drugs. Although both CBO and OACT account for manufacturer rebates by using net price estimates, they do not allow prices to change in the future. Prior Schaeffer Center research demonstrates multiple market dynamics that will impact future AOM prices.<sup>14</sup> First, branded price competition works to restrain net price growth in the pharmaceutical industry. This dynamic will produce net price declines for current AOMs in the coming years as more drugs enter the market. In fact, branded net prices across drug classes have fallen or remained relatively stable, in real terms, over the past decade.<sup>14,15</sup> Second, USC research estimates that, on average, prices fall 74% below the pre-expiration list price when generics enter the market, which happened last year for liraglutide.<sup>16</sup> Third, experience with other high-cost classes, like novel drugs for hepatitis C and HIV, suggests branded competition brings prices down before generic entry.<sup>17</sup> Accurately accounting for these pricing trends in the AOM market will reduce current budget impact estimates.

### **Broad access to AOMs will shrink existing health disparities**

Obesity disproportionately impacts Black and Hispanic beneficiaries, as well as patients with lower income and education.<sup>18</sup> The literature has explored cultural, behavioral, environmental and economic reasons for these disparities with little consensus on the primary drivers. However, research shows that current behavioral interventions for weight loss – the only treatments covered by Medicare for many beneficiaries - have proven less effective in minority populations, which only exacerbates existing disparities.<sup>19,20</sup> In other words, status quo AOM coverage policies risk widening existing disparities in obesity and related comorbid conditions like diabetes, hypertension, heart disease, lung disease, cancer and stroke. Our research shows how this outcome can be mitigated or even avoided: breakthroughs in medical technologies that simplify health care and reduce patient effort requirements can reduce health disparities.<sup>7</sup> For example, prior to the discovery of beta blockers, diet, exercise, and other behavioral self-management methods were the leading treatment options for hypertension. Following the initial FDA approval for beta blockers, we saw reductions in both hypertension and cardiac disease that were equal across income levels.<sup>7</sup> In the same way that beta blockers simplified the treatment of hypertension, new AOMs could help simplify the treatment of obesity and expanding Medicare coverage will help address health disparities.

### **Conclusion**

New AOMs represent a huge breakthrough in the treatment of obesity and give hope to millions of Americans who struggle with the disease. Our research shows that expanding access to the new treatments can generate positive social returns for patients of all ages while also potentially

shrinking existing health disparities. For these reasons, we support CMS' proposal to treat obesity like the chronic and relapsing disease that it is and to provide broader coverage of FDA approved treatments to Medicare and Medicaid patients.

We would also caution against placing too much emphasis on current Medicare budget impact analyses that may be too narrow in scope to account for spillover impacts of broader coverage for AOMs in Medicare and Medicaid. Broader coverage coupled with additional effective treatments is likely to strengthen price competition and drive down net prices further. Additionally, follow-on AOM coverage in the private insurance market could generate significant cost offsets for Medicare in the future. Our research consistently shows that AOMs may not pay for themselves in the short term, but they can provide tremendous value to patients and society over time.

We would welcome the opportunity to discuss our research findings in greater detail.

Sincerely,

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## References

1. Pollack A. A.M.A. Recognizes Obesity as a Disease. *The New York Times*. June 18, , 2013.
2. Administration FaD. Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction. In: Research CfDEa, ed. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/obesity-and-overweight-developing-drugs-and-biological-products-weight-reduction2025>.
3. Stierman B, Afful J, Carroll MD, et al. National Health and Nutrition Examination Survey 2017–March 2020 prepandemic data files development of files and prevalence estimates for selected health outcomes. 2021.
4. Allison DB, Fontaine KR, Manson JE, Stevens J, VanItallie TB. Annual deaths attributable to obesity in the United States. *Jama*. 1999;282(16):1530-1538.
5. Schweikert D. Obesity will cost U.S. up to \$9.1 trillion in medical costs over next decade, House GOP warns. Vol 2025. <https://schweikert.house.gov/2024/06/18/obesity-will-cost-u-s-up-to-9-1-trillion-in-medical-costs-over-next-decade-house-gop-warns/>: Congressman David Schweikert; 2024.
6. Weixel N. RFK Jr. vs. Oz sets up clash on weight loss drug coverage. *The Hill*. December 30, 2024, 2024.
7. Goldman DP, Lakdawalla DN. A theory of health disparities and medical technology. *Contributions in Economic Analysis & Policy*. 2005;4(1):1-30.
8. Rubin RJ, Bladen C. Hypertension and the Department of Health and Human Services. *Hypertension*. 1982;4(5\_pt\_2):III152.
9. Wilding JP, Batterham RL, Calanna S, et al. Once-weekly semaglutide in adults with overweight or obesity. *New England Journal of Medicine*. 2021;384(11):989-1002.
10. Goodman B. Insurance denials for popular new weight loss medications leave patients with risky choices. *CNN*. 2024(January 8, 2024). <https://www.cnn.com/2024/01/08/health/weight-loss-drug-insurance-denials/index.html>.
11. Ward AS, Tysinger B, Nguyen P, Goldman D, Lakdawalla D. Benefits of Medicare Coverage for Weight Loss Drugs. USC Schaeffer Center for Health Policy & Economics. 2023.
12. Japsen B. Employers May Follow Medicare Coverage Of GLP-1 Weight Loss Drugs. *Forbes*. Nov 26, 2024, 2024.
13. Japsen B. Not Many Employers Cover GLP-1 Weight Loss Drugs. *Forbs*. October 9, 2024, 2024.
14. Lakdawalla D, Li M. Association of drug rebates and competition with out-of-pocket coinsurance in Medicare Part D, 2014 to 2018. *JAMA network open*. 2021;4(5):e219030-e219030.
15. Hernandez I, San-Juan-Rodriguez A, Good CB, Gellad WF. Changes in list prices, net prices, and discounts for branded drugs in the US, 2007-2018. *Jama*. 2020;323(9):854-862.
16. Helland E, Seabury SA. *Are settlements in patent litigation collusive? Evidence from Paragraph IV challenges*. National Bureau of Economic Research;2016.
17. AbbVie Receives U.S. FDA Approval of VIEKIRA PAK™ (Ombitasvir/Paritaprevir/Ritonavir Tablets; Dasabuvir Tablets) for the Treatment of Chronic Genotype 1 Hepatitis C [press release]. December 19, 2014 2014.
18. Fouad MN, Waugaman KJ, Dutton GR. The Complex Contributors to Obesity-Related Health Disparities: Introduction to the Special Issue. *American Journal of Preventive Medicine*. 2022;63(1):S1-S5.

19. Davis KK, Tate DF, Lang W, et al. Racial differences in weight loss among adults in a behavioral weight loss intervention: role of diet and physical activity. *Journal of Physical Activity and Health*. 2015;12(12):1558-1566.
20. Lewis KH, Edwards-Hampton SA, Ard JD. Disparities in treatment uptake and outcomes of patients with obesity in the USA. *Current obesity reports*. 2016;5:282-290.