MILLIMAN REPORT

Impact of Anti-Obesity Medication Coverage in Medicare Part D

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I. EXECUTIVE SUMMARY

Novo Nordisk, Inc. (NNI) engaged Milliman to analyze the impact of modifying Part D policy to permit United States Food and Drug Administration (FDA) approved anti-obesity medications (AOMs) to be covered under Medicare Part D. In the past several years, there have been substantial changes in the perception of obesity treatments and advances in AOMs, specifically glucagon-like peptide-1 agonists (GLP-1s). The media attention and market demand for GLP-1 AOMs have been a significant topic in public discourse, especially since the launch of Wegovy in June 2021 and Zepbound in October 2023.[1] Both of these recently approved products are also indicated for Type 2 Diabetes Mellitus (T2DM) and are expected to receive expanded indications to treat a variety of other chronic diseases. These expanded indications would be eligible for Part D coverage, but obesity-specific indications remain non-covered by Medicare under current law.

This report focuses on how requiring Part D coverage of the AOM class could affect Medicare stakeholder costs. When AOM coverage is added, Part D costs increase as people who were not otherwise eligible to use an AOM begin therapy. Over time, the portion of patients who remain adherent to therapy and lose weight may begin to experience improved health outcomes, potentially causing both medical and Part D costs to decrease as certain services are reduced or avoided. We present a range of cost impacts incorporating different levels of potential medical and drug savings associated with weight loss.

We analyzed the impact over a 10-year time horizon from 2025 through 2034. Table 1 shows the estimated 10-year impact of AOM coverage on total Medicare costs.

Table 1
Impact of Adding AOM Coverage to Part D
2025 Through 2034 Estimated Changes in Stakeholder Costs

	In Billions	Per Member Per Month (PMPM)
Changes in Total Costs Relative to the Baseline		
Member[1]	$0.0 to $0.7	$0.00 to $0.10
Federal Government[2]	-$6.4 to $0.9	-$0.88 to $0.13
Manufacturer[3]	$0.5 to $0.7	$0.08 to $0.10
Total[4]	**-$5.8 to $2.3**	**-$0.79 to $0.33**
Changes in Part D Costs Relative to the Baseline		
Member[1]	$0.7 to $0.7	$0.10 to $0.11
Federal Government[2]	$0.8 to $1.6	$0.12 to $0.23
Manufacturer[3]	$0.5 to $0.7	$0.08 to $0.10
Total[4]	**$2.0 to $3.0**	**$0.29 to $0.43**
Changes in Medical Costs Relative to the Baseline		
Member[1]	-$0.7 to -$0.1	-$0.09 to -$0.01
Federal Government[2]	-$7.2 to -$0.7	-$0.99 to -$0.09
Manufacturer[3]	N/A	N/A
Total[4]	**-$7.9 to -$0.7**	**-$1.08 to -$0.10**

[1] Member cost includes cost sharing and premium. A portion of medical cost sharing may be covered by Medicaid or employers, but full cost sharing is shown here.
[2] Government costs include all government claim expenses for Medicare Parts A, B, and D, Medicare Advantage payment rates and Part C rebate payments, and Part D subsidies for low-income member cost sharing and premiums.
[3] Manufacturer costs include manufacturer discount program (MDP) payments and exclude rebates.
[4] Totals may not tie exactly to shown sums due to rounding.

Our analysis is based on a number of key assumptions regarding AOM market share, rebates, patient adherence, and the degree of cost offsets that could be associated with weight loss. The per AOM utilizer magnitudes of our cost offset assumptions are based on published literature on medical cost offsets resulting from weight loss, described in the methodology of this report. While we applied these literature-based assumptions to the portion of the population assumed to take AOMs in our analysis, we did not evaluate the efficacy of AOMs or longitudinal impacts of weight loss on medical costs.

[1] https://www.milliman.com/-/media/milliman/pdfs/2023-articles/8-28-23_glp-1s-for-weight-loss_20230824.ashx

Total Medicare program costs could increase or decrease depending on the degree of cost offsets achieved, with the change to total program costs over the ten-year period ranging from -$5.8 billion to +$2.3 billion, or -0.1% to +0.03% of Medicare costs. The results are sensitive to the assumptions used, which are detailed within the report. We only apply savings to patients using products with obesity indications, as any savings from weight loss associated with other GLP-1 use (e.g., diabetes) would exist in the baseline scenario.

Results under alternate scenarios for a few key scenarios are as follows:

- Long-term cost offsets resulting from obesity are difficult to predict. As such, we tested the impact of results absent any cost offsets, which would cause total program costs to increase by $3.1 billion between 2025 and 2034, which represents 0.02% of total Medicare costs.

- Differences in uptake would also impact results. We assume 4% of eligible patients will use AOMs. Assuming a lower or higher uptake and no cost offsets would result in an increase in total Medicare costs of $1.0 billion to $5.2 billion over the ten-year period.

- As described above, Wegovy and Zepbound are expected to receive additional indications covered under Part D. The results in Table 1 exclude beneficiaries with these conditions, as these beneficiaries would be able to access a GLP-1 under a Part D covered indication. However, these indications have not yet received FDA approval and we do not know with certainty that they will be approved. As such, we also tested the sensitivity of results in which we only consider currently approved indications with Part D coverage (T2DM). This results in a greater incremental impact of AOM coverage, resulting in a range of total costs to the program from -$16.8 billion to +$4.3 billion.

II. BACKGROUND

AOM LANDSCAPE AND RECENT MARKET EVENTS

Prior to December 2014, AOMs were comprised of a mix of brand and generic therapies, with phentermine-based products most frequently prescribed.[2] In December 2014, Saxenda (liraglutide) received FDA approval as the first GLP-1 approved for chronic weight management.[3] Saxenda grew its marketshare to become the leading brand AOM over the next several years. Further changing the landscape, in June 2021 the FDA approved Wegovy (semaglutide), another GLP-1.[4] Both Wegovy, approved for chronic weight management and Ozempic, which uses the same ingredient to treat Type 2 Diabetes Mellitus (T2DM), experienced significant growth and became the topic of significant media attention and market demand after the launch of Wegovy. The attention has expanded to Zepbound (tirzepatide), approved for chronic weight management in October 2023 and Mounjaro, which contains the same active ingredient, but is indicated for T2DM.[5] Both semaglutide and tirzepatide are anticipated to receive expanded indications to treat a variety of other chronic diseases as well.[6,7] In particular, we anticipate the following indications for Wegovy may be approved in 2024 or 2025, however, approval is not guaranteed:

- Atherosclerotic Cardiovascular Disease (ASCVD)
- Chronic Kidney Disease (CKD)
- Nonalcoholic steatohepatitis (NASH)

GLP-1s are being studied in additional areas including obstructive sleep apnea, Alzheimer's disease, and heart failure with preserved ejection fraction (HFpEF). These indication expansions may also be approved over the course of the next several years although this is not certain.

AOM COVERAGE IN PART D

Currently, the Part D program excludes "agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose (i.e., morbid obesity))," as well as products aimed to treat erectile dysfunction, promote fertility, and more.[8] These groups of products are referred to as non-covered Part D drugs. Medicare Plan sponsors can only cover these types of drugs on enhanced plan designs, and the claims are not adjudicated within the typical Part D design framework. This means that after patient cost sharing is determined, the plan sponsor must cover the remaining costs without manufacturer discount program (MDP) or reinsurance offsets, and non-covered Part D costs do not accumulate within the Part D benefit drug spend. With the exception of generic erectile dysfunction products and a few highly competitive regional markets, coverage of any non-covered Part D drugs is rare due to premium pressures and plan sponsor concerns regarding anti-selection.

AOM coverage in Part D would require congressional or administrative action differentiating between weight loss medications used solely for cosmetic purposes and FDA approved AOMs for treatment of a chronic disease (obesity).[9] From a congressional action standpoint, S.596 – Treat and Reduce Obesity Act (TROA) was introduced in the Senate in March 2021.[10]

[2] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3814438/*
[3] *https://www.prnewswire.com/news-releases/novo-nordisk-receives-fda-approval-for-saxenda-liraglutide-rdna-origin-injection-for-chronic-weight-management-300013975.html*
[4] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014*
[5] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management*
[6] *https://www.novonordisk.com/science-and-technology/r-d-pipeline.html*
[7] *https://www.lilly.com/discovery/clinical-development-pipeline*
[8] *CMS (January 15, 2016). Medicare Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements. Retrieved May 25, 2021, from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.*
[9] *https://www.milliman.com/-/media/milliman/pdfs/2023-articles/8-28-23_glp-1s-for-weight-loss_20230824.ashx*
[10] *https://www.congress.gov/bill/117th-congress/senate-bill/596/text*

III. RESULTS

STAKEHOLDER IMPACTS

Table 2 shows the estimated 10-year impact of AOM coverage on total Medicare costs by Medicare stakeholder.

Table 2
Impact of Adding AOM Coverage to Part D
2025 Through 2034 Changes in Stakeholder Costs

	In Billions	PMPM
Changes in Total Costs Relative to the Baseline		
Member[1]	$0.0 to $0.7	$0.00 to $0.10
Federal Government[2]	-$6.4 to $0.9	-$0.88 to $0.13
Manufacturer[3]	$0.5 to $0.7	$0.08 to $0.10
Total[4]	**-$5.8 to $2.3**	**-$0.79 to $0.33**
Changes in Part D Costs Relative to the Baseline		
Member[1]	$0.7 to $0.7	$0.10 to $0.11
Federal Government[2]	$0.8 to $1.6	$0.12 to $0.23
Manufacturer[3]	$0.5 to $0.7	$0.08 to $0.10
Total[4]	**$2.0 to $3.0**	**$0.29 to $0.43**
Changes in Medical Costs Relative to the Baseline		
Member[1]	-$0.7 to -$0.1	-$0.09 to -$0.01
Federal Government[2]	-$7.2 to -$0.7	-$0.99 to -$0.09
Manufacturer[3]	N/A	N/A
Total[4]	**-$7.9 to -$0.7**	**-$1.08 to -$0.10**

[1] Member cost includes cost sharing and premium. A portion of medical cost sharing may be covered by Medicaid or employers, but full cost sharing is shown here.
[2] Government costs include all government claim expenses for Medicare Parts A, B, and D, Medicare Advantage payment rates and Part C rebate payments, and Part D subsidies for low-income member cost sharing and premiums.
[3] Manufacturer costs only include MDP payments.
[4] Totals may not tie exactly to shown sums due to rounding.

In Table 2 and throughout this report, "Medical Costs" refer to costs attributable to Medicare Advantage and Medicare Fee-For-Service (FFS), including Medigap plans (Medicare Part A, B, and C). All results reflect Medicare beneficiaries that are enrolled in a Part D plan of any type (i.e., excludes costs for beneficiaries without MAPD or PDP coverage).

Results are dependent on several key assumptions discussed throughout this report. The range of values shown in Table 2 represents different levels of potential cost offsets associated with weight loss for the portion of utilizers who remain adherent to therapy. Our cost offset assumptions are based on published studies, but it is important to consider long-term longitudinal real-world cost offset studies are not yet available for GLP-1s. We anticipate Wegovy and Zepbound will capture the majority of the AOM market share in our projection, but these products launched within the last few years, so there have not been long-term analyses of health care cost offsets driven by these therapies. Actual cost offsets may deviate, either higher or lower, from these assumptions. We did not independently evaluate the efficacy of AOMs or longitudinal impacts of weight loss on medical costs.

We assumed 0.3% of all Part D beneficiaries would use AOMs, with an average of approximately seven scripts per patient taking an AOM. We developed assumptions based on commercial market experience and our review of literature related to changes in utilization resulting from changes in patient cost sharing. Our uptake assumption is 4% of *eligible* Part D beneficiaries (those with obesity or who otherwise meet the Wegovy or Zepbound label criteria) will use an AOM. We assumed a consistent level of uptake in all years. There are additional current and anticipated indications for the same active ingredient of some AOMs (e.g., semaglutide, tirzepatide). As such, we assumed the population of beneficiaries eligible to begin AOM therapy excludes beneficiaries eligible to be treated under a different indication, as this use would be covered under Part D in the baseline. We also tested the sensitivity of this approach by only excluding beneficiaries with a current approved indication (T2DM), which would result in 0.5% of Part D beneficiaries using AOMs. Further details on this testing can be found in the Sensitivity Testing section of this report.

Part D projections account for provisions of the IRA, including benefit redesign and price negotiation. We assume that Wegovy (semaglutide) and Zepbound (tirzepatide) will be negotiated upon initial eligibility. However, prior to negotiation, we anticipate a high degree of competition in the class, with high rebate levels similar to other highly competitive classes in Part D. Results are sensitive to rebate assumptions; lower rebate levels could result in an increase in costs for all stakeholders. Conversely, we assume MFP levels are approximately equal to ceiling prices; if the Centers for Medicare and Medicaid Services (CMS) negotiates a lower MFP, cost impacts could be lower than shown above.

All estimates assume CMS will change AOMs to a Part D-covered class, as opposed to optional supplemental coverage. The results are not appropriate if the AOM class remains excluded from Part D.

Appendix A includes the breakdown of values above by modeled cash flows from each stakeholder, both in billions and on a per member per month (PMPM) basis.

In this report and in Appendix A, we show impacts to the three primary Medicare stakeholders: the Federal government, beneficiaries, and pharmaceutical manufacturers. We treat plan sponsors as "pass-through" stakeholders, meaning they are not directly responsible for funding the program and the impacts of this analysis are fully captured by the cost impacts presented for the Federal government, beneficiaries, and pharmaceutical manufacturers. However, as part of this analysis we estimate the impact to risk adjusted plan bid amounts to range from $0.07 PMPM to $0.15 PMPM increases on average over the 10-year period. These costs are then covered through increases to direct subsidy and member premium. While these impacts do not directly increase plan costs, the incremental amount increases the degree of risk borne by plan sponsors.

Government Cost Impact

Table 3 shows further detail on the changes in Federal Government costs attributable to Part D coverage of AOMs.

Table 3
Impact of Adding AOM Coverage to Part D
2025 Through 2034 Changes in Federal Government Costs*

	In Billions	PMPM
Total	**-$6.4 to $0.9**	**-$0.88 to $0.13**
Part D	**$0.8 to $1.6**	**$0.12 to $0.23**
Direct Subsidy	$0.5 to $1.0	$0.07 to $0.15
Reinsurance	$0.0 to $0.2	$0.00 to $0.03
Low Income Cost Share Subsidy	$0.2 to $0.2	$0.02 to $0.03
Low Income Premium Subsidy	$0.0 to $0.0	$0.00 to $0.00
Government MDP	$0.1 to $0.1	$0.02 to $0.02
Medical	**-$7.2 to -$0.7**	**-$0.99 to -$0.09**
Medicare FFS	-$1.6 to -$0.2	-$0.62 to -$0.06
Medicare Advantage	-$5.6 to -$0.5	-$1.20 to -$0.11

**Totals may not tie exactly to shown sums due to rounding.*

Government costs for the Part D benefit increase in aggregate. This increase is attributable primarily to an increase in the direct subsidy, as well as increases to reinsurance, low income cost sharing (LICS), and the government share of MDP liability for negotiated drugs. However, increased government costs for Part D are partly or fully offset by lower expected Medicare FFS costs and Medicare Advantage payments related to medical services.

Member Cost Impact

Table 4 shows the changes in member premium and cost sharing attributable to Part D coverage of AOMs.

Table 4
Impact of Adding AOM Coverage to Part D
2025 Through 2034 Changes in Member Costs*

	In Billions	PMPM
Total	**$0.0 to $0.7**	**$0.00 to $0.10**
Member Premium	-$0.4 to -$0.1	-$0.05 to -$0.01
Member Cost Sharing	$0.4 to $0.7	$0.06 to $0.11
Part D	**$0.7 to $0.7**	**$0.10 to $0.11**
Member Premium	-$0.1 to $0.0	-$0.01 to $0.00
Member Cost Sharing	$0.7 to $0.8	$0.11 to $0.11
Medical	**-$0.7 to -$0.1**	**-$0.09 to -$0.01**
Member Premium	-$0.3 to $0.0	-$0.04 to $0.00
Member Cost Sharing	-$0.4 to $0.0	-$0.05 to $0.00

**Member cost includes cost sharing and premium. Medical cost sharing may be covered by Medicaid or employers. Totals may not tie exactly to shown sums due to rounding.*

The primary driver of increased member costs is an increase in Part D member cost sharing. Please note, this analysis assumes a defined standard plan design, as we expect most AOMs would be placed on a tier with limited benefit enhancement. Any Part D benefit enhancement would shift costs from member cost sharing to premium. Wegovy and Zepbound, which we project would make up the majority of AOM market share, would both be eligible for the specialty tier, for which nearly all plans apply defined standard cost sharing.

Different types of beneficiaries will be impacted differently by AOM coverage. Generally, only beneficiaries who use AOMs will experience meaningful changes in costs. Non-low income members using brand AOMs subject to a coinsurance would see the greatest cost sharing increase. Low income member cost sharing is highly subsidized, but these members would pay a nominal copay for each new fill. While any premium changes would flow to all Part D beneficiaries, the premium stabilization provision of the IRA—which increases the direct subsidy higher than it otherwise would have been—results in a negligible average nationwide premium impact.

On the medical side, cost offsets associated with weight loss result in decreases to member premium and cost sharing. Only members who are adherent to therapy would experience any kind of medical claim reduction and corresponding reduction in total cost sharing. Premium changes, on the other hand, would be spread across all Medicare beneficiaries, though the magnitude of premium reduction is negligible. Note, medical member premium includes Part B premiums, Medigap premiums, and the Part C portion of MAPD premiums.

Beneficiaries may be affected differently by AOM coverage depending on the plan type and market segment of enrollment, as plan decisions may differ. PDPs, focusing more on net drug cost, may have stricter coverage and more utilization management programs than MAPD plans. MAPD plans could benefit more from cost offsets from AOM use, where PDPs would be limited only to savings from any reduction in other drug therapies. The individual market and employer group waiver plans (EGWPs) may also be impacted differently. EGWPs, which tend to have more open formularies, richer benefits, and better member retention due to employer subsidies, may see higher AOM use and long-term benefits from medical cost offsets. We assumed no AOM coverage among EGWPs in the baseline, though because these plans tend to offer richer coverage that more closely mirrors the commercial market, it is possible EGWPs may choose to cover AOMs even without a policy change requiring coverage, which would slightly dampen our results.

Other Considerations

The timing of cost offsets is important. If short-term savings are not realized, or if a beneficiary switches plans before medical cost savings are seen, plans may have reduced incentives for strong coverage. In our cost offset scenarios, we assume savings begin in the second year of treatment and only continue for members who remain adherent to therapy.

We did not modify the risk score models for potential changes due to AOM coverage, though model changes, such as the incorporation of obesity diagnoses could occur. The Part D risk model is calibrated on overall Part D costs associated with a given condition, without consideration for actual drug utilization or differences in cost among different

therapies. As such, the risk model may result in underpayment for patients using brands or overpayments for patients using generics. Plans may consider this when deciding which AOMs to cover.

Part D premium stabilization began in 2024 as part of the IRA, which results in a greater direct subsidy and lower member premium than in the absence of premium stabilization. If premium stabilization was not in effect, federal government costs would be lower by way of lower direct subsidy payments and Part D member costs would increase, in the form of higher member premiums. While overall Part D premiums would be higher in the absence of premium stabilization, the impact of AOM coverage would still be minimal, due to assumed high rebate levels and price negotiation on the two leading AOM products.

More broadly, plans may also exhibit behavioral responses which impact beneficiary experience:

- *Formulary coverage:* Plan sponsors and PBMs will likely analyze AOM costs, including potential cost offsets, as they make formulary decisions. Given Part D formulary rules only mandate covering two drugs within each class, formulary design will likely focus on covering the products that optimize efficacy and financial results. Because Wegovy and Zepbound are similar products, competition is likely to be high, and coverage is likely to mirror other highly competitive classes, such as insulins, in which plans often cover a single manufacturer's products exclusively in exchange for high rebate levels.

  For products that are on formulary, plans will also need to make tiering decisions, though tiering decisions will be less impactful than they historically would have been due to the implementation of a maximum out-of-pocket and cost sharing smoothing flexibilities in Part D under the IRA.

- *Utilization management strategies:* AOMs would likely have utilization management criteria attached to them to prevent off-label utilization and ensure medical necessity, similar to the observed increases in GLP-1 utilization management for diabetes therapies in Part D over the past several years. Tighter utilization management is particularly likely in the PDP space, where plan sponsors would not benefit nearly as much from any potential medical cost savings offsets.

There are also incremental costs to pharmaceutical manufacturers in pharmacy costs in the form of additional MDP payments for applicable AOMs. MDP payments will also increase slightly for non-AOM brands as AOM scripts filled earlier in the benefit will shift the distribution of non-AOM costs to later in the benefit where manufacturer liability under the MDP program is higher.

Sensitivity Testing

Given AOMs have never been covered by Medicare before, and the market leading products were introduced within the last few years, a number of assumptions were necessary for this analysis. Among the assumptions used, the degree of AOM uptake and potential for cost offsets are difficult to predict. As such, we tested the sensitivity of these two assumptions, with the results shown in Table 5 below:

Table 5
Impact of Adding AOM Coverage to Part D
2025 Through 2034 Changes in Stakeholder Costs

	In Billions			PMPM		
	Low Uptake	Mid Uptake	High Uptake	Low Uptake	Mid Uptake	High Uptake
Member[1]	$0.2	$0.8	$1.3	$0.03	$0.11	$0.18
Federal Government[2]	$0.5	$1.7	$2.8	$0.08	$0.24	$0.40
Manufacturer[3]	$0.2	$0.7	$1.2	$0.03	$0.10	$0.17
Total[4]	**$1.0**	**$3.1**	**$5.2**	**$0.15**	**$0.45**	**$0.75**

[1] *Member cost includes cost sharing and premium.*

[2] *Government costs include all government claim expenses for Medicare Part D and Part D subsidies for low-income members.*

[3] *Manufacturer costs include MDP payments and exclude rebates.*

[4] *Totals may not tie exactly to shown sums due to rounding.*

Table 5 shows results under three different uptake scenarios. The "mid" uptake assumes 4% of eligible patients use AOMs, as discussed previously. The low and high uptake assumptions assume 1.3% and 6.7% of eligible patients use AOMs, respectively, which could increase or decrease total program costs by about $2 billion. Furthermore, all

scenarios in Table 5 assume no cost offsets associated with weight loss, as compared to Tables 1 through 4, which showed a low to high range of potential cost offsets. In the absence of any medical cost offsets, we estimate AOM coverage could increase total Medicare costs by $1.0 billion to $5.2 billion over the 10-year study period, or about 0.01% to 0.03% of total program costs. With potential savings, total program costs could increase or decrease, with the midpoint of our scenarios showing a decrease in costs of $1.8 billion.

Our results are also dependent on the assumption that semaglutide and / or tirzepatide receive approval for certain additional indications expected to be approved within the next year. As such, we exclude beneficiaries with these conditions, as they would be able to access GLP-1s with Part D coverage in the baseline. However, if these indications are not approved, the incremental impact of adding AOM coverage to Part D would be greater than presented in Tables 1 through 5. We tested a scenario in which we only exclude beneficiaries with T2DM (the currently approved Part D covered indication) from the pool of patients who would use an AOM. This increases the number of utilizers by approximately 90%. Results under this scenario are shown in Table 6 below:

Table 6
Impact of Adding AOM Coverage to Part D
2025 Through 2034 Estimated Changes in Stakeholder Costs
Excluding Current Approved Indications Only

	In Billions	Per Member Per Month (PMPM)
Changes in Total Costs Relative to the Baseline		
Member[1]	-$0.4 to $1.2	-$0.06 to $0.17
Federal Government[2]	-$17.3 to $1.8	-$2.38 to $0.26
Manufacturer[3]	$1.0 to $1.3	$0.14 to $0.18
Total[4]	**-$16.8 to $4.3**	-$2.29 to $0.62
Changes in Part D Costs Relative to the Baseline		
Member[1]	$1.1 to $1.3	$0.16 to $0.19
Federal Government[2]	$1.4 to $3.0	$0.20 to $0.43
Manufacturer[3]	$1.0 to $1.3	$0.14 to $0.18
Total[4]	**$3.5 to $5.6**	$0.50 to $0.81
Changes in Medical Costs Relative to the Baseline		
Member[1]	-$1.6 to -$0.1	-$0.21 to -$0.01
Federal Government[2]	-$18.7 to -$1.3	-$2.58 to -$0.17
Manufacturer[3]	N/A	N/A
Total[4]	**-$20.2 to -$1.4**	-$2.79 to -$0.19

[1] Member cost includes cost sharing and premium. Medical cost sharing may be covered by Medicaid or employers, but full cost sharing is shown here.
[2] Government costs include all government claim expenses for Medicare Parts A, B, and D, Medicare Advantage payment rates and Part C rebate payments, and Part D subsidies for low-income member cost sharing and premiums.
[3] Manufacturer costs include manufacturer discount program (MDP) payments and exclude rebates.
[4] Totals may not tie exactly to shown sums due to rounding.

The impact to Part D costs is greater in this scenario due to more assumed AOM utilizers. Note, semaglutide is currently seeking approval for other Part D covered indications such as Alzheimer's Disease, peripheral arterial disease, heart failure with preserved ejection fraction, and sleep apnea. If these additional indications are also approved, the incremental impact of adding obesity coverage could be lower because Part D beneficiaries would already be able to access these medications through a Part D covered indication.

IV. METHODOLOGY AND ASSUMPTIONS

Many assumptions were needed for this analysis. We used a combination of literature, claims data, and pipeline information to inform our work. Claims data was used to inform most of the assumptions in the model.

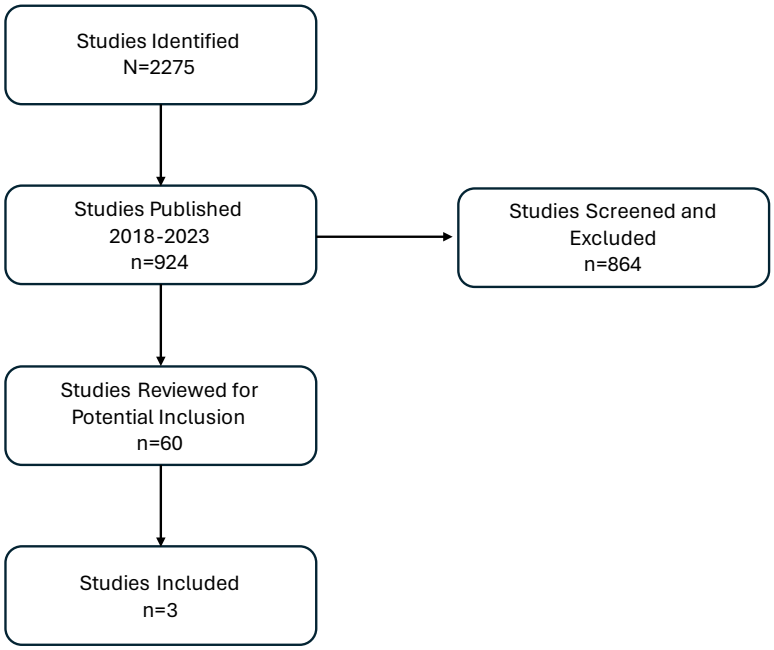
LITERATURE REVIEW

For literature-based questions, two approaches were used. First, published clinical trial results for liraglutide, semaglutide, and tirzepatide were included. Additionally, literature searches using PubMed were conducted to obtain cost-effectiveness values and medical cost savings associated with the following:

- Weight loss
- AOM discontinuation rates
- Long-term weight loss
- Percentage of individuals regaining lost weight and timing of weight regain
- Demographics and income of individuals associated with current GLP-1 use
- Cost associated with treating adverse effects of GLP-1 use

Criteria were defined and results had inclusion and exclusion criteria applied. The search was limited to publications from 2018 to 2023, and results needed to be available for a U.S. adult population. We excluded publications that included indirect costs, were study design only publications, were conducted outside of the U.S. only, or did not list a data value for one of the areas we targeted. The majority of trials were eliminated based on year published. That single criterion resulted in 60% of the articles being excluded. The remainder were excluded for one of the other reasons listed above. After exclusion, there were 60 remaining studies that could help inform assumptions. In the end, claims data was able to inform most of the assumptions used, so ultimately only three articles were used to inform the modeling. Two of the three provided values for medical cost offsets and the third was used in combination with claims-based analysis to inform the AOM uptake methodology. Figure 1 displays the process and cumulative number of articles meeting inclusion criteria for the literature searches.

Figure 1. Number of Articles Identified and Used to Inform Model Assumptions*



**Individual searches were conducted for each assumption. An article may inform multiple assumptions and appear in more than one search.*

KEY ASSUMPTIONS RELATED TO AOMS

One of the biggest assumptions underlying the results is the magnitude of cost offsets associated with weight loss. Cost offsets are only applied to adherent patients, in the year following adherence to therapy. In the year following the first year of non-adherence, patient costs return to what they were in the baseline scenario. For the magnitude of cost offsets, we relied on existing literature which studied longitudinal cost offsets resulting from weight loss and adjusted to suit the Medicare population as appropriate. We assumed cost offsets apply to both Part D and medical costs in this analysis. The low and high cost offset scenarios were projected as follows:

- *Low cost offset scenario*: This scenario used the implied per patient per year savings in the study "Benefits of Medicare Coverage for Weight Loss Drugs" from USC Schaeffer, with adjustments for the level of weight loss expected to be achieved.[11] This study modeled medical cost offsets associated with TROA, with projected 10-year savings of $175 billion to $245 billion. The low end savings assumed coverage was added to the Medicare market only, while the high end achieved additional savings to the Medicare program due to assumed AOM coverage in the commercial market as well, assuming people entering Medicare at age 65 would have better health and lower costs than if they had not lost weight. We used the low end savings, divided by the total number of treatment-eligible patients, and calculated an implied cost savings of $529 per member per year. This resulted in average cost savings of about 3% per adherent patient.

- *High cost offset scenario*: This scenario used the results of the study "Weight Loss-Associated Decreases in Medical Care Expenditures for Commercially Insured Patients With Chronic Conditions."[12] This study observed the second year healthcare costs for patients with various comorbidities who lost weight. We applied cost savings based on adherent patients if they had one of the comorbidities listed below. Many patients have more than one comorbidity, in which case we applied savings from the comorbidity with the greatest percentage savings, so as not to duplicate savings from overlapping groups:

  - Hyperlipidemia
  - Hypertension
  - Mental health disorders
  - Pulmonary disease
  - Arthritis
  - Back pain

  The study reported detailed costs by these comorbidities and by percent reduction in BMI. A large portion of savings in the study were for patients with diabetes, however we did not include any of this savings in our analysis as we excluded patients with T2DM. We applied savings on a percentage basis, using the average BMI reduction reported in clinical trials for each of the AOMs in our analysis, which ranged from 5.6% to 20.9% BMI reduction. Based on this approach, total average cost savings for adherent patients with specified comorbidities was about 18% of baseline medical and Part D costs.

Additional assumptions needed for adding AOM claims are as follows:

- **Eligible population:** We assumed beneficiaries eligible to use AOMs are those who meet the label criteria for AOM use, but who are not eligible for indications of AOM molecules approved for other conditions covered by Part D. We began by identifying all Part D beneficiaries with obesity or who are overweight with a comorbidity on either the Wegovy or Zepbound label. We excluded beneficiaries who currently use semaglutide (the active ingredient in Wegovy) or those with T2DM, as patients with T2DM are able to access GLP-1s under Part D today. In the "expanded indications" scenario, we further excluded beneficiaries who would be eligible to use semaglutide for the following indications expected to be approved prior to our study period:

  - ASCVD
  - CKD
  - NASH

  ASCVD, CKD, and NASH are all anticipated to have FDA approvals by 2025, and as such, Part D beneficiaries with these conditions would have access to GLP-1s without any AOM coverage policy change.

[11] *https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/*
[12] *https://pubmed.ncbi.nlm.nih.gov/34138824/*

- **Overall AOM class uptake in Part D:** To develop the percentage of eligible beneficiaries expected to utilize AOMs in Part D, we used commercial (primarily large group) market data from Q1 2023. We measured AOM utilization rates among groups assumed to have robust brand AOM coverage. We observed differences in AOM utilization by age, so we developed a regression model to estimate the utilization for Medicare Part D, calibrated to the average age of an eligible Medicare beneficiary.

  Since Zepbound was not on the market as of Q1 2023, we further increased the estimated uptake percentage to account for increased utilization stemming from this launch. We assumed total AOM utilization will grow, such that Zepbound and Wegovy market share are equal. Our best estimate uptake assumption as a percentage of eligible beneficiaries is 4.0%, which underlies the results shown in Tables 1 through 4. To test the sensitivity of uptake assumptions, we also estimated additional low and high uptake estimates as a percentage of eligible beneficiaries to be 1.3% and 6.7%, respectively, as shown in Table 5.

- **AOM market share distribution:** We relied on Q1 2023 commercial market data for market share. We adjusted the observed market share based on the following key market dynamics and events:

  - Average generic dispensing rate differences for non-AOMs between commercial and Part D markets.
  - The introduction of Zepbound in October 2023, assumed to grow to match the market share of Wegovy by our projection period.
  - The anticipated patent loss for Saxenda.

- **AOM gross and net prices:** We modeled the gross and net prices for AOMs as follows:

  - *Gross Price:* We relied on current WAC from Medi-Span for brand AOMs and average allowed cost per script from 2023 commercial claims data for generics. We applied trends each year based on the 2022 Medicare Trustees Report Part D per capita cost trends.
  - *Net Price:* Prior to the application of MFPs, we assumed net prices will decrease by about 6% per year. This is based on a combination of overall average brand net price changes and net price changes specific to insulins, as the AOM class is expected to have similar competitive dynamics as insulin.[13],[14] Once a brand is assumed to have an MFP, we remove all rebates and hold the price constant.
  - *Medicare Price Negotiation:* We assumed Wegovy (semaglutide) and Zepbound (tirzepatide) are negotiated upon initial eligibility. We estimated MFP levels would be equal to average net prices, and we assume there are no rebates once a product is negotiated.

- **AOM scripts per patient:** We developed the average scripts per patient assumption by studying both Medicare Part D and commercial utilization patterns for analog therapies which we believe will have similar utilization patterns compared to AOMs in Part D. We analyzed 30-day equivalent scripts per patient for Ozempic (semaglutide indicated for T2DM) in Medicare Part D and commercial markets, Wegovy (semaglutide indicated for obesity) in commercial, and Trulicity (dulaglutide, a GLP-1 indicated for diabetes). We reviewed these data points and accounted for known supply shortages for semaglutide loading dose NDCs in the data period, resulting in an average of 6.8 30-day scripts per AOM patient on average.

  We further reviewed the data to estimate the distribution of adherent and non-adherent patients. Based on our analysis, we assumed 69% of patients would be adherent, while 31% of patients would drop off therapy within a given year. In our analysis, we assign nine scripts to adherent patients and two scripts to non-adherent patients. Given the assumed 31% drop off rate, this results in the 6.8 scripts per AOM patient average described above.

CLAIMS PROJECTION METHODOLOGY

We relied on the CMS 100% Research Identifiable File (RIF) dataset, which includes all Medicare Parts A, B, and D paid claims and Medicare Part C encounter data for Medicare beneficiaries to estimate costs for each market by stakeholder. We only included beneficiaries with Part D coverage (i.e., excluding MA-Only plans). We also excluded all hospice costs from all projections. We developed a model leveraging this data to project historical claim data forward to estimate costs specific to each stakeholder liability.

[13] *https://www.drugchannels.net/2023/06/gross-to-net-bubble-update-2022-pricing.html*
[14] *https://www.milliman.com/-/media/milliman/pdfs/2021-articles/12-9-21-analysis-insulin-competition-costs-us.ashx*

We calibrated Part D gross costs to values from the 2023 Medicare Trustees Report. We apply manufacturer rebates at the therapeutic class level consistent with rebate data provided in the June 2023 Medicare Payment Advisory Commission (MedPAC) report.[15] In all scenarios, we reflected the changes impacting the Part D program resulting from the IRA, including the 2025 benefit design change, the MDP and phase-in provisions for specified and specified small manufacturers, price negotiation, and premium stabilization. We assumed a defined standard benefit design, with benefit parameters (i.e., deductible and maximum out-of-pocket limit) consistent with the 2023 Medicare Trustees Report.

We projected medical costs to future years using trends by service category, based on information from the 2023 Medicare Trustees report. We applied FFS cost sharing and an average Medigap plan design for members enrolled in those respective benefit types. For MA cost sharing, we started with an average 2024 MA plan design for Medicare covered services, projected forward to future years based on historical cost sharing trends by service category. The MA projections also include estimates for projected non-Medicare covered costs consistent with levels reported by the MedPAC in its 2023 Report to the Congress.[16]

We also made assumptions for Medigap and MA administrative expenses and margins, future Part B premium rates, and average Part B buy-down for MA members. We assumed MA premium levels would remain constant each year, similar to historical patterns, and that supplemental benefits would be adjusted to account for any changes needed to maintain premium levels.

To determine the total costs (in $B) for the Medicare markets (e.g., fee for service and Medicare Advantage), we used projected membership for each plan type and Part D income status. For both FFS (including Medigap) and MA, we used membership projections through 2032 consistent with the 2023 Medicare Trustees report, and estimated 2033 and 2034 using trends from 2025 through 2032.

[15] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.*
[16] *MedPAC (June 2023). Report to the Congress: Medicare and the Health Care Delivery System. Retrieved December 28, 2023, from* https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.

V. CAVEATS, LIMITATIONS, AND QUALIFICATIONS

This report was developed to provide Novo Nordisk with estimates of the combined medical and pharmacy costs of AOM coverage under Medicare Part D. This information may not be appropriate, and should not be used, for other purposes. This report is intended for Novo Nordisk. Novo Nordisk may share this information w/ external parties w/ Milliman's prior written consent. We do not intend this material to benefit any third parties receiving this work product. Any third-party recipient of this report desiring professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to their specific needs. Any release of this report to a third party should be in its entirety.

Milliman has developed certain models to estimate the values included in this report. The intent of the models was to estimate projected Parts A, B, C, and D claim costs, including member cost sharing, plan liability, and government funding. We have reviewed the models, including their inputs, calculations, and outputs, for consistency, reasonableness, and appropriateness to the intended purpose and in compliance with generally accepted actuarial practice and relevant actuarial standards of practice (ASOP).

The models rely on data and information as input to the models. We have relied upon certain data and publicly available information, for this purpose and accepted it without audit, though we reviewed for reasonability. To the extent that the data and information provided is not accurate, or is not complete, the values provided in this report may likewise be inaccurate or incomplete. The models, including all input, calculations, and output, may not be appropriate for any other purpose. Actual results will certainly vary for specific stakeholders due to differences in demographics, trends, discount arrangements, formulary, utilization patterns, and rebate arrangements, among other factors.

Katie Holcomb, Jake Klaisner, Maddie Cline, and Ali Heinrich are actuaries for Milliman, members of the American Academy of Actuaries, and meet the qualification standards of the Academy to render the actuarial opinion contained herein. To the best of their knowledge and belief, this information is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices. This report outlines the review and opinions of the authors and not necessarily those of Milliman. Milliman does not endorse any public policy or advocacy position on matters discussed in this report.

APPENDICES

Appendix A
Novo Nordisk, Inc.
2025 Through 2034 Changes in Stakeholder Costs Relative to Baseline
All Medicare Members

	In Billions			Per Member Per Month (PMPM)		
		Cost Offsets			Cost Offsets	
	Baseline	Assuming Current Approved Indications	Assuming Anticipated Indication Expansions	Baseline	Assuming Current Approved Indications	Assuming Anticipated Indication Expansions
Total Government Costs						
Total	$11,734	-$17.3 to $1.8	-$6.4 to $0.9	$1,625.65	-$2.38 to $0.26	-$0.88 to $0.13
Pharmacy	$1,435	$1.4 to $3.0	$0.8 to $1.6	$205.37	$0.20 to $0.43	$0.12 to $0.23
Direct Subsidy	$878	$0.8 to $2.0	$0.5 to $1.0	$125.64	$0.12 to $0.28	$0.07 to $0.15
Reinsurance	$310	$0.1 to $0.5	$0.0 to $0.2	$44.36	$0.01 to $0.07	$0.00 to $0.03
Low Income Cost Share Subsidy	$140	$0.3 to $0.3	$0.2 to $0.2	$20.00	$0.04 to $0.04	$0.02 to $0.03
Low Income Premium Subsidy	$87	-$0.1 to $0.0	$0.0 to $0.0	$12.40	-$0.01 to $0.00	$0.00 to $0.00
Government MDP	$21	$0.3 to $0.3	$0.1 to $0.1	$2.97	$0.04 to $0.04	$0.02 to $0.02
Medical	$10,299	-$18.7 to -$1.3	-$7.2 to -$0.7	$1,420.28	-$2.58 to -$0.17	-$0.99 to -$0.09
Medicare FFS	$3,317	-$4.2 to -$0.3	-$1.6 to -$0.2	$1,280.42	-$1.62 to -$0.11	-$0.62 to -$0.06
Medicare Advantage	$6,983	-$14.5 to -$1.0	-$5.6 to -$0.5	$1,497.99	-$3.11 to -$0.21	-$1.20 to -$0.11
Total Member Costs						
Total	$4,017	-$0.4 to $1.2	$0.0 to $0.7	$556.76	-$0.06 to $0.17	$0.00 to $0.10
Pharmacy	$537	$1.1 to $1.3	$0.7 to $0.7	$76.84	$0.16 to $0.19	$0.10 to $0.11
Member Premium	$248	-$0.2 to $0.0	-$0.1 to $0.0	$35.50	-$0.02 to -$0.01	-$0.01 to $0.00
Member Cost Sharing	$289	$1.3 to $1.4	$0.7 to $0.8	$41.34	$0.18 to $0.19	$0.11 to $0.11
Medical	$3,480	-$1.6 to -$0.1	-$0.7 to -$0.1	$479.92	-$0.21 to -$0.01	-$0.09 to -$0.01
Member Premium	$2,404	-$0.7 to $0.0	-$0.3 to $0.0	$331.55	-$0.10 to -$0.01	-$0.04 to $0.00
Member Cost Sharing	$1,076	-$0.8 to -$0.1	-$0.4 to $0.0	$148.37	-$0.11 to -$0.01	-$0.05 to $0.00
Total Manufacturer Costs						
Total	$266	$1.0 to $1.3	$0.5 to $0.7	$38.11	$0.14 to $0.18	$0.08 to $0.10
Pharmacy	$266	$1.0 to $1.3	$0.5 to $0.7	$38.11	$0.14 to $0.18	$0.08 to $0.10
Manufacturer Discount Program	$266	$1.0 to $1.3	$0.5 to $0.7	$38.11	$0.14 to $0.18	$0.08 to $0.10

Appendix B
Novo Nordisk, Inc.
Financial Liabilities Modeled for Medicare Stakeholders

Liability	Stakeholder	Market	Benefit	Description
Member Cost Sharing	Member	Medicare FFS, Medicare Advantage, Part D	Pharmacy and Medical	The portion of total cost sharing paid out-of-pocket by members (exclusive of government subsidies).
Member Premium	Member	Medicare FFS, Medicare Advantage, Part D	Pharmacy and Medical	The portion of total member premiums paid out-of-pocket by members (exclusive of government subsidies). For the purpose of our analysis, we focus on basic Part D premium, though plans with enhanced benefits also have additional supplemental premium. This also includes Part B premiums.
Reinsurance	Government	Part D	Pharmacy	The portion of claims paid by the federal government in the catastrophic phase. The government will pay 20% for applicable (typically brand) drugs and 40% for non-applicable (typically generic) drugs.
Medicare Advantage Payments	Government	Medicare FFS, Medicare Advantage	Medical	The government pays private MA plans a capitated amount per enrollee to provide all Part A and B benefits. MAOs must submit an MA bid to CMS. The bid must cover the costs for traditional Part A and Part B benefits, as well as administrative costs and margin.
Medicare FFS Hospital Insurance and Supplementary Medical Insurance Trust Funds	Government	Medicare FFS, Medicare Advantage	Medical	The Federal government pays providers directly for the majority of claim costs, according to an established fee schedule.
Direct Subsidy	Government	Part D	Pharmacy	The estimated direct subsidy paid from the federal government to plans. This covers the portion of the plan bid amount not funded by premium.
Low Income Cost Sharing Subsidy	Government	Part D	Pharmacy	The portion of total cost sharing subsidized by the federal government for low-income (LI) members.
Low Income Premium Subsidy	Government	Part D	Pharmacy	The portion of total member premiums paid by the federal government. The magnitude of both LICS and LIPS subsidies varies based on a member's income level and institutional status.
Manufacturer Discount Program Payments	Manufacturers	Part D	Pharmacy	The portion of claims paid by pharmaceutical manufacturers through the Manufacturer Discount Program (MDP). Note that for products subject to Medicare Price Negotiation, beginning in 2026, manufacturers will not be liable for MDP payments.

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