

How Much Will Covering Anti-Obesity Drugs Cost Medicare? Accounting for Commonly Overlooked Effects

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1

Introduction

A new class of anti-obesity medications (“AOMs”) called GLP-1s have been shown to be highly effective at treating people with obesity or overweight. Given the efficacy of GLP-1s and other classes of AOMs and the significant costs associated with treating obesity and its related diseases, there is increasing pressure on public and private health insurers to cover AOMs. Under current rules, AOMs are not reimbursed by Medicare for treating obesity and can only be reimbursed if they are approved for other conditions such as cardiovascular disease.¹ The Treat and Reduce Obesity Act (“TROA”) would enable Medicare beneficiaries to have AOMs reimbursed under their Part D plan. In this report, we assess the cost of that policy to the Medicare program from 2024 to 2030 after accounting for important factors that are likely to dampen Medicare expenditures.

The high prevalence of obesity and the cost of AOMs has raised concerns about the financial impact to the Medicare program. For example, the New York Times reported on an analysis by economists which concludes that “[u]nder reasonable assumptions and at current

prices, making this class of drugs available to all [Americans with obesity] could eventually cost over \$1 trillion per year,” which would equal the entire current Medicare budget.² Other analyses have produced similarly high estimates.³ As a general matter, studies in this vein assume that most or all affected Medicare beneficiaries will (1) be newly eligible for AOMs, (2) either be prescribed or opt for a GLP-1 injectable as opposed to an alternative pharmacotherapy, (3) remain on a GLP-1 indefinitely, and (4) not have other health care costs favorably affected by their obesity treatment. These analyses also generally base the estimated financial burden on product list prices, ignoring substantial discounting and rebating that is common in the biopharmaceutical marketplace, and they assume that increasing product competition will have a negligible effect on costs associated with these products. Further, some well-publicized estimates have not considered well-understood consumption behaviors and other features specific to this market that affect the utilization of these medicines. Adopting unrealistic assumptions is unhelpful when it comes to evaluating coverage policy.

1. There is an exception for Wegovy, which received FDA approval in March 2024 for reduction in MACE in individuals with established cardiovascular disease and obesity. See:

PRNewswire, “Wegovy Receives FDA Approval for Cardiovascular Risk Reduction in Adults with Known Heart Disease and Overweight or Obesity,” 3/8/2024, <https://www.prnewswire.com/news-releases/wegovy-receives-fda-approval-for-cardiovascular-risk-reduction-in-adults-with-known-heart-disease-and-overweight-or-obesity-302084454.html>.

2. The New York Times, “The Miracle Weight-Loss Drug Is Also a Major Budgetary Threat,” 3/4/2024, <https://www.nytimes.com/2024/03/04/opinion/ozempic-wegovy-medicare-federal-budget.html>.

3. Reuters, “Economists Warn of Costs if Medicare Covers New Obesity Drugs,” 3/11/2023, <https://www.reuters.com/world/us/economists-warn-costs-if-us-medicare-covers-new-obesity-drugs-2023-03-11/>.

In this assessment, we apply findings from the health economics literature to predict levels of uptake, adherence, persistence, and prices that accurately reflect historical experience. By considering each component relevant to the supply of and demand for AOMs for treating people with obesity, we calculate costs and usage that align with previous real-world utilization when new drugs have been introduced. Specifically, our cost assessment assumes:

- After accounting for existing GLP-1 use for diabetes and other adjustments, 3.2% of beneficiaries are prescribed an AOM specifically for obesity in a given year;
- Less than half of beneficiaries will take GLP-1s while the remaining will be treated with existing other AOMs based on the current market share distribution of the AOM class seen today;
- As with many chronic conditions like obesity, individuals are not always adherent to a course of therapy. In fact, fewer than half of beneficiaries will persist on AOM therapy over the course of a year;
- Increasing competition within the AOM market will result in markedly lower net prices to health insurers, leading to substantial discounts for Medicare Part D Plans; and
- Reducing obesity-related health complications and comorbidities will reduce Medicare costs by an estimated \$0.41 to \$0.54 billion per year between 2025 and 2030. This is conservative compared to other estimates incorporating cost offsets.⁴

Our analysis shows that a combination of utilization governors, including payor-induced constraints, competition among products, and patient persistence and adherence will have limiting effects on the AOM spend. Although it is difficult to derive an estimate of new product spending with any degree of certainty, the current market dynamics (largely commercial coverage, Federal Employee coverage, and cash pay) provides a strong analogue for what we might observe in the Medicare Part D population. Under assumptions grounded in previous experience, there are reasonable scenarios in which the net cost of coverage will range from \$1.6 to \$2.1 billion per year between 2024 and 2030, or 0.8% to 1.3% of the forecasted Medicare prescription drug budget. Without including estimated cost offsets from the health effects of treating obesity, our analysis suggests spending levels between \$1.9 and \$2.7 billion per year on AOM coverage, or 1.0% to 1.6% of the forecasted Medicare prescription drug budget. In summary, applying existing research and data sources surrounding other new drug introductions, we find that it is reasonable to expect that the net cost impacts to the Medicare program are positive, but much smaller than other estimates suggest.

4. See for example:

Milliman, "Impact of Anti-Obesity Medication Coverage in Medicare Part D," 2/23/2024, at 1, available at: https://us.milliman.com/-/media/milliman/pdfs/2024-articles/3-6-24_impact-of-covering_anti-obesity-medications-in-medicare-part-d.ashx.

The methodology used by the authors of the New York Times piece estimates cost offsets of over \$3,000 per beneficiary. See:

MIT, "Methodological Background for 'The Miracle Weight-Loss Drug Is Also a Major Budgetary Threat,'" c. 3/2024, <https://economics.mit.edu/sites/default/files/2024-03/%282024-03-04%29%20Methodology%20document%20for%20Deese%2C%20Gruber%2C%20Cummings%20NYT.pdf>.

2

Expected Uptake of Anti-Obesity Medications

Our assessment begins with an analysis of predicted demographic characteristics of the Medicare population. Figure 1 below summarizes the series of thresholds that were applied to arrive at our assumed uptake rate. According to weight distribution from the CDC's National Health and Nutrition Examination Survey ("NHANES"), 51% of Medicare beneficiaries meet or exceed the criteria for having obesity (BMI ≥ 30 kg/m²) or overweight (BMI ≥ 27 kg/m²) and suffering from an additional comorbidity.⁵

The data further indicate that 26% of this population are already eligible for GLP-1 coverage because they have type 2 diabetes.⁶ As a result, the population that will be newly eligible for AOM coverage will be approximately 45% of the Medicare Part D population (labeled as "AOM drug eligible" in Figure 1).⁷

The evidence to date also suggests that only a fraction of eligible beneficiaries will fill a prescription for, and

consistently take, an AOM. For example, a 2023 study by the Kaiser Family Foundation ("KFF") finds that while 45% of all respondents initially express interest in taking a safe and effective weight loss medication, this number falls when respondents learn more about the AOMs that are available.⁸ The KFF study also finds that the percentage of interested respondents falls to 14% when they learn these drugs are intended for long term use, and they may gain the weight back if they stop using the medication. Applying this adjustment further limits the projected uptake to only 6.4% of beneficiaries that will actively seek an AOM prescription (labeled as "eligible and interested" in Figure 1).

We then consider how the high likelihood of prior authorization ("PA") requirements will also deter usage. Peer-reviewed studies of prior authorization policies have shown that PA requirements significantly decrease prescription fills. Studies that specifically examine government health

5. National Center for Health Statistics, 2017-March 2020 Pre-Pandemic Examination Data - Continuous NHANES, <https://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=Examination&Cycle=2017-2020> (accessed 3/13/2024).

6. This analysis does not account for the fact that Wegovy was recently approved to treat those with heart disease. This may cause us to overstate budgetary impacts.

PRNewswire, "Wegovy Receives FDA Approval for Cardiovascular Risk Reduction in Adults with Known Heart Disease and Overweight or Obesity," 3/8/2024, <https://www.prnewswire.com/news-releases/wegovy-receives-fda-approval-for-cardiovascular-risk-reduction-in-adults-with-known-heart-disease-and-overweight-or-obesity-302084454.html>.

7. The analysis assumes that only those that would have taken a GLP-1 for treating obesity will take it for diabetes treatment. Thus, our analysis includes beneficiaries that may take a non-GLP-1 for diabetes and also a non-GLP-1 specifically for treating obesity.

8. KFF, "KFF Health Tracking Poll July 2023: The Public's Views of New Prescription Weight Loss Drugs and Prescription Drug Costs," 8/4/2023, <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/>.

insurance programs and how often PA exceptions are denied suggest average decline rates of between 6% and 12.5%.⁹ However, these studies only tell half of the story, as PA exclusions can occur at both the physician level (if the physician does not submit the required materials to the health insurer) or at the insurance level (i.e. the request is denied). This suggests that a 6%–12.5% PA decline rate represents a lower bound as it does not account for failures at other stages of the prescribing and dispensing process (e.g., prescribers choosing not to prescribe because of the effort required for approval, filled prescriptions not claimed at the pharmacy, etc.).

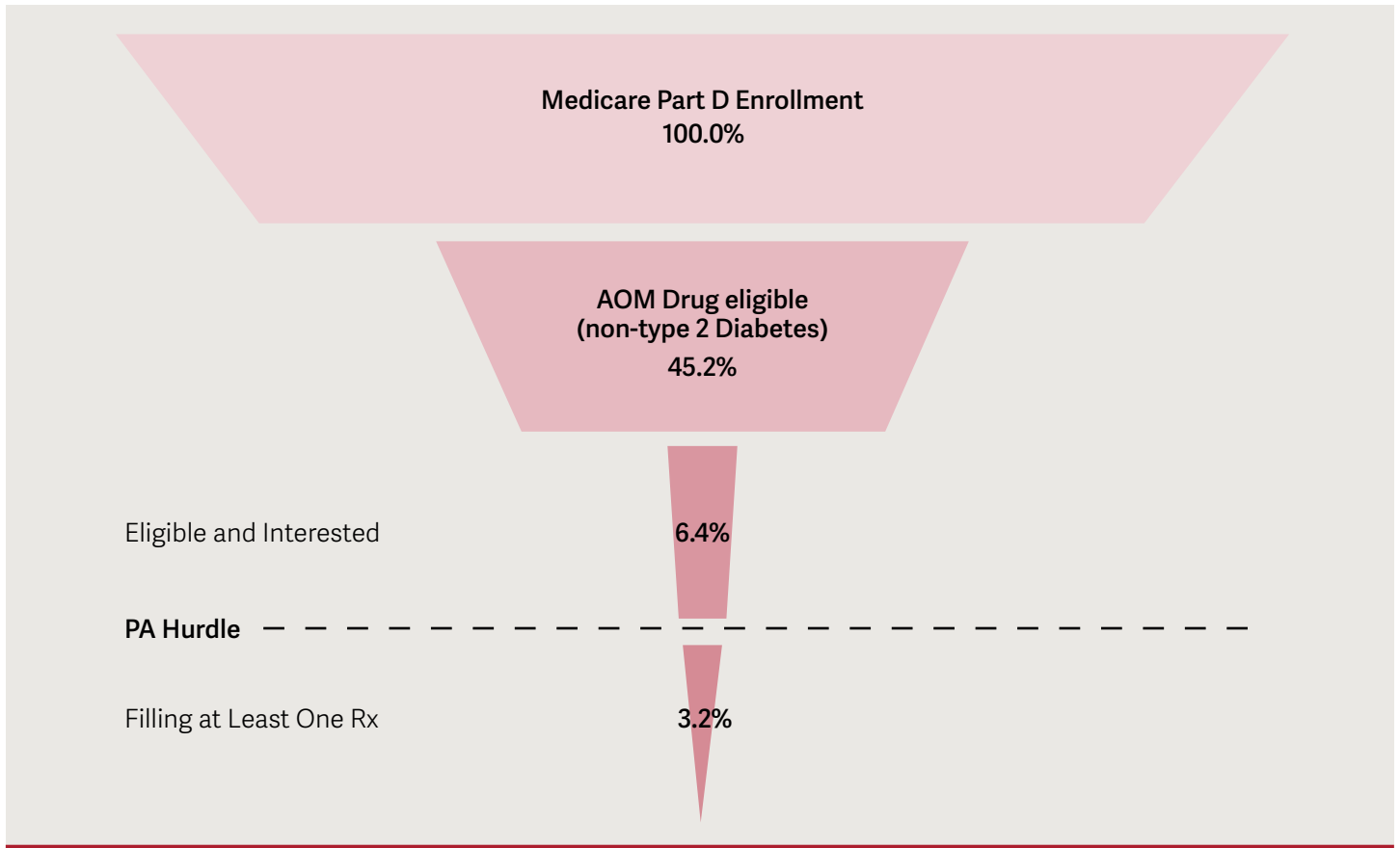
To better assess how PA requirements may ultimately impact the filling of an AOM prescription, we turn to studies that analyze usage of prescriptions following a change in PA policies. The dynamics of PA utilization and success include two key elements, which are 1) the ability of physician offices to successfully respond to the varying levels of administrative burden of a PA, and 2) the ability of the individual to meet the clinical requirements of the PA. One study of the Medicare population found that when PA requirements were removed from buprenorphine-naloxone, the number of prescriptions filled doubled, suggesting that PA requirements limited access to this prescription drug by 50%.¹⁰ This finding is consistent with

another study that found implementing PA requirements for NSAIDs reduced uptake by 50% among Medicaid beneficiaries.¹¹ A working paper that analyzed low-income Medicare Part D beneficiaries between 2007–2015 found that when participants suddenly faced PA requirements for a medication, they reduced their usage by 26.8%.¹² However, the authors found that for the Medicare-aged population in the sample (those greater than 67 years old), reduction in usage was larger, around 33%.¹³ The decrease in utilization was also greater for branded drugs and those treating chronic conditions. Therefore, this study supports a higher PA failure rate for the Medicare population seeking AOMs, which suggests that a 50% rate is reasonable.

Applying this 50% success rate to the population of Medicare beneficiaries seeking a prescription AOM suggests that around 3.2% of beneficiaries are likely to fill at least one prescription per year. These effects are summarized in Figure 1 below. While the AOM uptake implied by these adjustments is lower than assumed by other studies, this result is still higher than other recent studies conducted among patients with commercial insurance finding that fewer than 2% of eligible individuals have used an AOM.¹⁴

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9. KFF, "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021," 2/2/2023, <https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/OIG>, "High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care," 7/2023, at 7, available at: <https://oig.hhs.gov/oei/reports/OEI-09-19-00350.pdf>.
 10. Mark, Tami L., William J. Parish, and Gary A. Zarkin (2020), "Association of Formulary Prior Authorization Policies with Buprenorphine-Naloxone Prescriptions and Hospital and Emergency Department Use Among Medicare Beneficiaries," *JAMA Network Open* 3(4).
 11. Hartung, Daniel M. et al. (2004), "Effects of a Prior-Authorization Policy for Celecoxib on Medical Service and Prescription Drug Use in a Managed Care Medicaid Population," *Clinical Therapeutics* 26(9): 1518–1532.
 12. Brot-Goldberg, Zarek C. et al. (2023), "Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare," NBER Working Paper, https://www.nber.org/system/files/working_papers/w30878/w30878.pdf.
 13. *Ibid.*
 14. MacEwan et al. (2021) find that only 1.18% of eligible individuals with commercial insurance have used an AOM. Similarly, Saxon et al. find that only 1.3% of eligible individuals filled an AOM prescription. Lyu et al. find usage rates as low as 0.5% for eligible individuals.
MacEwan, Joanna et al. (2021), "Antiobesity Medication Use Among Overweight and Obese Adults in the United States: 2015–2018," *Endocrine Practice* 27:1139–1148.
Saxon, David R. (2019), "Antiobesity Medication Use in 2.2 Million Adults Across Eight Large Health Care Organizations: 2009–2015," *Obesity* 27(12): 1975–1981.
Lyu, Beini (2022), "Socioeconomic Status and the use of Obesogenic and Anti-Obesity Medication in the United States: A Population-Based Study," *The Lancet Regional Health – Americas* 11: 100249.

Figure 1: Analysis of AOM Uptake for Medicare Part D Enrollees



3

Substitution and Persistence/ Adherence Effects

The recent and well-publicized estimates on AOM spend focus primarily on GLP-1 utilization, but there are other approved AOM products that serve as effective alternatives.¹⁵ As demonstrated by the current utilization patterns, there is a distribution of use among AOMs. In addition to GLP-1s, phentermine, bupropion/naltrexone, and phentermine/topiramate are oral medications approved by the FDA for treating obesity.¹⁶ If AOM coverage were permitted in Medicare, we anticipate that health plans would provide coverage for multiple options consistent with the formulary guidance from CMS.¹⁷ Moreover, recent market share data for obesity treatments in the commercial market show a distribution of use. Fewer than half of AOM prescriptions are for GLP-1s.¹⁸ The remainder of sales is for less expensive drugs, including generic phentermine (approximately 50% of prescriptions), bupropion/naltrexone and phentermine/topiramate. These shares are presented in Figure 2.

It is important to note that the application of this distribution to the estimates assumes that new coverage of these products imposes similar relative out-of-pocket costs for each of the products. For now, our assessment assumes the distribution will remain the same. In Section 6, we compute the impact to Medicare spend if the share of GLP-1s is higher than assumed.

In addition to looking at “starts,” our analysis estimates the length of time a beneficiary choosing to start therapy will take an AOM (“persistence”) and how often they will take the AOM as prescribed (“adherence”). As a general matter, persistence and adherence for any pharmaceutical therapy rarely, if ever, comes close to 100%. Even in situations where the medical benefit of adherence is clear, such as statin therapy for high-cholesterol in patients with diabetes and cardiovascular conditions, inadequate adherence to therapy is an important

15. The New York Times, “The Miracle Weight-Loss Drug Is Also a Major Budgetary Threat,” 3/4/2024, <https://www.nytimes.com/2024/03/04/opinion/ozempic-wegovy-medicare-federal-budget.html>.

16. Qsymia Label, last revised 7/2012, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022580s000lbl.pdf.

Contrace Label, last revised 9/2014, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/200063s000lbl.pdf.

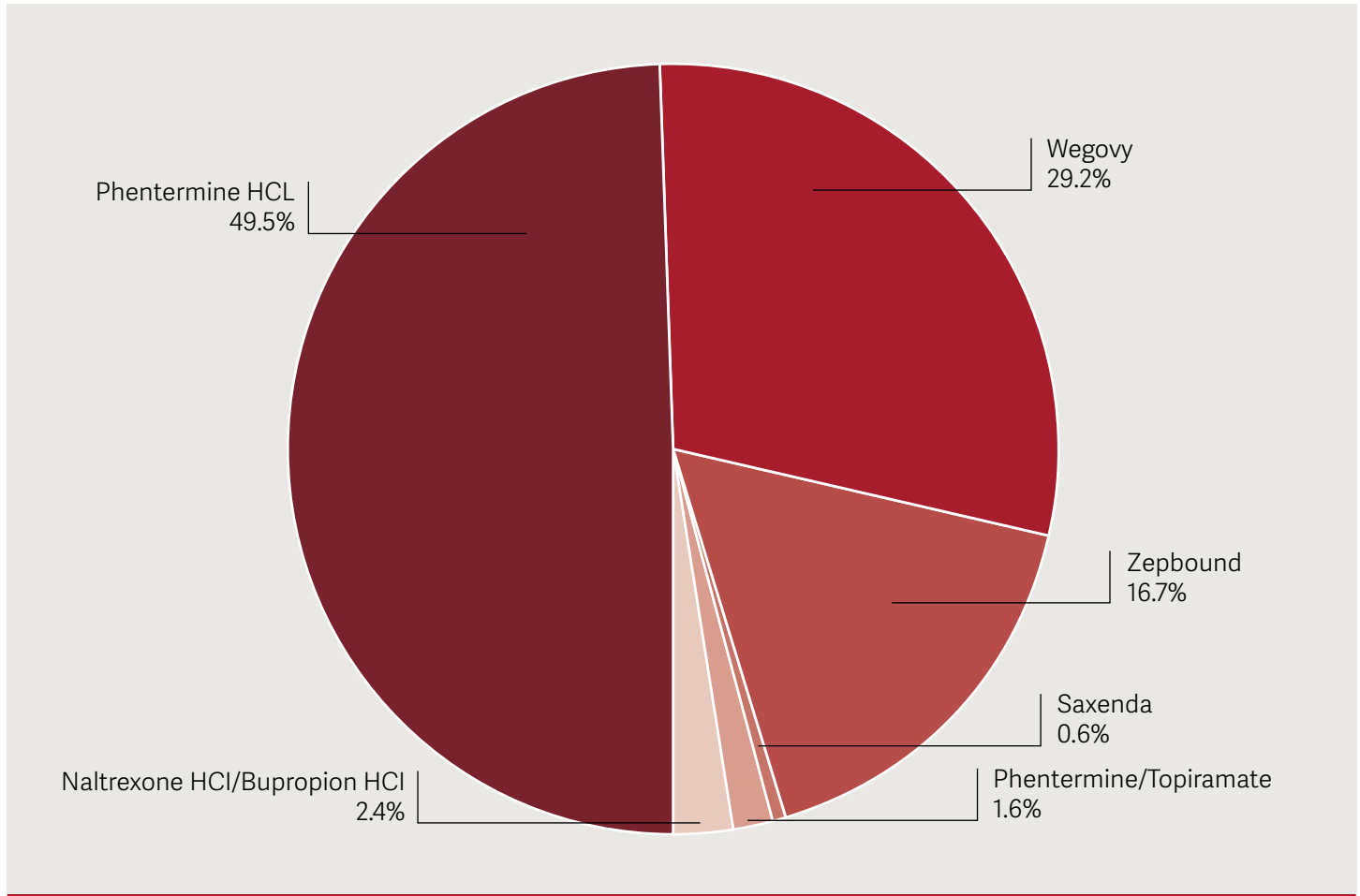
Phentermine Hydrochloride Label, last revised 6/2013, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202088s005lbl.pdf.

17. According to the Medicare website, “[a]ll Medicare drug plans generally must cover at least 2 drugs per drug category, but plans can choose which drugs covered by Part D they will offer.” See:

Medicare.gov, “What Medicare Part D Drug Plans Cover,” <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover> (accessed 5/7/2024).

18. IQVIA National Prescription Audit 1Q 2024.

Figure 2: Estimated Future AOM Market Share Based on Current Data



concern.¹⁹ This condition exists despite the fact that the statin class of drugs is now fully genericized, suggesting low barriers to access. Studies looking at the AOMs or similar medications find that both persistence and adherence trend towards 50% after twelve months. For

example, the average patient taking a GLP-1 is expected to use it for just over 6 months before they stop filling their prescription altogether.²⁰ Peer reviewed studies have found that the average patient tends to use bupropion/naltrexone, phentermine/topiramate, and

19. See, for example:

Rodriguez, Fatima et al. (2019), "Association of Statin Adherence with Mortality in Patients with Atherosclerotic Cardiovascular Disease," *JAMA Cardiology* 4(3): 206–213.

20. Gasoyan, Hamlet, et al. (2024), "Early- and Later-Stage Persistence with Antiobesity Medications: A Retrospective Cohort Study," *Obesity* 32(3): 486–493.

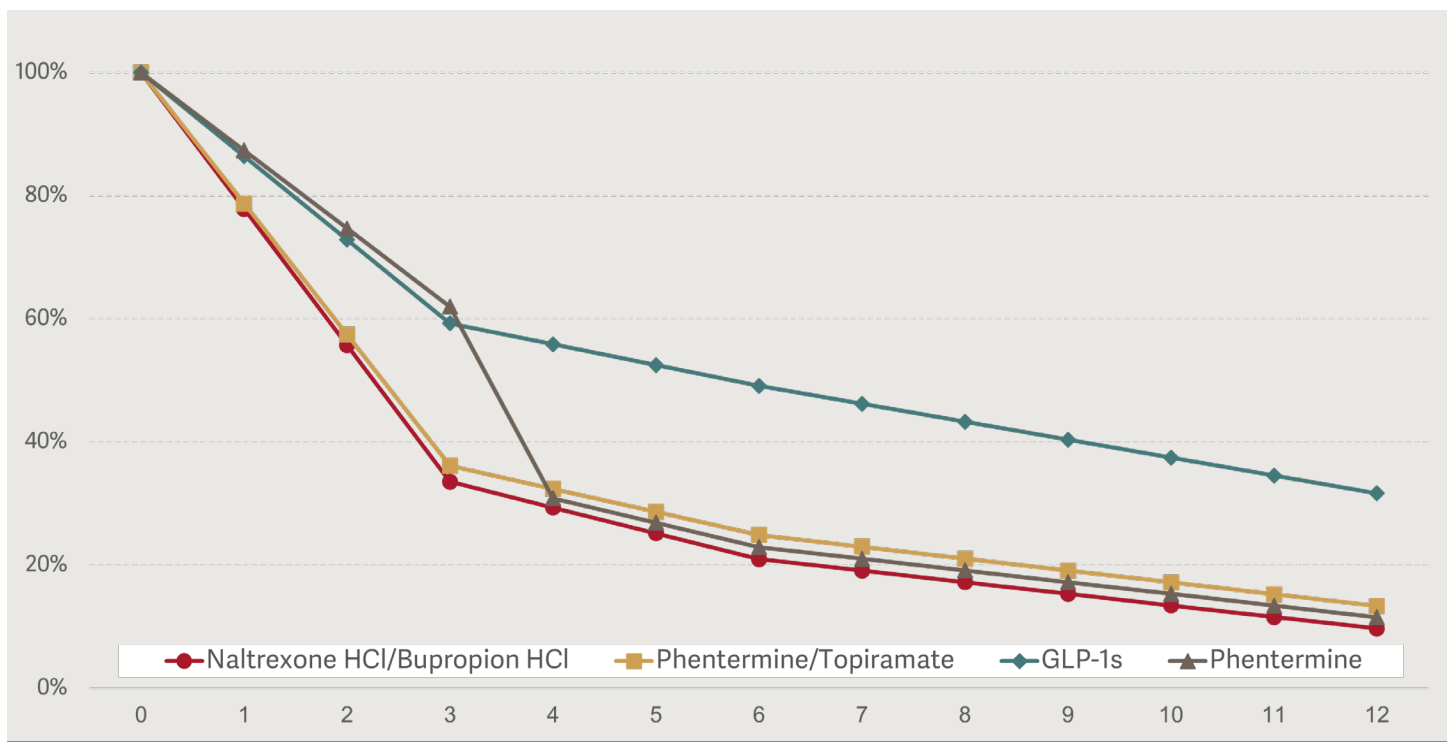
See also:

Novo Nordisk, Investor Presentation, Q1 2024, at 58, available at: <https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/financial-results/2024/q1-2024-investor-presentation.pdf>.

phentermine for four months before stopping.²¹ Results from studies on AOM persistence are presented in Figure 3. As illustrated, usage of these medicines falls quickly in the first few months – by the end of a twelve-month period, between only 10% to 40% are still filling their prescription.²²

Even when filling prescriptions, beneficiaries are not expected to fill them precisely on schedule. Based on the data from a meta-analysis of adherence to type-two diabetes medications, presented in Figure 4, we estimate that beneficiaries filling these AOMs will be only 67%

Figure 3: Percentage of Patients Still Taking AOM by Month



21. *Ibid.*

All results are in line with other studies we reviewed, including the following:

Ganguly, Rahul et al. (2018), "Persistence of Newer Anti-Obesity Medications in a Real-World Setting," *Diabetes Research and Clinical Practice* 143: 348–356.

Wharton, Sean et al. (2019), "Real-World Clinical Effectiveness of Liraglutide 3.0 mg for Weight Management in Canada," *Obesity* 27(6): 917–924.

Uzoigwe, Chioma et al. (2021), "Semaglutide Once-Weekly Persistence and Adherence Versus Other GLP-1 RAs in Patients with Type 2 Diabetes in a US Real-World Setting," *Diabetes Ther* 12: 1475–1489.

We use Gasoyan et al. (2024) because it is the most recent study set in the U.S. that examines persistence rates among the three branded drug classes.

Kim, Hyun Ok et al. (2013), "Postmarketing Surveillance Study of the Efficacy and Safety of Phentermine in Patients with Obesity," *Korean Journal of Family Medicine* 34(5): 298–306.

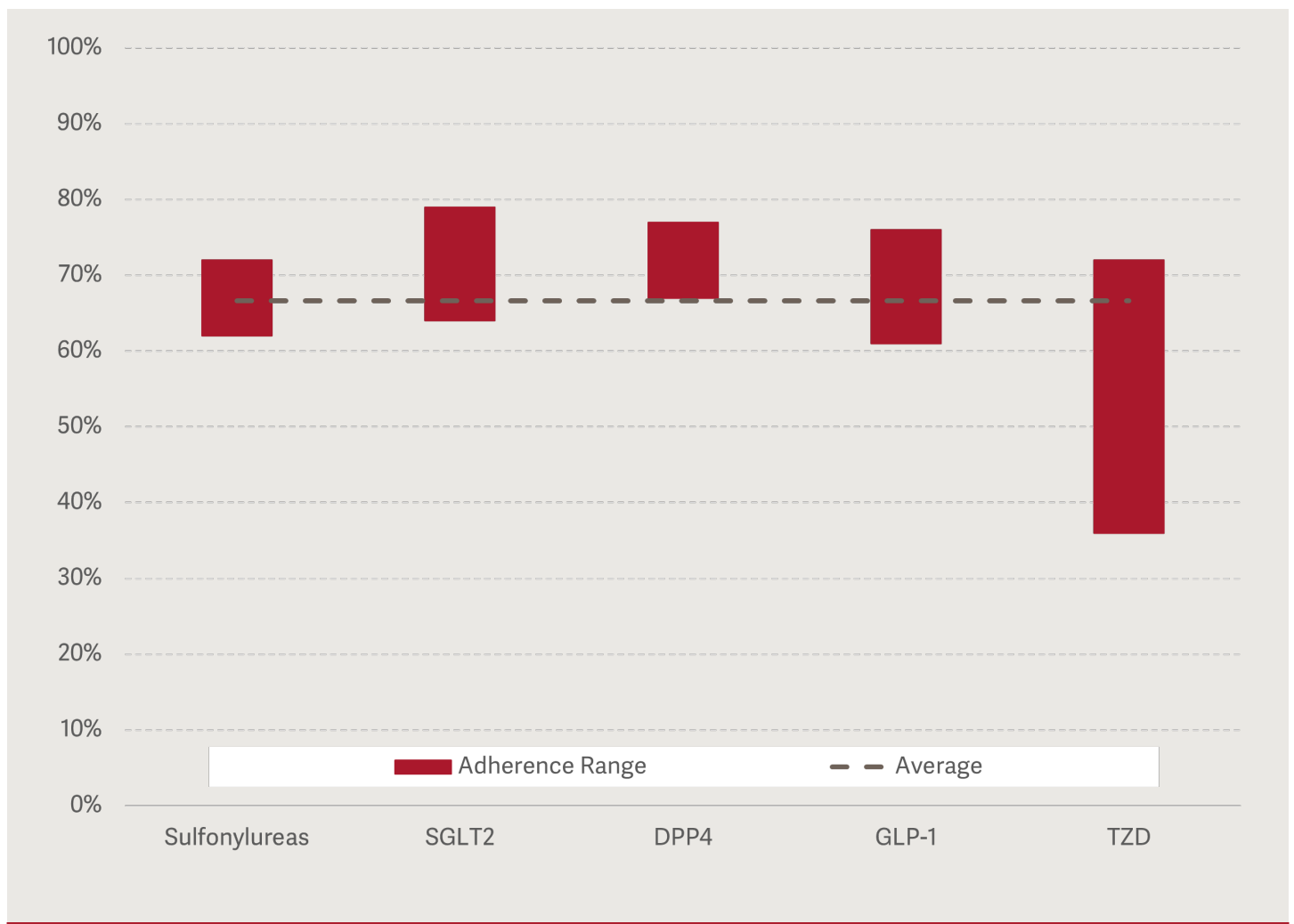
Data from Kim et al. (2013) show that at the 3-month mark, 62% of patients are still taking phentermine. This study was set in South Korea between 2006–2007. Therefore, these findings may not translate to the American Medicare population. Given the paucity of persistence studies on phentermine usage after 3 months, the average persistence of bupropion/naltrexone and phentermine/topiramate is used as a proxy for subsequent months.

22. As is the case with all estimates generated at specific times and under specific conditions, they may either underestimate or overestimate expected future behavior. For example, if there are issues around patient coverage or supply shortages, as have been experienced with some of these medications, this could significantly impact a patient's ability to take his or her medicines as prescribed.

adherent.²³ As we understand them, other estimates have assumed that prescriptions will be filled every month for the full twelve months of a given year. In contrast, using available analyses, we assume beneficiaries on AOMs

will go over a month between fills. Since medications are paid for on a per-unit basis, this will reduce total costs paid by both the beneficiary and Medicare.

Figure 4: Reported Adherence Rates for Type 2 Diabetes Medication



23. Lee, David Seung U. and Howard Lee, (2022), "Adherence and Persistence Rates of Major Antidiabetic Medications: A Review," *Diabetology & Metabolic Syndrome* 14(12).

See also:

Farr, Amanda M. et al. (2014), "Retrospective Analysis of Long-Term Adherence to and Persistence with DPP-4 Inhibitors in US Adults with Type 2 Diabetes Mellitus," *Advances in Therapy* 31: 1287–1305.

4

Rebates and Cost-Sharing will Impact the Amount Medicare Pays

The Wholesale Acquisition Cost (“WAC”) prices of GLP-1s have received outsized attention in both the popular press as well as some of the recent cost estimates.²⁴ Some studies have confused this price with the price Medicare will pay for each drug. This will not be the case as there are two factors limiting the prices Medicare pays: (1) rebates negotiated through Part D sponsors and (2) cost-sharing by beneficiaries.

The price Medicare will pay for branded AOMs over the next ten years is uncertain. However, it will certainly be lower than the stated list prices that have received so much media attention. It is well understood that the private insurance sponsors contracting with Medicare negotiate discounts (often referred to as rebates) from branded WAC

prices and that these discounts can be very high. PBMs will often negotiate rebates as a percentage of the list price of the prescription drug and are generally confidential.²⁵ However, certain studies have provided estimates of the level of rebates offered by pharmaceutical manufacturers:

- In its 2024-Q1 investor presentation, Novo Nordisk stated that “In the US, net prices have declined in the last five years[,]” including “Net prices across the full Novo Nordisk portfolio[.]”²⁶ Novo Nordisk reports that the change in average net price across its U.S. product portfolio when compared to the previous year declined by 12.3%, 12.7%, and 8.2% for 2021, 2022, and 2023, respectively.²⁷

24. The New York Times, “Senate Committee Investigates Ozempic and Wegovy Costs,” 4/24/2024, <https://www.nytimes.com/2024/04/24/well/live/ozempic-cost-senate.html>.

Axios, “Steep Ozempic, Wegovy Prices Face Fresh Scrutiny from Officials,” 4/29/2024, <https://www.axios.com/2024/04/29/weight-loss-drugs-cost-glp-1>.

The New York Times, “The Miracle Weight-Loss Drug Is Also a Major Budgetary Threat,” 3/4/2024, <https://www.nytimes.com/2024/03/04/opinion/ozempic-wegovy-medicare-federal-budget.html>

Reuters, “Economists Warn of Costs if Medicare Covers New Obesity Drugs,” 3/11/2023, <https://www.reuters.com/world/us/economists-warn-costs-if-us-medicare-covers-new-obesity-drugs-2023-03-11/>.

25. As described by the Brookings Institute: “First, manufacturers and PBMs (who negotiate on behalf of health plans) regard the terms of rebate agreements as confidential trade secrets. Second, the exact amount of a rebate frequently reflects actual performance computed after the end of a specified period (such as a quarter or year), making the contractually specified amount not known when a prescription is dispensed. Third, antitrust authorities such as the Federal Trade Commission (FTC) have a long-standing position that transparency regarding actual prices will impair competition, facilitate collusion, and result in higher actual prices.” See:

The Brookings Institution, “Sharing Drug Rebates with Medicare Part D Patients: Why and How,” 9/14/2020, <https://www.brookings.edu/articles/sharing-drug-rebates-with-medicare-part-d-patients-why-and-how/>.

26. Novo Nordisk, Investor Presentation – First Three Months of 2024, 5/2/2024, at 108, available at: <https://investor.novonordisk.com/q1-2024-presentation/?page=1>.

27. Novo Nordisk, Investor Presentation – First Three Months of 2024, 5/2/2024, at 157, available at: <https://investor.novonordisk.com/q1-2024-presentation/?page=1>.

- In its 2023 annual report, Novo Nordisk stated that “rebates amount[ed] to 74% of gross sales in the US” in 2023.²⁸
- A 2023 study by the American Enterprise Institute estimate that “net prices received by drugmakers [for drugs to treat diabetes and obesity] are 48–78 percent lower than list prices.”²⁹
- A 2020 study by the Brookings Institute stated that “[d]rug rebates have increased considerably over the past decade, sometimes reaching 50 percent or even more of list price.”³⁰
- A report by MedPAC finds that for diabetic therapy, negotiated rebates in 2021 were greater than 50% of gross spending.³¹
- One study estimates average Medicare Part D rebates of 37.3% in 2018 and growth in this rate year over year.³²

Studies have found that rebates or discounts tend to increase rapidly. In several classes, including non-insulin anti-diabetic drugs, this growth in rebates will offset any increase in list price.³³ Another study has found that average rebates are higher (and increase faster) when drug classes are more competitive.³⁴

Based on findings from the literature, we estimate that Medicare Part D Plans will negotiate a rebate of around 50% of the WAC price with branded drug manufacturers and that rebate growth will offset any increases in WAC such that net prices remain constant through 2030.³⁵ We think this is likely conservative given the number of AOMs currently being developed that could be approved and compete with AOMs currently in the market, and given that some of the more costly GLP-1s may be subject to price negotiations for Medicare under the new Inflation Reduction Act provisions.³⁶ In many drug classes, average

28. Novo Nordisk, Annual Report 2023, at 55, available at:

https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2024/novo-nordisk-annual-report-2023.pdf.

29. American Enterprise Institute, “Estimating the Cost of New Treatments for Diabetes and Obesity,” 9/2023, at 1, available at: <https://www.aei.org/wp-content/uploads/2023/09/Estimating-the-Cost-of-New-Treatments-for-Diabetes-and-Obesity.pdf?x91208>.

30. The Brookings Institution, “Sharing Drug Rebates with Medicare Part D Patients: Why and How,” 9/14/2020, <https://www.brookings.edu/articles/sharing-drug-rebates-with-medicare-part-d-patients-why-and-how/>.

31. MedPAC, “Medicare and the Health Care Delivery System,” 6/2023, at 77, available at: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.

Gross spending is “payments from all payers, including beneficiaries (through cost sharing), but does not include rebates and postsale fees from pharmacies and manufacturers that are not reflected in prices at the pharmacies.”

32. Feldman, William B. et al. (2021), “Estimating Rebates and Other Discounts Received by Medicare Part D,” JAMA Health Forum 2(6): e210626.

33. Hernandez, Inmaculada et al. (2020), “Changes in List Prices, Net Prices, and Discounts for Branded drugs in the U.S., 2007-2018,” JAMA 323(9): 854–862.

34. Lakdawalla, Darius and Meng Li (2021), “Association of Drug Rebates and Competition with Out-of-Pocket Coinsurance in Medicare Part D, 2014 to 2018,” JAMA Network Open 4(5): e219030.

35. When a drug manufacturer offers a rebate, the rebate is often shared between the PBM and Medicare Part D. According to the GAO, PBMs associated with Part D plans recoup only 0.4% of the rebate, and the rest is passed back to Medicare by the plan sponsor. Sponsors are required to report these rebates to be factored into Medicare’s calculation of reimbursements owed to the plan sponsors. Therefore, we assume that Medicare receives 99.6% of the manufacturer’s rebate. See:

GAO, “Medicare Part D Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization,” 7/2019, at 16, available at: <https://www.gao.gov/assets/gao-19-498.pdf>.

CMS, “Medicare Part D – Direct and Indirect Remuneration (DIR),” 1/19/2017, <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

We further assume that not all Medicare Part D plans negotiate rebates. According to a 2019 GAO report, only 83% report doing so.

We note as well the general trend of increasing list prices of drug products accompanied by greater rebates such that net prices have been falling. See, for example: Drug Channels, April 5, 2024, “Tales of the Unsurprised: U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year—And Will Fall Further in 2024 (rerun),” <https://www.drugchannels.net/2024/04/tales-of-unsurprised-us-brand-name-drug.html>.

36. GoodRx Health, “The Latest Updates: 14 New Weight Loss Drugs on the Horizon,” 4/12/2024, <https://www.goodrx.com/conditions/weight-loss/new-weight-loss-drugs>.

WAC prices fell when other competing medicines entered the market. The net cost of Hepatitis C treatments and PCSK9 inhibitors (cholesterol reducing therapies) were dramatically reduced once the incumbent products faced similar, but not therapeutically equivalent, competition. Given the degree of actual and expected entry into this market, there is good economic reason to expect the same to occur in the AOM space.³⁷

In addition to accounting for rebates, we account for the cost sharing that Medicare beneficiaries are expected to incur. Cost-sharing is a key mechanism used by prescription drug plans to induce a consumer response to higher prices or costs. For example, a beneficiary in a plan with a deductible would pay higher amounts out of pocket for any of the branded AOMs than they would for generic phentermine. Cost sharing also decreases the amount paid by Medicare since it serves to offset the drug's total cost.

Medicare Part D beneficiaries will pay some standard form of cost-sharing, either a copay or coinsurance each time they fill a prescription. Many will also pay a deductible before Medicare contributes payment.³⁸ To model patient out of pocket spending, we assume that once the average deductible is met, the cost of the medicine³⁹ will be shared by Medicare and the beneficiary until the beneficiary reaches the \$2,000 out of pocket maximum⁴⁰ through a combination

of AOMs and other prescriptions filled.⁴¹ We predict this amount of cost sharing using information about maximum Medicare deductibles and coinsurance percentages. Based on our model, beneficiaries are expected to pay on average about 25% of the total per patient costs.

After accounting for actual costs Medicare is likely to incur per-beneficiary on each AOM, estimated costs per beneficiary are significantly below recent predictions. We estimate an average cost to Medicare of around \$1,140 per patient per year, with variation depending on which class of AOM the beneficiary ultimately chooses. This stands in sharp contrast with other recent estimates. For example, the analysis by Deese, Gruber, and Cumming published in the New York Times relied on an estimated per-beneficiary annual cost of \$15,000 using the reported list price of Ozempic and "a doctor visit or two."⁴² A similar approach is used in Baig et al. (2023), published in the New England Journal of Medicine.⁴³ While these authors consider a range of uptake scenarios, their findings rely on the assumption that all users take these medications consistently for a full year, and that Medicare pays the list price for these drugs, leading to an overestimation of actual costs. The Institute for Clinical and Economic Review conducted an analysis similar to Baig et al. (2023), assuming persistent (and consistent) usage of AOMs with, in some conditions, insurers paying the current list price.⁴⁴

37. See, for example:

FiercePharma, "Amgen Escalates PCSK9 Pricing War with Permanent 60% Price Cut on Repatha," 10/25/2019, <https://www.fiercepharma.com/pharma/cholesterol-war-escalates-as-amgen-makes-60-price-cut-repatha-permanent>.

Milliman, "Analysis of Prescription Drugs for the Treatment of Hepatitis C in the United States," 5/2021, available at: <https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx>.

38. We assume this maximum deductible grows at a rate of 8% every year, as it has in the past. We assume 50% of beneficiaries are in full-deductible plans. This is reasonable given 2018 data, in which 4 out of 10 Medicare Part D beneficiaries were in plans with no deductible. See:

KFF, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," 5/17/2018, <https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/>.

39. While a coinsurance percentage is applied to a drug's retail price, in practice this is often (as we do here) approximated as the WAC price.

40. CMS.gov, "Inflation Reduction Act and Medicare," 9/12/2023, <https://www.cms.gov/inflation-reduction-act-and-medicare>.

41. We use estimates of average prescription drug spending to estimate the amount beneficiaries are expected to spend each month on non-AOMs.

42. The New York Times, "The Miracle Weight-Loss Drug Is Also a Major Budgetary Threat," 3/4/2024, <https://www.nytimes.com/2024/03/04/opinion/ozempic-wegovy-medicare-federal-budget.html>.

Scientific American, "Ozempic and Other Weight-Loss Drugs Are Sparking a Risky New War on Obesity," 1/24/2024, <https://www.scientificamerican.com/article/ozempic-and-other-weight-loss-drugs-are-sparking-a-risky-new-war-on-obesity>.

43. Baig, Khrysta et al. (2023), "Medicare Part D Coverage of Antiobesity Medication – Challenges and Uncertainty Ahead," *NEJM* 388(11): 961–963.

5

Cost Offsets

As the last broad category impacting future Medicare spending, we consider how those beneficiaries that use AOMs long-term may experience fewer medical episodes related to their condition and thus see reduced costs related to their care.

Calculating a precise average expected offset from obesity treatments is a complicated and highly uncertain exercise. While there is an abundance of evidence that obesity is associated with other conditions that are costly to treat, to calculate cost offsets implies that these conditions are caused by obesity (and not just correlated with obesity) and that one can accurately measure the costs that will be avoided with treatment.

Despite these complications, several academic studies have tried to assess how the utilization of AOMs could impact the total healthcare costs related to obesity. For example, Kabiri et al. (2021) predicted that with a 100% uptake of AOMs, Medicare would save \$231.5 billion over 75 years.⁴⁵

In this analysis, we account for the fact that any potential savings associated with obesity treatment loss reduction will only occur for patients that are able to decrease their BMI over the long term, as has been illustrated in academic literature. We also account for the fact that with some AOMs, with persistent usage, patients may achieve more weight loss than with others. There may also be idiosyncratic response among patients to given treatments, but we do not have sufficient data to account for such effects.

The basis for calculating cost offsets comes from a 2021 study on the direct medical costs of obesity in the United States, which finds that adults with obesity incur an additional \$2,505 in annual health care costs.⁴⁶ This study also finds that the “marginal effect of an additional unit of BMI on annual expenditures paid by public insurance was particularly large: \$240, or 6.9% of the annual mean predicted expenditures.”⁴⁷

44. Atlas, Steven J. et al. (2022), “Medications for Obesity Management: Effectiveness and Value,” *Institute for Clinical and Economic Review*, available at <https://icer.org/assessment/obesity-management-2022/>.

45. Kabiri, Mina et al. (2021), “Simulating the Fiscal Impact of Anti-Obesity Medications as an Obesity Reduction Strategy,” *Inquiry* 58: 10.1177/0046958021990516.

46. Cawley, John et al. (2021), “Direct Medical Costs of Obesity in the United States and the Most Populous States,” *J Manag Care Spec Pharm*. 27(3): 354–366. This study uses an instrumental variables approach in an attempt to tease out correlation from causation. These results are generally consistent with the results of other studies. For example:

Kim, Nina, et al. (2023), “The Relative Value of Anti-Obesity Medications Compared to Similar Therapies,” *ClinicoEconomics and Outcomes Research* 15: 51–62.

Other studies, that do not account for potential confounding effects, find higher estimates. For example, one study finds that patients with obesity incur an additional \$4,217 in annual healthcare costs.

Ding, Yuchen, et al. (2021), “Economic Value of Nonsurgical Weight Loss in Adults with Obesity,” *J Manag Care Spec Pharm* 27(1): 37–50.

47. Cawley, John et al. (2021), “Direct Medical Costs of Obesity in the United States and the Most Populous States,” *J Manag Care Spec Pharm*. 27(3): 354–366.

Using demographic data,⁴⁸ we estimate the average BMI for eligible Medicare beneficiaries and the percent BMI reduction for patients who have used a specific AOM for a one-year period.⁴⁹ With these inputs, we estimate the expected cost savings for each beneficiary given his or her expected weight loss, limiting the savings to only

those who are persistent for at least one year. Given these inputs, we estimate that Medicare will save roughly \$500 million in obesity-related costs per year. Estimates of total costs and total costs after accounting for offsets are presented in Figure 5 below. These estimates range from \$1.1 to \$1.6 billion per year.

48. National Center for Health Statistics, 2017-March 2020 Pre-Pandemic Examination Data - Continuous NHANES, <https://www.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=Examination&Cycle=2017-2020> (accessed 3/13/2024).

This is accomplished by combining the "Body Measures" and "Demographic Variables and Sample Weights" files.

49. For the GLP-1s, we estimate an average 11.2% reduction in BMI after a year of use; for phentermine/topiramate, we estimate an average 7.8% loss in BMI after a year of use; for bupropion/naltrexone we estimate an average 5.0% loss in BMI after a year of use; and for phentermine we estimate an average 3.75% loss in BMI after 12 weeks of use.

Kim, Bo-Yeon et al. (2020), "Current Long-Term Pharmacotherapies for the Management of Obesity," *Journal of Obesity and Metabolic Syndrome* 29(2): 99–109.

Shibuya, Kelly, et al. (2019), "The Benefit of Short-Term Weight Loss with Anti-Obesity Medications in Real-World Clinical Practice," *Endocrine Practice* 25(10): 1022–1028.

Ghusn, Wissam, et al. (2022), "Weight Loss Outcomes Associated with Semaglutide Treatment for Patients with Overweight or Obesity," *JAMA Network Open*. 5(9): e2231982

Greenway, Frank L. et al. (2010), "Effect of Naltrexone Plus Bupropion on Weight Loss in Overweight and Obese Adults (COR-1): a Multicentre, Randomised, Double-Blind, Placebo-Controlled, Phase 3 Trial," *Lancet* 376: 595–605.

O'Neil, Patrick M. et al. (2018), "Efficacy and Safety of Semaglutide Compared with Liraglutide and Placebo for Weight Loss in Patients with Obesity: A Randomised, Double-Blind, Placebo and Active Controlled, Dose-Ranging, Phase 2 Trial," *Lancet* 392: 637–49, at 637.

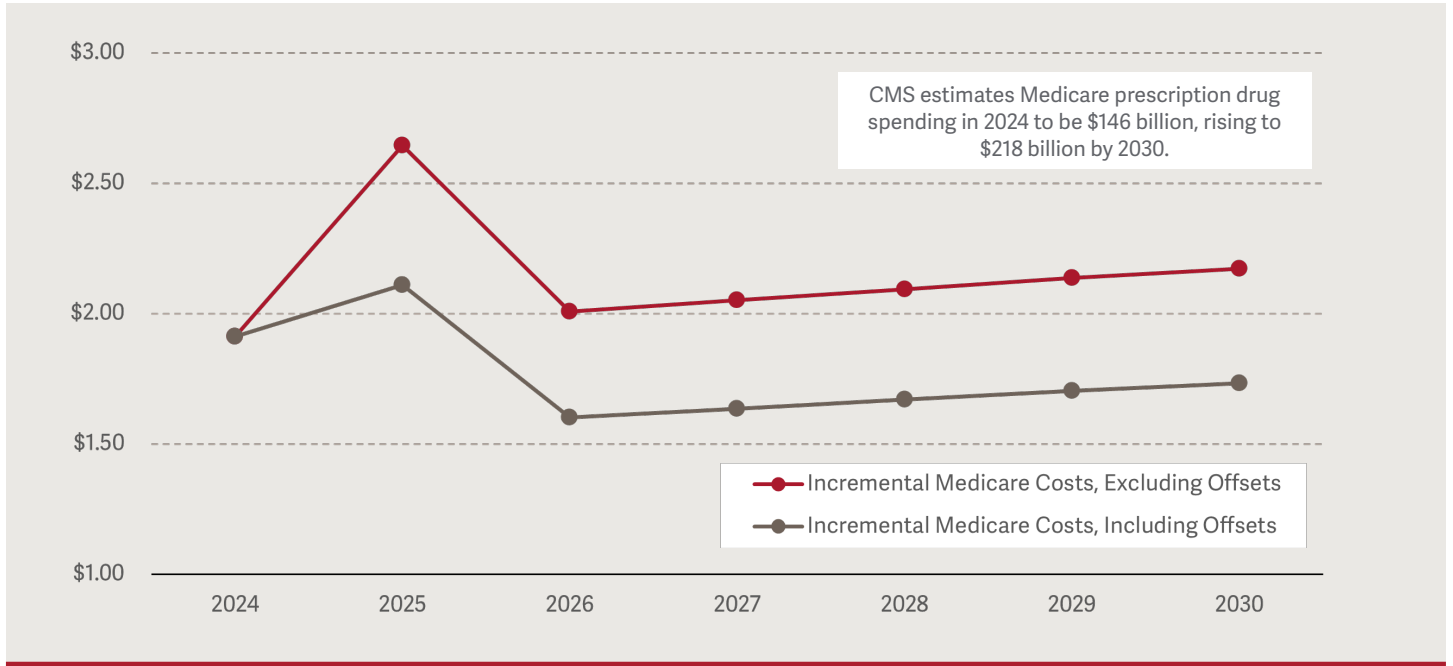
We use the mean weight loss of 11.2% for the 0.3 mg dosing, since Wegovy is available in dosing strengths from 0.25 mg to 2.4 mg.

Gadde, Kishore M. et al. (2011), "Effects of Low-Dose, Controlled-Release, Phentermine Plus Topiramate Combination on Weight and Associated Comorbidities in Overweight and Obese Adults (CONQUER): A Randomised, Placebo-Controlled, Phase 3 Trial," *Lancet* 377(9776): 1494.

Novo Nordisk, Wegovy® Dosing Schedule, <https://www.wegovy.com/taking-wegovy/dosing-schedule.html> (accessed 5/7/2024).

For further support, the following study estimates an 8.1% loss in weight in excess of a placebo after using phentermine resin for 36 to 52 weeks. See: Glazer, Gary (2001), "Long-term Pharmacotherapy of Obesity: A Review of Efficacy and Safety," *Arch Intern Med*. 161(15):1814-1824.

Figure 5: Estimated Incremental Costs Following AOM Coverage, 2024–2030



6

Sensitivity Analyses

The results presented above are sensitive to some assumptions more than to others. For example, were we to assume that Medicare beneficiaries will only use GLP-1s, yearly net spend would only increase by \$1.7 billion dollars (or increase Medicare spending from approximately 0.8% to 1.6%). Were we to assume that half of all eligible enrollees fill an AOM prescription (approximately 23% of all beneficiaries), yearly Medicare net spend would increase to around \$12.15 billion, or a 5.6% increase in Medicare Part D spending.

Only under the most extreme assumptions (all patients take only GLP-1s, 100% of eligible patients initiate a prescription each year, all of these patients are adherent to their medications, all patients take them continuously and long term, and rebates to those that negotiate them are relatively low) do we estimate figures that represent an extreme budgetary concern like those expressed by certain analysts. Table 1 includes an assessment of costs to Medicare under a variety of assumptions about usage and rebates.

Table 1: Differences in Medicare Costs and Offsets Under Various Scenarios

	% Enrollees Treated	GLP-1 Market Share	Perfect Adherence & Yearly Use	% Rebate	"Est. Yearly Spend, 2030 (in billions)"	"Est. Yearly Spend, Net Offsets, 2030 (in billions)"	% Increase in Prescription Drug Spending
Scenario 1	3.2%	46.5%		50%	\$2.17	\$1.73	0.8%
Scenario 2	3.2%	70%		50%	\$3.02	\$2.57	1.2%
Scenario 3	3.2%	100%		50%	\$3.87	\$3.40	1.6%
Scenario 4	half eligible	46.5%		50%	\$15.24	\$12.15	5.6%
Scenario 5	half eligible	46.5%		35%	\$18.42	\$15.34	7.0%
Scenario 6	half eligible	46.5%	X	50%	\$50.81	\$47.73	21.9%
Scenario 7	all eligible	100%	X	25%	\$238.34	\$231.83	106.1%

7

Conclusion

Under current rules, Medicare is prohibited from covering treatments solely for the purpose of treating obesity. Proposals to expand coverage of these products to include obesity treatments have been met with very large and well publicized estimates of budget impact to the Medicare program. These estimates have typically not accounted for a range of well-established effects that will likely serve to limit the continued utilization and financial impact of these products in the Medicare population. We account for such effects and model incremental Medicare spending for obesity specific use and find that reasonable estimates of incremental Medicare spending

are far lower than commonly suggested. Our baseline assessment suggests incremental annual spending of 1.0% to 1.6% of Medicare prescription drug spending from 2024 to 2030. Accounting for the potential impact of lower health care spending for patients that lose weight on these drugs reduces the projected incremental spending to an amount equal to approximately 0.8% to 1.3% of Medicare prescription drug spending from 2024 to 2030. This is equivalent to approximately 0.09% to 0.17% of total projected Medicare spending from 2024 to 2030.⁵⁰

50. CMS.gov, Projected National Health Expenditure Data, 9/6/2023, <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected>.

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