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# **Medicare Coverage of Anti-Obesity Medications**

The proposed reinterpretation of Medicare Part D coverage of anti-obesity medications may provide approximately 3.4 million Medicare beneficiaries who have obesity with access to these innovative therapies. Medicare coverage would reduce out-of-pocket costs for these prescription drugs by as much as 95 percent for some enrollees. Approximately 4 million adult Medicaid enrollees may also gain new access to these medications.

#### **KEY POINTS**

- CMS has proposed to reinterpret the statutory exclusion of agents when for weight loss to allow Medicare Part D coverage of anti-obesity medications (AOMs) when used to treat beneficiaries with obesity. Currently, these medications can only be covered by Part D for other FDA-approved indications such as type 2 diabetes or cardiovascular disease or if that coverage is offered as an enhanced Part D benefit.
- CMS estimates that the proposed reinterpretation would expand coverage to an additional 7 percent of the Part D population or 3.4 million enrollees who have obesity not combined with a condition for which these medications are already covered. They estimate this expansion will cost the Medicare program \$24.8 billion over a ten-year period.
- Use of AOMs has been steadily expanding in the Medicare Part D population and across the United States due to new drug approvals and expanded FDA indications.
- Most AOM manufacturers have been steadily raising U.S. list prices for AOMs on or entering the market since 2017. The U.S. prices for these drugs are significantly higher than prices in comparator countries, even after accounting for rebates and other discounts in the United States.
- On average, Medicare Part D enrollees paid \$60 out-of-pocket (OOP) for a one-month supply of AOMs in 2023, with the majority of patients having OOP costs of \$15 or less per month.
- Part D enrollees in the low-income subsidy (LIS) program had lower OOP costs than other enrollees, with average OOP costs of \$3 for a one-month supply.
- The proposed reinterpretation of the statutory exclusion would also affect the Medicaid program. States that cover prescribed drugs would be required to cover AOMs when used to treat enrollees with obesity, meaning around 4 million adult enrollees may newly gain access to the AOMs they are prescribed. CMS projects that total Medicaid spending would increase by \$14.8 billion over a 10-year period. \$11 billion of the ten-year cost would be borne by the federal government and \$3.8 billion by the states.

# **BACKGROUND**

In November 2024, the Centers for Medicare & Medicaid Services (CMS) released the Medicare Program; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly proposed rule.<sup>1</sup> The Medicare Part D provisions of the proposed rule includes language "to reinterpret the statutory exclusion of agents when used for weight loss such that it would not apply to drugs when used to treat beneficiaries with obesity." The proposed reinterpretation would also apply to the Medicaid program.

The proposed reinterpretation of Medicare coverage for anti-obesity medications (AOMs) is a critical inflection point in how the federal government approaches the treatment of obesity. While Medicare Part D enrollees currently have access to some glucagon-like-peptide-1 (GLP-1) receptor agonists\* for indications other than obesity, the proposed reinterpretation to include Part D enrollees for the treatment of obesity could significantly improve access to these medications and health outcomes for enrollees. These medications, which have demonstrated remarkable effectiveness in weight management, have now transformed the therapeutic landscape. As Medicare considers broadening access to these medications, policymakers face a number of considerations. The expansion could substantially improve health outcomes for millions of Medicare beneficiaries with obesity. At the same time, there are concerns about the cost associated with expanding coverage for additional conditions. Understanding cost dynamics is important as policymakers seek to improve patient access to innovative therapies with responsible stewardship of public resources.

This brief examines the potential impact of Medicare's proposed reinterpretation, analyzing both the benefits for beneficiaries and the broader economic implications for the Medicare program and its enrollees. We first provide an overview of AOMs, including specific drugs and indications that they have been approved by the Food and Drug Administration (FDA) to treat. Next, we compare existing estimates of the impact of expanding access of Medicare Part D to include these treatments for obesity. We continue by examining the growth in utilization of these drugs since their launch in the United States overall and among Medicare and Medicaid populations, we compare prices and spending for these medications in the United States and comparator countries. Finally, we look at out-of-pocket (OOP) costs for certain medications in the Medicare population.

#### **OVERVIEW OF ANTI-OBESITY MEDICATIONS**

Millions of Medicare beneficiaries have obesity and its related health complications. More than 20 percent of Medicare beneficiaries (or 14 million) have been diagnosed with obesity. Several drugs within the GLP-1 receptor agonist drug class have emerged as transformative treatment options in metabolic health. In this analysis, we focus on seven key drugs in the class (listed alphabetically), referred to as "specified drugs": Mounjaro, Ozempic, Rybelsus, Saxenda, Victoza, Wegovy, and Zepbound. Wegovy and Zepbound have been approved by the FDA to reduce excess body weight and maintain weight reduction long term; Saxenda is approved for chronic weight management. The remaining four have not been approved for the use of weight reduction, however, they share the same active ingredients as those that have been approved for this use, and as such, physicians may prescribe them off-label for the treatment of obesity and weight management.

Each medication in this class carries specific FDA-approved indications that guide their clinical use, summarized in table 1. In addition to the three approved for an indication related to chronic weight management, four are approved for type 2 diabetes management, and three are approved for cardiovascular risk reduction.

<sup>\*</sup> This brief will use the term "GLP-1 receptor agonists" and "GLP-1s" to include GLP-1 receptor agonists liraglutide and semaglutide, as well as drugs containing tirzepatide (Mounjaro and Zepbound), which is a dual GIP/GLP-1 receptor agonist.

<sup>&</sup>lt;sup>†</sup> The active ingredients are liraglutide, semaglutide, and tirzepatide.

Table 1. FDA Approved Indications\* for Specified Anti-obesity Medications (Listed Alphabetically)

Drug	Active Ingredient	Weight Reduction**	Type 2 Diabetes Mellitus***	Risk Reduction of Cardiovascular Events****
Mounjaro	tirzepatide		X	
Ozempic	semaglutide		Χ	X
Rybelsus	semaglutide		X	
Saxenda	liraglutide	X		
Victoza	liraglutide		X	X
Wegovy	semaglutide	X		X
Zepbound	tirzepatide	X		

Notes: BMI=Body Mass Index. \*Indications shown selected based on relevance to subject matter. \*\*The indication specifies that the medication is an adjunct to a reduced calorie diet and increased physical activity. It targets patients with obesity or those with overweight with a weight-related comorbid condition. For Wegovy and Zepbound, the indication specifically reads "to reduce excess body weight and maintain weight reduction long term." \*\*\*Adjunct to diet and exercise to improve glycemic control in adults. \*\*\*\*In adults with established cardiovascular disease, type 2 diabetes mellitus, obesity and/or overweight. Major events include cardiovascular death, non-fatal myocardial infraction, or non-fatal stroke.

Source: package inserts for Mounjaro, Ozempic, Rybelsus, Saxenda, Victoza, Wegovy, and Zepbound.

More than 26 percent of Medicare beneficiaries (or 17.7 million) have type 2 diabetes, putting them at risk for serious complications.<sup>3</sup> GLP-1 medications help manage type 2 diabetes by stimulating insulin release when blood sugar is high, reducing excess glucagon (a hormone that raises blood sugar), and slowing digestion to better control post-meal blood sugar spikes.<sup>4</sup> These medications have also shown the potential to protect kidney function.<sup>5</sup>

Over 4.6 million and 4.1 million Medicare beneficiaries have been diagnosed with atrial fibrillation and heart failure, respectively,<sup>6</sup> conditions which are exacerbated by obesity.<sup>7,8</sup> Cardiovascular protection has emerged as a crucial benefit of GLP-1 receptor agonists. Clinical studies have shown some of these medications can reduce the risk of major adverse cardiovascular events, particularly in patients with established cardiovascular disease.<sup>9</sup> They have demonstrated positive effects on blood pressure and lipid profiles, contributing to their overall cardiovascular benefits.<sup>10</sup>

Finally, there is evidence that GLP-1 receptor agonists improve sleep apnea, and Eli Lilly has submitted application for approval for this indication to the FDA for Zepbound.<sup>11</sup>

With the approval of additional GLP-1 receptor agonists for obesity treatment and the proposed reinterpretation to allow Medicare Part D enrollees to gain access to these treatments for weight reduction and management, Medicare enrollees may soon have access to a new tool to address this pressing health challenge. Helping these individuals access and utilize these innovative medications could significantly improve their health outcomes and reduce the burden of obesity-related complications on the Medicare program.

# ESTIMATES OF COST IMPACTS OF EXPANDING MEDICARE COVERAGE FOR OBESITY

Given the health risks of obesity and the effectiveness of GLP-1s in weight reduction, proposals for expanding access to them in Medicare and estimates of the costs of those proposals have been made previously. The statutory definition of a covered Part D drug at section 1860D-2(e)(2) of the Social Security Act (the Act) excludes certain drugs and uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act. This includes "[a]gents when used for anorexia, weight loss, or weight gain." Currently, Medicare Part D enrollees do not have access to these medications under Part D when used solely for to treat beneficiaries with obesity. However, GLP-1s that have been approved for the management of type 2 diabetes

are covered by Medicare Part D under current policy. In addition, in March 2024, Wegovy, which had previously only been approved by FDA for weight management, was approved to reduce the risk of major adverse cardiovascular events in patients with either obesity or overweight combined with cardiovascular disease. At that point, Medicare Part D enrollees gained access for that combination of conditions.<sup>‡</sup>

Table 2 summarizes the differences in assumptions and results of three published cost estimates of different AOM expansions in Medicare: one by a team of researchers (Ippolito and Levy) <sup>12</sup>, one by the Congressional Budget Office (CBO) <sup>13</sup>, and the estimate by CMS Office of the Actuary (OACT) made for the proposed rule. Both Ippolito and Levy and CBO analyze policies involving wider expansions than the reinterpretation being proposed by CMS since they estimate the effect of a policy expanding access to the AOMs for weight management among enrollees with either obesity alone or overweight combined with a weight-related condition (such as high blood pressure or high cholesterol). § In comparison, CMS is only proposing to reinterpret access to AOMs for the treatment of enrollees with obesity and not to enrollees with overweight.

<sup>\*</sup> See: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-march-18-22.

<sup>&</sup>lt;sup>§</sup> CBO notes that the policy they study is similar to a proposed bill, the Treat and Reduce Obesity Act (TROA) of 2023 (H.R. 4818 and S. 2407).

**Table 2. Comparison of Cost Estimates for Expansions of AOM Coverage in Medicare** 

Source	Policy evaluated	Obesity/over- weight rate	Share of obese/overweight enrollees with existing coverage for GLP-1s due to comorbid medical conditions	Share of Medicare Part D enrollees newly eligible	Rate of take-up of GLP-1 receptor agonists among newly eligible	Discontinuation rate among new initiators of GLP-1 receptor agonist treatment	
CMS Office of the Actuary (OACT)	Expanding access to prescribed AOMs to Medicare enrollees for the treatment of obesity	Obesity: 22%	73% Includes type 2 diabetes, cardiovascular disease, and sleep apnea	7% (2022)	10% in the first year, grows by 0.3% annually	52.5% will stop after two months	\$1.4 billion in first year; \$24.8 billion total over a ten-year period.
Congressional Budget Office (CBO)	Expanding access to AOMs to Medicare enrollees with obesity alone or overweight accompanied with a weight-related condition	Obesity: 34% Overweight: 35%	"About half" in 2026, rising to ~64% by 2034 Includes diabetes and cardiovascular disease	~35% in 2026	2% in 2026, rising to 14% in 2034.	65% of new users will discontinue AOM treatment in the first year in 2026, dropping to 50% by 2034.	year (2026); \$35.5
Ippolito & Levy	Expanding access to AOMs to Medicare enrollees with obesity alone or overweight accompanied with a weight-related condition.	Obesity and overweight with a comorbid condition: 39%	43% Includes diabetes and estimates of off-label use. Did not take into account new indication for Wegovy as of March 2024.	~22%	Two scenarios: 5% or 10% of newly eligible take up AOMs in first year	70% of prescribed days are filled.	\$3.1 billion in first year (2025) under 59 take-up assumption and \$6.1 billion under 10% assumption.

There is uncertainty around each of the underlying assumptions that drive the projections presented in Table 2, leading to variations across the different cost estimates in both the setting of assumptions and in the results. The first key assumption in the cost estimates is how many Medicare Part D enrollees fall into the relevant body mass index (BMI) category for the policy under consideration. CMS OACT based its assumption for the obesity rate among Part D enrollees of 22 percent on diagnoses in Medicare claims. This is likely to be an underestimate, however, since there may not have been an incentive to report these diagnoses in claims. CBO used the rates from the Medicare Current Beneficiary Survey (MCBS) and found a significantly higher obesity rate of 34 percent.

The next key assumption is what share of these enrollees already have a medical condition entitling them to access to GLP-1 treatment. As noted above, these currently include type 2 diabetes and cardiovascular disease. CMS OACT also assumes in its estimate that sleep apnea will be included as a covered condition because of a recent application for approval for this indication to the FDA by Eli Lilly for Zepbound. They estimated that 73 percent of enrollees with obesity already have access to the AOMs they are prescribed under Part D for GLP-1 treatment using diagnoses in claims. The other two cost estimates find lower rates, largely because they are also including enrollees with overweight and a comorbid condition in their pool of enrollees potentially affected by the proposed reinterpretation. The first two key assumptions together give the share of all Part D enrollees who would gain access to the AOMs that are prescribed solely to treat obesity by the proposed reinterpretation; CMS OACT finds that this share is 7 percent. Both CBO and Ippolito and Levy find higher shares, again because they are analyzing a wider expansion of access.

It is not expected that all newly eligible enrollees will take up AOM treatment immediately, so all three cost estimates make assumptions about the take-up rates by the newly eligible. CBO estimates that 2 percent of the newly eligible will take up AOM treatment in the first year and that this rate will gradually rise over time. CMS OACT and Ippolito and Levy both assume significantly higher initial take-up rates.

Of note, patients who are treated with GLP-1s discontinue such treatment at a relatively high rate. One study found that 52.5 percent of patients with overweight or obesity taking semaglutide followed for up to a year discontinued treatment during that time. A survey of patients with type 2 diabetes who discontinued GLP-1 treatment cited gastrointestinal side effects most often as their reason for stopping treatment. All three cost estimates make assumptions about adherence or discontinuation; CMS OACT assumes based on the study cited above that 52.5 percent of patients taking AOMs will stop taking them within two months. CBO made a similarly high estimate of discontinuation, but Ippolito and Levy assumed that 70 percent of prescribed days will be filled, implying a lower rate of stopping.

An additional source of uncertainty (not addressed in Table 2) is that the pool of enrollees made eligible to access AOMs under this proposed reinterpretation may decrease further in the future if the drugs are approved for new indications for other conditions, in which case patients with those conditions could access GLP-1 treatment without the proposed reinterpretation. Ippolito and Levy, for example, estimate based on Phase 3 clinical trials of GLP-1 treatment for different conditions expected to be completed soon that the pool of patients that would access the AOMs they are prescribed for weight management could decrease by around 80 percent by 2026 relative to the 2024 baseline.

In addition, the future path of prices of drugs in this class will be affected by the number of approved conditions for each drug, whether any of the drugs are selected for price negotiation by Medicare, and the number of new drugs that become available, including potential future new entrants into the market. With these multiple variables, pricing dynamics in this environment are hard to predict. While CMS has not announced any drugs selected by Medicare for the next round of negotiation, CBO's modeling included the outcome of potential selection of semaglutide for negotiation by Medicare in that round and the potential for prices of semaglutide products (Ozempic, Wegovy, and Rybelsus) to subsequently drop significantly in 2027.

CBO modeled this outcome to best understand what the impact could be on Medicare of the proposed reinterpretation described in this brief.

A final issue potentially affecting future costs is whether there will be offsets in medical spending by beneficiaries whose health has improved from AOM treatment. CBO noted that there does not seem to be any direct empirical evidence on this issue. CMS OACT did not estimate any offsets, citing the uncertainty and lack of clear evidence for the specific population impacted by the reinterpretation. CBO and Ippolito and Levy made estimates of offsets from improved health but find that they are small, less than 10 percent of the total cost.

In summary, the last column gives the estimates of costs to the Medicare program of the proposed policies. In the first year, Ippolito and Levy have a higher cost estimate than the other two sources, partly due to their significantly higher assumption about patient adherence to treatment; they assume 70 percent of prescribed days are filled while CBO and CMS OACT each assume roughly half of patients initiating treatment will drop out. CBO and CMS OACT's estimates for the first year are roughly equal at around \$1.4-1.5 billion; while CBO examines a wider expansion of access to include overweight as well as obesity, they also assume a take-up rate of the drugs by newly eligible patients of only 2 percent in the first year while CMS OACT assumes a higher initial take-up rate of 10 percent. CBO's estimates that the cost of the wider policy to the Medicare program over a nine-year period is \$35.5 billion. CMS OACT estimated that CMS's proposed reinterpretation of more narrowly expanding Part D access to GLP-1 receptor agonists to treat enrollees with obesity would cost the Medicare program \$24.8 billion net of premiums over a ten-year period.

# **Medicaid Coverage**

As discussed in the proposed rule, the reinterpretation of the statutory exclusion of drugs used to treat individuals with obesity to allow Part D coverage of AOMs means that this use can no longer be excluded from Medicaid under the prescription drug benefit that all states currently opt to cover. CMS OACT therefore also estimated the cost of the proposed reinterpretation to the Medicaid program. Based on an assumed obesity rate of 45 percent and assuming that Medicaid enrollees who have comorbid conditions already have access at the same rate as Medicare Part D enrollees, 12 percent of adult Medicaid enrollees (or around 4 million) would gain access to the AOMs they are prescribed for AOM treatment solely for treating obesity under the proposed reinterpretation.\*\* CMS OACT also takes into account that fifteen states already give Medicaid enrollees access to AOM treatment for weight management since Medicaid allows (but does not require) inclusion of weight management drugs under current policy. Overall, CMS OACT projects that total Medicaid spending will increase by \$500 million in the first year, rising to \$2 billion by year ten, for a total of \$14.8 billion over a tenyear period; \$11 billion of the ten-year cost will be borne by the federal government and \$3.8 billion by the states.\*

## **USE OF ANTI-OBESITY MEDICATIONS OVER TIME**

To help understand the potential future impact of expanding Medicare Part D enrollees' access to medications to treat obesity, we start by examining the growth of AOM medications over time across the U.S. market, in Medicaid, and in Medicare Part D.<sup>‡‡</sup>

Figure 1 shows the total number of prescriptions for all FDA approved GLP-1 drugs since October 2020. On average, Medicare makes up 24 percent of total US market prescriptions and Medicaid makes up 10 percent.

<sup>\*\*</sup> Approximately 4 million individuals represent 12% of the non-dual Medicaid population, which constitutes 80% of the 42 million adults enrolled in Medicaid as of July 2024 (source: Medicaid & CHIP Enrollment Data Snapshot. Medicaid.gov, July 2024, p. 6. Available at: https://www.medicaid.gov/resources-for-states/downloads/eligib-oper-and-enrol-snap-jul.pdf).

<sup>&</sup>lt;sup>††</sup> CMS OACT notes in their projection that costs may be significantly higher or lower than projected. Please see <u>full NPRM</u> for details. <sup>‡‡</sup>All data sources and methods are included in the appendix.

Note that the prescriptions included in the total U.S. market include all approved indications, while prescriptions for Medicare were for control of type 2 diabetes or reduction of cardiovascular risk. While all three markets have seen growth over time, the total U.S. market seems to be growing at a faster rate, particularly in recent years.

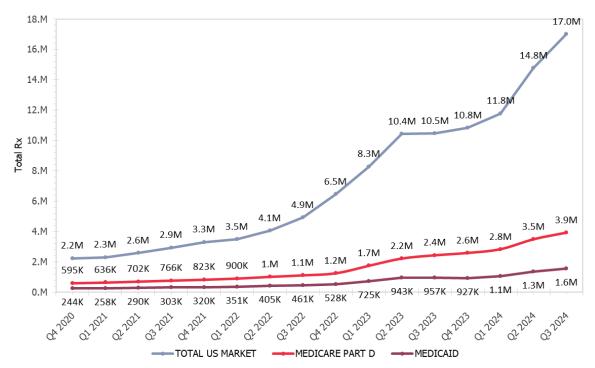


Figure 1. Total U.S. Market Prescriptions for Anti-obesity Medications, 2020-2024

Notes: Total Rx=total prescriptions. M=millions. Q=calendar quarter. Medicaid includes Fee-for-Service (FFS) Medicaid and Medicaid Managed Care.

Source: IQVIA Payer Track data.

Figure 2 shows the proportion of all prescriptions for the specified AOMs for the commercial, Medicare, and Medicaid markets. We see some prescriptions for medications with FDA approvals only for weight management, such as Wegovy and Zepbound, for Medicare, suggesting that there is either some off-label use of these drugs or enrollees are receiving these drugs without using their Medicare Part D coverage. However, these medications are a much smaller proportion of total prescriptions in either Medicare or Medicaid as compared to the commercial market.

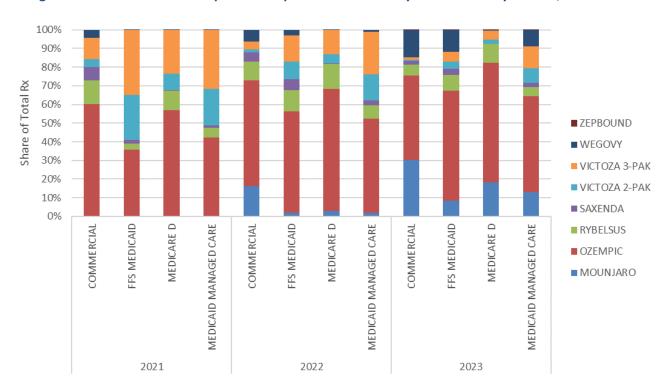


Figure 2. Share of Total Prescriptions for Specified Anti-Obesity Medications by Market,\* 2021-2023

Notes: Total Rx=total prescriptions. FFS Medicaid=Fee-for-Service Medicaid. Prescriptions with cash as method of payment excluded. \*Medicare Part D does not currently provide access to drugs to treat obesity alone; these enrollees may have been prescribed the medications for another condition such as type-2 diabetes or cardiovascular disease combined with obesity. \*\*Zepbound entered the market in 2023 so had very little utilization during the 2021-2023 period Source: IQVIA Payer Track data.

## PRICES AND SPENDING ON ANTI-OBESITY MEDICATIONS

To further understand the impact of CMS' proposed reinterpretation, we compare three price measures for the specified AOMs (Table ). We evaluate the cost of a typical one-month supply of the specified AOMs. For the U.S. market as a whole,\*\*\* including both commercial and government payors, we show both the list price—the "sticker price"—and the net price—the price paid after negotiations and rebates. We compare this to the range of international prices.

<sup>§§</sup> All data sources and methods are included in the appendix.

<sup>\*\*\*</sup> U.S. Market net price excludes Medicaid statutory rebates.

Table 3. Prices for a one-month Supply of Specified Anti-Obesity Medications (AOMs), 2023

Brand Name	U.S. List Price	U.S. Net Price	International Prices* (range)	
Mounjaro	\$1,069.08	\$291.67	\$319-\$444	
Ozempic	\$968.52	\$290.08	\$83-\$169	
Rybelsus	\$968.52	\$296.33	\$69-\$203	
Saxenda	\$1,349.00	\$703.08	n/a	
Victoza	\$271.76	\$282.75	n/a	
Wegovy	\$1,349.08	\$649.42	\$296-\$398	
Zepbound	\$1,059.88	\$809.67	n/a	

Notes: n/a=not available. Information on international prices is not available for some of the specified drugs. \*International prices based on prices for Australia, Canada, France, Germany, Japan, the Netherlands, Sweden, Switzerland, and the United Kingdom. Sources: Peterson Center-KFF (international prices); SSR Health data (U.S. net prices); AnalySource (U.S. list prices).

In the U.S., net prices are between 24 and 73 percent lower than list prices. This indicates that most payers are paying less than the manufacturer's list price. Internationally, both U.S. list and net prices for the specified AOMs are generally higher than prices in comparator countries (one drug has a lower U.S. net price). This means that even after adjusting for rebates and other discounts in the United States, and assuming no such adjustments in the other countries, prescriptions filled in the United States have higher prices.

## **Analysis of Prices over Time**

To understand the historical trajectory of prices, we examine both list and net prices between 2017 and 2024 (Table 4). We see that as in the 2023 data presented above, net prices are lower than list prices in each year, reflecting substantial discounts that insurers receive below the list price.

Table 4. Historical Trends in List and Net Prices for Specified Anti-Obesity Medications (AOMs)

Drug Name	Manu- facturer	Price	2017	2018	2019	2020	2021	2022	2023	2024
Mounjaro	Eli Lilly	List						\$974.32	\$1,023.04	\$1,069.08
		Net						\$122.92	\$241.00	\$291.67
Ozempic	Novo	List		\$676.00	\$729.40	\$772.43	\$811.05	\$851.60	\$892.06	\$968.52
	Nordisk	Net		\$531.08	\$498.83	\$460.75	\$430.92	\$369.75	\$319.67	\$290.08
Rybelsus	Novo	List				\$772.43	\$818.00	\$851.60	\$892.06	\$968.52
	Nordisk	Net				\$376.75	\$347.25	\$333.83	\$325.83	\$296.33
Saxenda	Novo	List	\$1,154.25	\$1,154.25	\$1,200.40	\$1,247.25	\$1,297.15	\$1,349.00	\$1,349.00	\$1,349.00
	Nordisk	Net	\$842.17	\$867.75	\$885.08	\$865.67	\$833.58	\$780.67	\$674.75	\$703.08
Victoza	Novo	List	\$249.21	\$268.89	\$290.13	\$307.26	\$322.62	\$338.75	\$354.87	\$271.76
	Nordisk	Net	\$541.83	\$527.00	\$492.00	\$463.17	\$406.50	\$344.33	\$276.92	\$282.75
Wegovy	Novo	List					\$1,349.08	\$1,349.08	\$1,349.08	\$1,349.08
	Nordisk	Net					\$534.00	\$646.17	\$665.83	\$649.42
Zepbound	Eli Lilly	List							\$1,059.88	\$1,059.88
		Net							n/a*	\$809.67

Notes: \*Net Price is not available for this drug because it is computed as a four-quarter rolling average and Zepbound did not have enough quarters in 2023 to compute a net price.

Sources: List price is sourced from AnalySource and Net Price is from SSR Health. Please see appendix for more details regarding data sources and methods.

While almost all prices have increased substantially over time, the data suggest varying list pricing strategies among manufacturers over the observed period. Mounjaro, manufactured by Eli Lilly, shows a progressive increase in its list price from \$974 in 2022 to \$1,069 in 2023. Ozempic, produced by Novo Nordisk, also demonstrates a consistent upward trajectory, escalating from \$676 in 2017 to \$969 by 2024, reflecting an overall increase of approximately 43 percent. In contrast, Saxenda's price remains relatively stable after 2019, with a final list price of \$1,349 in 2023 and 2024. Wegovy, by Novo Nordisk, also maintains a stable price of \$1,349 from 2020 through 2024.

In the net prices, we see evidence of the impact of competition as new drugs in the class enter the market. While list prices are consistently stable or increasing, for many of these drugs, including Ozempic, Rybelsus, Saxenda, and Victoza, net prices fell.

# **OUT-OF-POCKET COSTS FOR MEDICARE ENROLLEES**

We evaluate Medicare enrollee OOP costs for AOMs to understand the impact of the proposed reinterpretation on enrollees.\*\* We evaluate OOP spending for the full Medicare Part D population, as well as separately for enrollees in Medicare's low-income subsidy (LIS) program\*\* and for enrollees in Medicare Advantage prescription drug plans (MA-PDs) as compared to standalone prescription drug plans (PDPs).\*\*

Table 5 shows the range of OOP spending for AOM prescriptions for the specified AOMs for all Medicare Part D enrollees. Only 4 of the drugs (Mounjaro, Ozempic, Rybelsus, and Victoza) had 2023 Part D claims to be used for our analysis.\*\*\*\* While the average OOP cost for a one-month supply was \$60, the majority of AOM prescriptions were filled for \$15 or less for a one-month supply (median OOP cost, data not shown).

On average, OOP costs for a one-month supply were \$60, and average annual out-of-pocket costs were \$391. The most expensive AOM for enrollees in 2023 was Mounjaro, with a one-month supply costing \$68 and an annual cost of \$379.\*\*\* Other AOMs ranged from \$51-\$60 for a one-month supply and \$278-\$376 annually. Overall annual average OOP spending on AOMs, \$391, is higher than for any of the four drugs because some enrollees used more than one of these drugs during the year.

Comparing the average Medicare Part D OOP costs with the list prices shown in Table 3 above suggests that the proposed reinterpretation would reduce out-of-pocket costs for enrollees who would otherwise pay the list price of the drug by 95 percent for Rybelsus and 94 percent for Mounjaro and Ozempic.

<sup>\*\*\*</sup> All data sources and methods are included in the appendix.

<sup>\*\*\*</sup> The LIS program, also known as Extra Help, provides additional financial assistance for enrollees who meet certain income and limited resource qualifications to lower the cost of Part D prescription drug coverage.

<sup>§§§</sup> Many Medicare Advantage (MA) enrollees have the option of electing a Part D plan along with their MA plan. PDPs are available to all Part D enrollees.

<sup>\*\*\*\*</sup> Only Mounjaro, Ozempic, Rybelsus, and Victoza had Part D claims in 2023, but Medicare enrollees may have still received these drugs without using their Part D coverage.

<sup>\*\*\*\*</sup> Note that average annual costs are may not equal to 12 times the average monthly cost as not all enrollees take the medication for the full year.

Table 5. Medicare Part D Out-of-Pocket (OOP) Costs for Specified Drugs, 2023

Brand Name*	Number of Enrollees	Average 30-Day Supply OOP Cost	Average Annual OOP Cost
ALL	2,143,505	\$60	\$391
Mounjaro	370,392	\$68	\$379
Ozempic	1,465,184	\$60	\$376
Rybelsus	285,792	\$52	\$278
Saxenda	n/a	n/a	n/a
Victoza	189,418	\$51	\$355
Wegovy	n/a	n/a	n/a
Zepbound	n/a	n/a	n/a

Note: \*Some drugs did not have any Part D claims in 2023, but Medicare enrollees may still have received these drugs without using their Part D coverage.

Source: ASPE analysis of Medicare Prescription Drug Event (PDE) and enrollment data.

Tables 6 and 7 examine OOP costs for different groups of enrollees. Table 6 compares OOP costs for LIS and non-LIS enrollees. OOP costs are much lower for enrollees receiving the LIS benefit, with average costs for a one-month supply of \$3 as compared to \$107 for enrollees not receiving the LIS benefit. Average annual out-of-pocket costs were \$22 for LIS enrollees and \$651 for non-LIS enrollees. Enrollees receiving the LIS benefit also have less variation in OOP costs across the different AOMs, with average one-month OOP costs of about \$3 for each of the four drugs. Average monthly costs for non-LIS enrollees ranged from \$487 for Rybelsus to \$656 for Victoza.

Table 6. Medicare Part D Out-of-Pocket (OOP) Costs for Specified Drugs, by Low-Income Subsidy (LIS) Status, 2023

Brand Name	Number of Enrollees			One-Month OOP Cost	Average Annual OOP Cost		
	LIS Non-LIS		LIS	Non-LIS	LIS	Non-LIS	
ALL	886,604	1,256,901	\$3	\$107	\$22	\$651	
Mounjaro	150,266	220,126	\$3	\$120	\$20	\$624	
Ozempic	599,917	865,267	\$3	\$106	\$21	\$621	
Rybelsus	126,894	158,898	\$3	\$97	\$15	\$487	
Saxenda	n/a	n/a	n/a	n/a	n/a	n/a	
Victoza	89,578	99,840	\$3	\$101	\$20	\$656	
Wegovy	n/a	n/a	n/a	n/a	n/a	n/a	
Zepbound	n/a	n/a	n/a	n/a	n/a	n/a	

Source: ASPE analysis of Medicare Prescription Drug Event (PDE) and enrollment data.

Table 7 compares average OOP costs for MA-PD and PDP enrollees. On average, and across the four drugs, OOP costs are lower for MA-PD enrollees than for PDP enrollees. MA-PD enrollees paid 44 percent less for a one-month supply for the specified drugs, on average, than PDP enrollees. As recent research suggests, the responsibility of MA-PD plan sponsors for overall medical costs may lead them to offer lower patient cost-sharing on drugs in hope of averting hospitalizations or other expensive nondrug treatments. PDPs, in contrast, are responsible for drug costs only, and do not benefit from averted nondrug costs.<sup>17</sup>

Table 7. Medicare Part D Out-of-pocket (OOP) Costs for Specified Drugs, by Plan Type, 2023

Brand Name	Number of Enrollees		Average One-M OOP C		Average Annual OOP Cost		
	Medicare Advantage Prescription Drug Plan (MA-PD)	Prescription Drug Plan (PDP)	Medicare Advantage Prescription Drug Plan (MA- PD)	Prescription Drug Plan (PDP)	Medicare Advantage Prescription Drug Plan (MA- PD)	Prescription Drug Plan (PDP)	
ALL	1,356,224	787,281	\$46	\$82	\$293	\$559	
Mounjaro	249,992	120,400	\$55	\$95	\$302	\$539	
Ozempic	910,875	554,309	\$46	\$82	\$277	\$538	
Rybelsus	183,042	102,750	\$41	\$70	\$209	\$401	
Saxenda	n/a	n/a	n/a	n/a	n/a	n/a	
Victoza	120,374	69,044	\$39	\$72	\$260	\$521	
Wegovy	n/a	n/a	n/a	n/a	n/a	n/a	
Zepbound	n/a	n/a	n/a	n/a	n/a	n/a	

Source: ASPE analysis of Medicare Prescription Drug Event (PDE) and enrollment data.

# **CONCLUSION**

The Medicare Part D provisions of the proposed rule includes language "to reinterpret the statutory exclusion of agents when used for weight loss such that it would not apply to drugs when used to treat beneficiaries with obesity." CMS estimates that the proposed reinterpretation would expand access to an additional 7 percent of the Part D population, or 3.4 million enrollees, with a cost of \$24.8 billion to the Medicare program from over a ten-year period. For Medicaid, CMS projects that the proposed reinterpretation would expand access to 12 percent of adult Medicaid enrollees, or around 4 million people, with estimated federal costs of \$11 billion and state costs of \$3.8 billion over the same period.

Most AOM manufacturers have been steadily raising U.S. list prices for AOMs on or entering the market since 2017. The U.S. prices for these drugs are higher than prices in comparator countries, even after accounting for rebates and other discounts in the U.S.

While the U.S. health care system, including Medicare, pays high prices for AOMs, Medicare enrollees' OOP costs have been relatively low with a median of \$15, meaning that half of AOM prescriptions are filled with enrollees paying \$15 or less for a one-month supply. If Medicare Part D plans continue to cover these medications with low copays, CMS' reinterpretation is likely to significantly improve access to these new, innovative drugs.

## **APPENDIX: DATA AND METHODS**

In this brief, we compare prices and out-of-pocket (OOP) costs for GLP-1 or AOM medications. We start by examining the growth of AOM medications over time across the U.S. market, in Medicaid, and in Medicare Part D.

We then compare three price measures for seven key drugs in the class ("specified drugs"): Mounjaro, Ozempic, Rybelsus, Saxenda, Victoza, Wegovy, and Zepbound. We look at the Wholesale Acquisition Cost (WAC) or "list price," of a typical one-month prescription of the medication. We compare this to the average price in other countries. Finally, we include net prices that approximate the price ultimately paid for the medication.

The drug pricing and spending measures included in our analysis provide valuable, but distinct, insights into drug pricing. The WAC represents the baseline list price set by the manufacturer, before any discounts or rebates. The drug net price is the actual amount paid for a medication after accounting for discounts, rebates, and other price reductions, reflecting the true cost to the payer, such as an insurer or healthcare provider. The international prices provide a comparison of these list and net prices to countries with differing pharmaceutical pricing policies.

Finally, we examine cost sharing for enrollees receiving these medications in the Medicare program to better understand how CMS' proposed change to allow Medicare Part D enrollees to receive these drugs for the treatment of obesity may impact the Medicare program.

The data sources and details of these measures are described below.

## Wholesale Acquisition Cost or "List Price"

Manufacturers report their list prices for drugs at the 11-digit National Drug Code (NDC-11) level to independent databases known as pricing compendia. For context, an NDC identifies a drug's labeler code (in this brief, we define a product at the full eleven-digit NDC level unless otherwise noted), product code (which identifies the drug's strength, dosage form, and formulation), and package code (which identifies package size and type); thus, any given drug may have a single NDC or many NDCs, for example, if the drug has multiple formulations or package sizes. The pricing compendia vendors aggregate this information for purchasers such as wholesalers, pharmacies, and hospitals. The databases are available for purchase under subscription licenses allowing for daily updates.

Our primary data source for list prices is AnalySource, a pricing compendia database that reports list prices for drugs at the NDC-11 level. The drug pricing and product data underlying AnalySource is from First DataBank's MedKnowledge data resource. AnalySource data provide daily updates on market entry price and list price changes for millions of products (including drugs covered under Medicare Part B and Part D) and includes information on product type, marketing status, drug class, and drug indication. For this analysis, we used the list price as the price for a given NDC at the unit level. List price, as published by First Databank and available through AnalySource, represents the labeler's published catalog or list price for a drug product to wholesalers as reported to First Databank by the labeler. List price does not represent actual transaction prices and does not include discounts, rebates, or other reductions in price, which are considered confidential and proprietary. The list price holds significance as a measure of drug cost because it represents the price set by the manufacturer and influences prices throughout the reimbursement system, including prices paid by Medicare enrollees with coinsurance.

In general, the retail price of a drug at the pharmacy counter is in part determined by negotiations between pharmacies and insurers (or their pharmacy benefit managers (PBMs)) and reflects both wholesale and retail

markups. Those markups compensate the wholesaler and pharmacy, respectively, for the services they provide and for their inventory costs. Analysis by the CBO suggests the retail price of a given drug is generally similar for most payers (public and private insurers and cash-pay patients). Consumers with health coverage who have not yet satisfied their plan's annual deductible typically pay the full retail price. They might pay a lower price if the manufacturer has a discount program for that drug, such as a coupon or rebate program. As specified by their plan's copayment or coinsurance schedule, consumers who have met their deductible pay only a portion of the retail price (or nothing, if they have met their plan's annual out-of-pocket limit). The remainder is paid by their plan or its PBM. Consumers without insurance may pay a pharmacy's "usual and customary" price — which tends to be higher than the net price paid by other payers — or may pay a lower amount using a manufacturer discount program.

#### **U.S. Market Utilization**

Our analysis additionally uses data from IQVIA PayerTrak in order to provide estimates of pricing and revenue expenditures for the aggregate pharmacy retail sector<sup>‡‡‡‡</sup> in the United States market. IQVIA PayerTrak measures the United States' pharmaceutical drug supply via revenue and volume sales purchased through retail pharmacies. It directly captures approximately 93 percent of the total pharmaceutical market sales and further utilizes a proprietary projection methodology stratified by geography and outlet characteristics to provide comprehensive estimates that reflect the total estimated utilization within the United States. The underlying data for IQVIA is sourced from actual prescription fills stemming from 49,000 pharmacies.

#### **International Prices**

We use data reported by the Peterson Center on Healthcare and the Kaiser Family Foundation (KFF)<sup>19</sup> on 2023 prices for Ozempic, Rybelsus, Wegovy, and Mounjaro in Australia, Canada, France, Germany, Japan, the Netherlands, Sweden, Switzerland, and the United Kingdom. We compare the minimum and maximum prices reported for a one-month supply of medication to average prices in the United States. The Peterson Center-KFF report did not include data on Saxenda, Victoza, or Zepbound. Additional information on the international data and methods used is available from the Peterson Center on Healthcare and KFF.

#### **Net Prices**

Using SSR Health's US prescription brand pricing data tool, net pricing quarterly data was obtained. These data include net prices for approximately 1,000 drugs from approximately 100 companies, and for each product, list pricing, unit volume, and net pricing are available. There are separate estimates of WAC-to-net discounts for Medicaid and non-Medicaid markets, and the latter were used.

# **Medicare Spending and OOP costs**

Analyses of Medicare Part D enrollee out-of-pocket costs for specified AOMs are based on Medicare Part D Prescription Drug Event (PDE) data and Medicare enrollment data. All estimates of out-of-pocket costs refer to what patients actually paid rather than to the True Out of Pocket (TrOOP) costs that advance Part D enrollees through the phases of the Part D benefit, which may include Coverage Gap Discount payments by manufacturers and other third-party spending as well as patient payments.

<sup>\*\*\*\*</sup> In this brief, pharmacy retail refers to retail pharmacies, mail-order pharmacies, and long-term care facilities.

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