

MILLIMAN REPORT

# Impact of Covering Anti-Obesity Medications in Medicare Part D

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## I. EXECUTIVE SUMMARY

Novo Nordisk (Novo) engaged Milliman to analyze the impact of modifying Part D policy to permit anti-obesity medications (AOMs) to be covered under Medicare Part D. Currently, AOMs are not covered by Part D and, as such, AOM claims are not adjudicated within the typical Part D design framework. This report focuses on how requiring Part D coverage of the AOM class could affect Medicare as a whole, including both the costs of AOM claims, as well as potential savings offsets related to weight loss achieved by AOM users. For illustration, we present a range of potential savings associated with weight loss in this study, from no savings to aggressive savings. However, a cost effectiveness analysis was outside of the scope of our study. We analyzed the impact over a 10-year time horizon from 2022 through 2031.

Figure 1 shows the estimated 10-year impact of AOM coverage in Medicare Part D on total Medicare costs. Our results reflect assumptions for total AOM utilization and the level of offsetting claim savings from published literature, with two primary limitations: the literature does not specifically address the over 65 population, and the medical costs for patients that lose weight are assumed to decrease in proportion to BMI (as there is limited research available specifically relating weight loss to future healthcare costs). Our analysis makes assumptions for Part D formulary coverage and patient adherence, but excludes any additional Part D stakeholder behavioral changes, such as potential benefit design modifications. The five scenarios shown vary in terms of the degree of medical savings and AOM uptake assumed.

Figure 1 2022 Through 2031 Potential Changes in Stakeholder Costs (in billions) by Scenario All Medicare Members					
Changes in Pharmacy Costs Relative to Baseline					
	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Member <sup>1</sup>	-\$0.2	\$1.1	\$1.1	\$0.1	\$2.5
Federal Government <sup>2</sup>	\$1.0	\$2.5	\$4.5	\$0.6	\$3.6
Manufacturer <sup>3</sup>	-\$0.9	-\$0.1	-\$1.4	-\$0.1	\$0.9
Total <sup>4</sup>	-\$0.1	\$3.5	\$4.3	\$0.5	\$6.9
Changes in Medical Costs Relative to Baseline					
	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Member <sup>1</sup>	-\$1.5	-\$0.6	-\$2.6	-\$0.3	\$0.0
Federal Government <sup>2</sup>	-\$9.0	-\$4.4	-\$16.8	-\$2.1	\$0.0
Manufacturer <sup>3</sup>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Total <sup>4</sup>	-\$10.5	-\$5.0	-\$19.4	-\$2.4	\$0.0
Changes in Total Costs Relative to Baseline					
	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Member <sup>1</sup>	-\$1.6	\$0.5	-\$1.5	-\$0.2	\$2.5
Federal Government <sup>2</sup>	-\$8.0	-\$1.9	-\$12.3	-\$1.5	\$3.6
Manufacturer <sup>3</sup>	-\$0.9	-\$0.1	-\$1.4	-\$0.1	\$0.9
Total <sup>4</sup>	-\$10.6	-\$1.5	-\$15.1	-\$1.9	\$6.9

<sup>1</sup> Member cost includes cost sharing and premium. For FFS members, cost sharing may be covered by Medicaid or employers.

<sup>2</sup> Government costs include all government claim expenses for Medicare Parts A, B, and D, Medicare Advantage payment rates, and Part D subsidies for low-income members.

<sup>3</sup> Manufacturer costs only include CGDP claims.

<sup>4</sup> Totals may not tie exactly to shown sums due to rounding.

Results are provided for each of the following scenarios, relative to a projected baseline in which AOMs continue not to be covered in Part D:

- **Scenario 1 – AOM coverage with moderate uptake and high medical savings:** This scenario assumes 1.6% AOM uptake among Part D members, and we assume a high level of claim savings offsets for the portion of AOM users that lose weight.
- **Scenario 2 – AOM coverage with moderate uptake and low medical savings:** This scenario is consistent with Scenario 1, except that we assume a level of savings offsets at the low end of the considered range of savings offsets.
- **Scenario 3 – AOM coverage with high uptake and moderate medical savings:** This scenario assumes moderate claim savings, between those assumed in Scenarios 1 and 2, and that the overall AOM class uptake

is assumed to be greater, with 4.0% of all Part D members using an AOM.

- **Scenario 4 – AOM coverage with low uptake and moderate medical savings:** This scenario is consistent with Scenario 3, except that the overall AOM class uptake is assumed to be lower, with 0.5% of all Part D members using an AOM.
- **Scenario 5 – AOM coverage with moderate uptake and no medical savings:** This scenario assumes 1.6% AOM uptake among Part D members and assumes no medical savings.

In Scenario 5, absent consideration for any medical savings offsets, government costs are projected to increase by \$3.6 billion, and total program costs are projected to increase by \$6.9 billion. Across scenarios which consider potential savings offsets, government costs are projected to decrease by \$1.5 billion to \$12.3 billion over the 10-year period, while total program cost decreases range from \$1.5 billion to \$15.1 billion. If weight loss is able to lower future medical and drug claim spending, as is assumed in Scenarios 1 through 4, total costs are projected to decrease, as the savings related to weight loss more than offsets the projected cost of new AOM claims. There are potential outcomes on the spectrum between these four scenarios and Scenario 5, including those that may not generate enough savings offsets to counteract the increase in pharmacy costs from AOM coverage. For example, the Congressional Budget Office (CBO) typically assumes a 0.2% medical savings for each 1% increase in prescription utilization, which would be unlikely to result in savings across both the medical and pharmacy benefits in aggregate.<sup>1</sup> Please note, these estimates assume the Centers for Medicare and Medicaid Services (CMS) will change AOMs to a Part D-covered class, as opposed to optional supplemental coverage. This range is not appropriate if the AOM class remains excluded from Part D.

The results are particularly sensitive to the assumptions used. The scenarios modeled reflect estimates of the following three critical assumptions:

- **Overall uptake of the AOM class in Part D:** We assumed 0.5% to 4.0% of Part D members would use AOMs, with an average of four scripts per utilizer. We developed assumptions based on research from Novo and studies on obesity prevalence from the Centers for Disease Control and Prevention (CDC). Our moderate uptake scenarios assume about 1.6% of Medicare Part D members will use an AOM. We assume a consistent level of uptake in all years of the projection.
- **Frequency of AOM patients achieving weight loss:** Any savings generated from coverage of AOMs will come from reductions in future health costs from patients who achieve and sustain weight loss. We assumed 22% of AOM users would achieve some level of weight loss, with 50% of those AOM users (11% in total) achieving sustained weight loss.
- **Magnitude of savings offsets:** Coupled with the frequency of AOM patients achieving weight loss, the corresponding change in projected healthcare costs resulting from weight loss is a key assumption in this analysis. It is difficult to predict how AOM utilization will impact future health costs. Scenario 5 represents adding AOM medication coverage with no corresponding future medical savings. While we believe it is likely some level of cost savings can be achieved through weight loss, there is limited research available on the direct impact of AOM utilization, particularly within the Medicare population.

Savings offset assumptions are developed based on reported healthcare cost relativities between cohorts of patients with an obesity related condition (ORC). The research we relied on, funded by Novo, shows different costs for patient cohorts by body mass index (BMI) bands, suggesting a correlation between healthcare costs and BMI for specific condition categories.<sup>2</sup> Leveraging this study, we assume the portion of members who achieve weight loss have lower future healthcare costs.

These assumptions have a material impact on the overall projected use and average costs of AOM patients. These assumptions and others are based on data sources discussed in greater detail in the Methodology and Assumptions section of this report. Throughout the report we discuss the relative impacts of varying these three assumptions.

<sup>1</sup> Buntin, Melinda & Hayford, Tamara. (2012). Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services.

<sup>2</sup> Divino, V. et al. (February 2021). Complication-specific direct medical costs by body mass index for 13 obesity-related complications: a retrospective database study. *J Manag Care Spec Pharm*. Funded by Novo Nordisk. Retrieved May 25, 2021, from <https://pubmed.ncbi.nlm.nih.gov/33307936/>.

## II. RESULTS

### STAKEHOLDER IMPACT OF AOM COVERAGE IN MEDICARE PART D

Figure 2 summarizes the 10-year impact to each stakeholder for five scenarios where AOMs are covered by Medicare. The scenarios, described below, vary in terms of the level of savings generated by weight loss, as well as the proportion of members using AOMs. We present a range of potential savings associated with weight loss in this study, from no savings to aggressive savings. However, a cost effectiveness analysis was outside of the scope of our study.

Figure 2 2022 Through 2031 Potential Stakeholder Costs and Changes (in billions) by Scenario All Medicare Members					
Changes in Pharmacy Costs Relative to Baseline					
	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
<b>Member<sup>1</sup></b>	-\$0.2	\$1.1	\$1.1	\$0.1	\$2.5
<b>Federal Government<sup>2</sup></b>	\$1.0	\$2.5	\$4.5	\$0.6	\$3.6
<b>Manufacturer<sup>3</sup></b>	-\$0.9	-\$0.1	-\$1.4	-\$0.1	\$0.9
<b>Total<sup>4</sup></b>	-\$0.1	\$3.5	\$4.3	\$0.5	\$6.9
Changes in Medical Costs Relative to Baseline					
	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
<b>Member<sup>1</sup></b>	-\$1.5	-\$0.6	-\$2.6	-\$0.3	\$0.0
<b>Federal Government<sup>2</sup></b>	-\$9.0	-\$4.4	-\$16.8	-\$2.1	\$0.0
<b>Manufacturer<sup>3</sup></b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total<sup>4</sup></b>	-\$10.5	-\$5.0	-\$19.4	-\$2.4	\$0.0
Changes in Total Costs Relative to Baseline					
	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
<b>Member<sup>1</sup></b>	-\$1.6	\$0.5	-\$1.5	-\$0.2	\$2.5
<b>Federal Government<sup>2</sup></b>	-\$8.0	-\$1.9	-\$12.3	-\$1.5	\$3.6
<b>Manufacturer<sup>3</sup></b>	-\$0.9	-\$0.1	-\$1.4	-\$0.1	\$0.9
<b>Total<sup>4</sup></b>	-\$10.6	-\$1.5	-\$15.1	-\$1.9	\$6.9

<sup>1</sup> Member cost includes cost sharing and premium. For FFS members, cost sharing may be covered by Medicaid or employers.

<sup>2</sup> Government costs include all government claim expenses for Medicare Parts A, B, and D, Medicare Advantage payment rates, and Part D subsidies for low-income members.

<sup>3</sup> Manufacturer costs only include CGDP claims.

<sup>4</sup> Totals may not tie exactly to shown sums due to rounding.

In Scenario 5, absent any medical savings offsets, government costs are projected to increase by \$3.6 billion, and total program costs are projected to increase by \$6.9 billion. Across the scenarios which assume potential savings offsets, the estimated change in total program costs ranges from a \$1.5 billion to \$15.1 billion decrease. In these same four scenarios, federal government costs also decrease, ranging from \$1.5 billion to \$12.3 billion in savings. In all scenarios, we project increased Part D claim costs associated with the AOMs themselves. Any net savings are the result of assumed reductions to medical and prescription drug claims for the portion of AOM users who lose weight. Our assumptions related to weight loss rely on a published study funded by Novo showing cost differentials by BMI group for certain ORCs. For most ORCs, members with lower BMIs typically have lower claim costs, though total claim costs can fluctuate among certain BMI ranges. We applied the results of this study, assuming the portion of AOM users who achieve weight loss will have lower future claim costs proportionate to the differentials observed in the study. This is a key assumption, as there is limited research available showing whether a member who shifts from a higher BMI to a lower BMI due to weight loss will experience the same degree of cost differential as a member who was always at a lower BMI for a given ORC. The development of savings offsets leverages relative costs by BMI and does not account for the impact of any permanent increase in healthcare cost due to having ever been obese. Members with obesity who lose weight may have different sustained costs relative to a member with the same BMI who was never obese.

Based on our assumed differences in future costs by ORC, members with osteoarthritis of the knee and heart failure with preserved ejection fraction (HFpEF) with sustained weight loss would have the greatest savings relative to the baseline. These two ORCs contribute the most toward overall savings due to their high cost differential among higher and lower BMI groups and their relative frequency within the Medicare population. Other ORCs with large differences in projected costs include obstructive sleep apnea, asthma, and musculoskeletal pain. Note, the primary study we relied on for savings by ORC does not address the Medicare population, but we assumed similar cost differentials by ORC and BMI among the commercial and Medicare populations, and applied those differentials to Medicare-specific costs and frequency within our data.

The sections below provide further detail on the impact of these scenarios on each of the three stakeholders who ultimately fund the Medicare program: the federal government, members, and manufacturers (in Part D). Appendices A and B include changes by stakeholder and by year and are split between medical and pharmacy costs. Appendix A shows these values in billions of dollars, while Appendix B shows these values on a per member per month (PMPM) basis.

### STAKEHOLDER IMPACT: FEDERAL GOVERNMENT

Figure 3 shows the 10-year impact to federal government Medicare spending of mandating coverage of AOMs, in billions of dollars:

Figure 3 2022 Through 2031 Total Federal Government Medicare Costs and Changes (in billions) by Scenarios All Medicare Members						
	Baseline	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
<b>Pharmacy Costs</b>	\$1,440.3	\$1,441.3	\$1,442.7	\$1,444.8	\$1,440.9	\$1,443.9
<b>Change From Baseline - Pharmacy</b>	N/A	\$1.0	\$2.5	\$4.5	\$0.6	\$3.6
<b>Medical Costs</b>	\$8,559.9	\$8,550.9	\$8,555.5	\$8,543.1	\$8,557.8	\$8,559.9
<b>Change From Baseline - Medical</b>	N/A	-\$9.0	-\$4.4	-\$16.8	-\$2.1	\$0.0
<b>Total Government Costs</b>	\$10,000.2	\$9,992.2	\$9,998.3	\$9,987.9	\$9,998.7	\$10,003.8
<b>Change From Baseline - Total</b>	N/A	-\$8.0	-\$1.9	-\$12.3	-\$1.5	\$3.6

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

There are numerous components of federal government funding. Across all five scenarios the impact to the government of AOM coverage is directionally consistent with the projected impact to total medical and pharmacy costs. However, the relative magnitudes for the individual components vary depending on the assumptions. Below we discuss each source of government funding:

- Medicare FFS claims:** In Scenario 5, we project no changes to FFS claim costs. In Scenarios 1 through 4, we project a total decrease in claims for FFS (including Medigap) members. This is due to assumed medical savings offsets from the portion of members using AOMs who achieve weight loss. The level of the savings offset increases over time as a portion of members have achieved sustained weight loss, resulting in lower future medical claim costs. The differential between government costs in the baseline and in each scenario grows most quickly in Scenario 3, which assumes the highest AOM uptake percentage (4%). The high level of uptake in this scenario results in the highest projected number of members with sustained, as well as short-term, weight loss.
- Medicare Advantage bid and rebate:** The impact to these values is largely consistent with those described above for Medicare FFS. In addition to claim costs, which the federal government funds for FFS and Medigap members, the federal government also funds the administrative expenses and margin for the MAO and rebates for plans bidding below their benchmark payment rates.
- Part D federal reinsurance:** In all scenarios, federal reinsurance is projected to increase. This represents the largest component of federal costs in Part D today and the largest portion of the total Part D cost increase. Due to the average cost of AOM medications and existing claim costs of potential AOM users, many of these claims are anticipated to fall within the catastrophic benefit phase where the government bears 80% of claim cost before rebates. The increases to federal reinsurance are most pronounced where uptake is higher, such as in Scenario 3.

- **Part D direct subsidy:** In all scenarios, direct subsidy payments increase initially due to increased cost of AOMs without any realized savings. In Scenario 5, which considers no savings offsets, we project direct subsidy payments to remain higher in all years. In Scenarios 1 through 4, the direct subsidy payments eventually decrease slightly relative to the baseline as the impacts of savings accumulate (generally within five years). The direct subsidy represents the government-funded portion of plan liability, which is highest in the earlier phases of the benefit. As members realize decreases in total claim costs due to weight loss, direct subsidy payments decrease over time relative to the baseline, but the impact is relatively small.
- **Low income cost sharing subsidies (LICS):** The direction and magnitude of LICS changes among the scenarios are generally consistent with the dynamics of Part D member cost sharing described below. Overall, LICS increases to cover additional cost sharing paid on the new AOM claims.
- **Low income premium subsidies (LIPS):** The direction and magnitude of LIPS changes among the scenarios are generally consistent with the dynamics of Part D member premium described below. For both LICS and LIPS, the government impact is smaller than the member impact, as the government only covers a portion of costs for low-income (LI) members.

Federal government costs in Figure 3 encompass Medicare program spending only, thus, exclude medical claim costs associated with members who are dually eligible for Medicare and Medicaid. If AOM coverage results in savings to member cost sharing for medical costs (as seen in Figure 4 below), a portion of this savings would be realized by the federal and state government through lower subsidies for dual eligible members. Medical cost sharing for these beneficiaries is typically fully covered by the government through Medicaid. Part D subsidies for dual eligible members are captured in the government totals above, as they are Medicare, rather than Medicaid, costs. In 2019, there were about 11 million dual eligible beneficiaries out of the total 60 million Medicare lives.

#### STAKEHOLDER IMPACT: MEMBERS

Figure 4 shows the impact on member premium and cost sharing on a PMPM basis, broken out by medical and pharmacy benefit. The total member impact in billions of dollars can be seen in Figure 2 above.

**Figure 4**  
**2022 Through 2031 Member Costs and Changes (PMPM) by Scenario**  
**All Medicare Members**

<b>Pharmacy PMPM</b>						
	<b>Baseline</b>	<b>Scenario 1</b>	<b>Scenario 2</b>	<b>Scenario 3</b>	<b>Scenario 4</b>	<b>Scenario 5</b>
<b>Member Premium</b>	\$29.80	\$29.85	\$29.87	\$29.95	\$29.83	\$29.88
<b>Member Cost Sharing</b>	\$60.10	\$60.03	\$60.20	\$60.12	\$60.09	\$60.39
<b>Total</b>	\$89.90	\$89.88	\$90.07	\$90.07	\$89.91	\$90.27
<b>Changes in Pharmacy Costs PMPM Relative to Baseline</b>						
<b>Member Premium</b>	N/A	\$0.04	\$0.07	\$0.14	\$0.02	\$0.08
<b>Member Cost Sharing</b>	N/A	-\$0.07	\$0.10	\$0.02	-\$0.01	\$0.29
<b>Total</b>	N/A	-\$0.03	\$0.17	\$0.17	\$0.01	\$0.36
<b>Medical PMPM</b>						
<b>Member Premium</b>	\$280.05	\$279.97	\$280.01	\$279.90	\$280.03	\$280.05
<b>Member Cost Sharing</b>	\$105.17	\$105.08	\$105.13	\$105.02	\$105.15	\$105.17
<b>Total</b>	\$385.21	\$385.05	\$385.14	\$384.92	\$385.18	\$385.21
<b>Changes in Medical Costs PMPM Relative to Baseline</b>						
<b>Member Premium</b>	N/A	-\$0.08	-\$0.04	-\$0.15	-\$0.02	\$0.00
<b>Member Cost Sharing</b>	N/A	-\$0.08	-\$0.03	-\$0.15	-\$0.02	\$0.00
<b>Total</b>	N/A	-\$0.17	-\$0.07	-\$0.30	-\$0.04	\$0.00
<b>Medical and Pharmacy Combined PMPM</b>						
<b>Member Premium</b>	\$309.85	\$309.81	\$309.88	\$309.85	\$309.86	\$309.93
<b>Member Cost Sharing</b>	\$165.27	\$165.11	\$165.33	\$165.14	\$165.23	\$165.55
<b>Total</b>	\$475.12	\$474.92	\$475.21	\$474.99	\$475.09	\$475.48
<b>Changes in Total Costs PMPM Relative to Baseline</b>						
<b>Member Premium</b>	N/A	-\$0.04	\$0.03	-\$0.01	\$0.00	\$0.08
<b>Member Cost Sharing</b>	N/A	-\$0.15	\$0.07	-\$0.13	-\$0.03	\$0.29
<b>Total</b>	N/A	-\$0.19	\$0.10	-\$0.13	-\$0.03	\$0.36

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

For medical costs, the combination of changes to member premiums and member cost sharing result in savings of up to \$0.30 PMPM. Any decreases in premium and cost sharing are driven by projected savings for AOM users who achieve and sustain weight loss either long-term or for a shorter term. If weight loss results in decreased total claim costs, member premiums and cost sharing would decrease in turn. Medical savings are most significant in aggregate in Scenarios 1 and 3 where savings and uptake, respectively, are assumed to be higher than our moderate assumptions. FFS members without Medigap have the greatest potential for savings, as they pay a higher proportion of total claim costs. For Medigap members, cost sharing only decreases slightly, if at all, as the vast majority of their cost sharing is already filled in by their Medigap plans in the baseline. Note, for medical costs we did not attempt to quantify the portion of cost sharing or premium that may be subsidized by employers or Medicaid for FFS members. A portion of any medical savings may flow to these entities.

The impact to pharmacy costs is generally reversed from medical costs—in four of the five scenarios, total member costs increase. Member premiums increase relative to the baseline in all scenarios to cover the increase in net plan liability resulting in the coverage of AOM products. This increase may be partially offset in some scenarios if members who achieve weight loss have a corresponding reduction in Part D claims spending. This potential savings for members achieving weight loss is most impactful in Scenario 1 where savings is highest. However, in three of the five scenarios total cost sharing still increases slightly due to the cost sharing associated with the new AOM claims.

If medical cost offsets are achieved, member cost sharing increases are larger in the earlier years of the projection, as members using AOMs will have more Part D claims with fewer savings offsets. However, in later years, once more AOM users have achieved weight loss, member cost sharing could eventually become lower relative to the baseline due to savings offsets. In Scenarios 1 and 3, this dynamic is more pronounced, resulting in overall lower member cost sharing over the 10-year period. Note, for Part D costs, Figure 4 only includes costs actually funded by the member and does not include premium or cost-sharing subsidies from the government. LIPS and LICs are both accounted for in the changes to the federal government costs in Figure 3 above.

There are differences among members who use AOMs with respect to their costs and potential for long-term savings. Within the cohort of members projected to use AOMs, we anticipate 22% of users will achieve weight loss, with half of the 22% regaining weight within three years of using an AOM, and the other half achieving sustained weight loss. In summary, we model four cohorts of members:

- Group 1: Members who do not use an AOM
- Group 2: Members who use an AOM but do not achieve weight loss
- Group 3: Members who use an AOM and achieve weight loss, but regain the loss within three years
- Group 4: Members who use an AOM and achieve sustained weight loss

Each of these subsets may experience different cost changes. Group 1 does not use AOMs and therefore has no expected claim cost impact. However, Group 1 is still affected by changes in total premium, which are spread across all members. Among AOM users, Group 2 would experience increased cost sharing in the year they are projected to use an AOM. Group 3 would have higher cost sharing in the year they use an AOM, but could potentially have a net cost-sharing decrease for the subsequent two years, prior to regaining the lost weight. Lastly, Group 4 would be similar to Group 3, but these members would maintain sustained weight loss and therefore could potentially achieve the greatest degree of savings. Figure 8, in the Methodology and Assumptions section below, demonstrates this development.

## STAKEHOLDER IMPACT: MANUFACTURERS

Figure 5 shows the impact on manufacturer costs in billions, specifically related to the CGDP.

Figure 5 Total Manufacturer Costs and Changes (in billions) by Scenarios All Medicare Members						
	Baseline	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
<b>Total</b>	\$174.3	\$173.4	\$174.2	\$172.9	\$174.1	\$175.2
<b>Total Change From Baseline</b>	N/A	-\$0.9	-\$0.1	-\$1.4	-\$0.1	\$0.9

Consistent with the other increases in stakeholder costs observed above, manufacturer costs increase in Scenario 5. However, in Scenarios 1 through 4, manufacturer costs decrease as the impact of assumed Part D cost savings resulting from weight loss is high enough to offset the increase in CGDP from brand AOM claims. This is dependent on the degree of savings assumed and is due to fewer beneficiaries reaching the coverage gap as they use fewer drugs associated with ORCs. The impact by manufacturer will be variable—manufacturers of brand AOM products will absorb all increases in CGDP, resulting from the increased use of their products by non-low-income (NLI) members. Other manufacturers could experience some savings if fewer claims for their products are paid during the coverage gap. Note, Figure 5 excludes any sales revenue or rebate payments made by AOM manufacturers, as well as any reductions in revenue due to fewer sales of drugs used to treat ORCs for all manufacturers.

## ADDITIONAL CONSIDERATIONS

The following considerations relate to the concept of requiring AOM coverage in Part D:

- **AOM use may evolve over time:** Often with newly covered classes or ground-breaking therapies, coverage and utilization do not reach a steady state until several years later. This can be due to a variety of factors including (but not limited to) rapid improvement in contractual arrangements, from the plan sponsor and pharmacy benefit manager (PBM) perspective, and physician education. This can cause large swings in both the distribution among competing products within a class, but also in overall uptake of the therapies. For simplicity, our analysis assumed constant utilization in all years (with any assumed savings building gradually over time for users achieving sustained weight loss), but savings could be lower if uptake is initially lower, such as in Scenario 4.

AOM utilization may be influenced by future launches in the space. There are currently AOM products in the pipeline that show initial promise of greater efficacy.<sup>3</sup> If newer products are more efficacious, this could increase utilization. Greater efficacy could produce greater total savings, if it results in a larger proportion of users with medical and drug cost offsets. This would be somewhat dampened if the cost of a new treatment is significantly more than the current average cost, or if a new treatment is required to be used for a longer period of time.

To the extent a competitor launches a product with similar efficacy, there may be increased competition among branded products, which could drive the overall cost of AOMs down.

- **Plan behavioral responses:** Our analysis includes the cost impact of AOM claims and potential corresponding medical and drug cost savings offsets, but it does not include any additional stakeholder behavioral responses. Mandatory coverage of AOMs may cause other changes to stakeholder and plan sponsor behavior that may have secondary impacts. The considerations below represent some of the potential changes:
  - **Formulary coverage and utilization management strategies:** Plan sponsors and PBMs will likely analyze AOM coverage, including any potential cost offsets as they make formulary and other utilization management decisions. Given that the existing 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. For products that are on formulary, plans will also need to make tiering decisions.
    - Generic AOMs are relatively inexpensive compared to brand AOMs and would likely be on tiers 1 or 2, resulting in copays under \$20 for most plans. However, generics may not always be the lowest-cost option for plans—if rebates are large enough, plans may prefer coverage of brand AOMs.
    - For brands, the 30-day cost assumed in our analysis would make these products eligible for the specialty tier, which has a coinsurance benefit. Specialty tier placement could stymie patient utilization given that the cost sharing to begin therapy would be great.

AOM products would likely have utilization management criteria attached to them to prevent unwarranted access and to encourage use of the lower net cost products on formulary. Formulary management is much more likely in the PDP space, where plan sponsors would not benefit nearly as much from any potential claim savings offsets. Total savings in Scenarios 1 through 4 could be lower if PDPs are able to limit AOM use beyond the assumptions used in our analysis.

<sup>3</sup> Pilitsi, E. et al. (October 23, 2018). Pharmacotherapy of obesity: Available medications and drugs under investigation. *Metabolism Clinical and Experimental*. Retrieved May 25, 2021, from <http://website60s.com/upload/files/vol-92-a18.pdf>.

- **Less focus on nonpharmaceutical weight loss approaches:** Both MA plans and members may focus less on and provide leaner benefits for nonpharmaceutical weight loss approaches if AOMs are covered through Part D. As a result, MAOs may choose to reduce their supplemental benefits if Part D coverage is achieving similar goals. Plans would also need to consider the selection advantages and disadvantages those benefits provide when determining coverage changes in addition to the first-level financial impacts.
- **Enhanced benefit designs will be impacted differently:** The modeling in this report assumes the Part D defined standard benefit design, which, after the deductible, is a coinsurance benefit. Therefore, members are consistently charged a percentage of the point-of-sale cost, rather than a copay. However, a vast majority of members in Part D, especially NLI members, are enrolled in non-defined standard plans, which typically have copays for generics and many non-specialty brand products. As discussed above, the cost of brand AOM products would make them eligible for the specialty tier, which has a coinsurance benefit, even for enhanced plan designs. The large differential between brand and generic cost sharing a patient sees may further incentivize generic use for enhanced plans, though a manufacturer may be able to use rebates to buy down the brand coverage to a preferred brand tier.
- **Savings offsets, if any, benefit all stakeholders on average:** To the extent savings offsets occur, as modeled in Scenarios 1 through 4, the savings will flow to all stakeholders including the member, federal government, and manufacturers (to the extent savings occur for pharmacy costs). Therefore, the total savings will not directly flow to members via premium decrease or cost sharing reductions, but will also serve to lower government and manufacturer liabilities. As discussed above, the impact on manufacturers for CGDP liability will vary greatly by manufacturers, and some manufacturers, such as those who manufacture brand AOMs, may see increases in liability.
- **AOM coverage may warrant risk adjustment model changes:** Adjustments are regularly made to the CMS risk adjustment model to update the relative impact of different disease states on overall member claim costs. The coverage of AOMs in Part D may require a reevaluation of the obesity diagnosis and recalibration of the model.

Classes with utilization of both brand and generic products may have more variable risk adjustment results. The risk score model does not consider actual drug utilization and is calibrated based on overall Part D costs, including a mix of brand and generic users. As such, the risk score coefficients will be appropriate on average, but may underpay plans for brand utilizers while overpaying for generic utilizers. This may be something plans analyze and consider when choosing which AOM products to cover on formulary.

- **Different plan types and market segments will be impacted differently:** The impact of AOM coverage may vary by plan type and market segment. PDP plans tend to focus more on net drug cost when considering product coverage and utilization management decisions and they do not benefit from any medical cost offsets. This may lead to stricter coverage and a higher prevalence of utilization management programs than in MAPD plans where plan costs could benefit if medical cost offsets result from AOM use. The timing of potential offsets may play a key role in their evaluation as well. If savings are not realized in the short term, a member's future plan may benefit from a prior plan's AOM coverage, lessening the incentives for plan coverage of AOMs. The individual market may also be impacted differently from employer group waiver plans (EGWPs). EGWPs tend to have more open formularies with much richer benefits, typically copays, as well as having better member retention than the individual market due to employer subsidies. This may result in higher use of AOMs given fewer access constraints and lower point-of-sale costs for patients in EGWPs relative to the individual market, as well as more long-term benefits from medical cost offsets for EGWPs given higher retention.

## AOM MEMBER PROFILES AND AOM PRODUCT COST

We summarized data from Milliman's 2019 *Consolidated Health Cost Guidelines*<sup>™</sup> Sources Database (CHSD) to develop a patient profile for those likely to use an AOM if AOMs were to become a Part D-covered class. We summarized members who fit the following criteria and used those members as our set of potential AOM Part D users:

1. Had at least one diagnosis code for obesity on one of their claim records.
2. Had at least one claim for a non-GLP-1 diabetic medication and no GLP-1 medication claims.
3. Both of the above.

For these members, Figure 6 summarizes their annual number of scripts and claim costs.

Figure 6 Annual Scripts and Claim Costs for Potential Part D AOM Users 2019 Consolidated Health Cost Guidelines Sources Database		
	Scripts	Part D Claim Costs
10th Percentile	12	\$51
25th Percentile	30	\$233
50th Percentile	56	\$1,035
75th Percentile	87	\$4,144
90th Percentile	119	\$8,324
<b>Average</b>	62	\$3,912

As Figure 6 suggests, the average claim costs for a potential AOM member are significantly higher than the median as the distribution of members is skewed by a relatively small frequency of high-cost claimants. Members identified via an obesity diagnosis tended to be less costly when compared to those identified using the non-GLP-1 diabetic medication criteria. As expected, those members who both had an obesity diagnosis code and were using a non-GLP-1 diabetic medication had significantly higher claim costs than either cohort that only met one of the criteria. We also summarize the medical costs for both FFS and Medicare Advantage members likely to use AOMs in Appendices C1 and C2, respectively.

Under mandated AOM coverage, patients would have incremental costs associated with the AOMs. Absent offsetting savings, this results in an increase in Part D claim costs. Figure 7 summarizes the modeled incremental impact on annual use and claim costs for AOM users.

Figure 7 Annual Claim Cost by Product Type* Part D AOM Patients		
AOM Product Type	Incremental Annual Gross Claim Cost	Market Share
Branded AOM	\$3,445	21%
Generic AOM	\$40	79%
<b>Average / Total</b>	<b>\$755</b>	<b>100%</b>

\*Members taking any AOM are assumed to use four scripts on average, annually.

The market share distribution shown in Figure 7 is consistent across all non-baseline scenarios. This distribution between generic and brand AOM medications results in an average increase of \$755 in annual claim costs per AOM user, though as Figure 7 shows, the impact is variable depending on whether a patient uses a brand or generic product. Given the large cost differential between generic and brand AOM medications, variance from this assumed distribution in practice could have a material impact on the results in this report. To the extent the distribution in Figure 7 shifts to a greater proportion of brand medications, projected government costs could increase.

In addition to the different costs associated with brand and generic AOMs, members will experience different cost-sharing impacts depending on three critical variables:

- **Benefit design:** As discussed previously, branded AOM products would be eligible for the specialty tier, which has coinsurance ranging from 25% to 33% in the initial coverage phase. However, plans are permitted to place brands on lower tiers, which could result in lower cost sharing (copay of up to \$100) or higher cost sharing (coinsurance of up to 50% is permitted on the non-preferred brand tier), depending on the plan.
- **AOM claim timing:** Depending on when AOM claims occur during the year, a member may be in any one of the four Part D benefit phases. This dynamic can produce wide differences in the actual cost sharing attributable to AOM claims as the percentage of claim costs varies widely, from 100% in the deductible to as little as 5% in the catastrophic phase. Therefore, the cost sharing due to AOM claims will depend significantly on other claim costs and when they occur in the Part D benefit in relation to the AOM claims.
- **Income status:** The changes in patient cost sharing due to AOM coverage vary by income status as LI members have a significant percentage of their cost sharing subsidized through the LICS program. The increase in cost sharing is more substantial for NLI members because their cost sharing is not subsidized as it is for LI members' Part D-covered drugs.

## III. BACKGROUND

### MEDICARE BENEFIT STRUCTURE

#### Medicare fee-for-service (Medicare FFS)

Medicare FFS is the traditional Part A and B medical coverage offered through the federal government. Part A provides coverage for inpatient hospital stays, while Part B covers outpatient and professional services. Under the FFS benefit, the member must fulfill a Part A deductible (\$1,484 in 2021), followed by \$0 cost sharing for days 1 through 60 and a copay for days 61 and beyond. Members must also fulfill a Part B deductible (\$203 in 2021), followed by 20% coinsurance on all future Part B costs. The member does not have a maximum out-of-pocket (MOOP) limit, therefore, there is no cap to member spend. There are about 38 million beneficiaries with traditional FFS benefits in 2021, though the majority of these beneficiaries receive supplemental coverage from Medigap, employers, or Medicaid.

#### Medigap

Medigap policies, also known as Medicare Supplement, are sold by private companies and provide coverage to supplement member cost sharing beyond traditional Medicare FFS coverage. We estimate about 16 million beneficiaries are enrolled in a Medigap plan in 2021. There are 10 standardized Medigap benefit designs, with the majority of members enrolled in Plans F, G, and N, all of which cover a vast majority of FFS cost sharing. Note, Plan C and Plan F cover the Part B deductible, but as of 2020, new members may not enroll in plans covering the Part B deductible. In our analysis, we assume an average benefit design, developed using projected enrollment by plan in each year, for Medigap members.

#### Medicare Advantage (MA)

MA plans are offered through a Medicare Advantage organization (MAO) as an alternative to traditional FFS. MA plans currently cover about 26 million enrollees and are growing each year as a percentage of the Medicare-eligible population. In MA, Part C provides combined Part A and B coverage, and most plans also include Part D coverage of prescription drugs. MA plans typically offer enhanced benefits above and beyond traditional FFS through decreased cost sharing and supplemental benefits not covered under FFS. MA plans are also required to include a MOOP—this limit cannot exceed \$7,550 in 2021.

#### Prescription drug (Part D)

Prescription drug coverage is available through Medicare Part D, either via an MA plan with drug coverage included (MAPD) or a standalone prescription drug plan (PDP). All Part D plans are offered by private insurance companies, which participate in a competitive bidding process. CMS defines a standard benefit design; plans can offer alternative designs that are either enhanced relative to the defined standard benefit or are actuarially equivalent to the standard benefit. About 49 million beneficiaries are enrolled in Part D.

### MEDICARE FUNDING COMPONENTS

Medicare is funded by the federal government through the Hospital Insurance (HI) Trust Fund and the Supplementary Medical Insurance (SMI) Trust Fund, which together fund Parts A, B, and D, as well as Medicare program administration costs. The various Medicare benefit structures discussed above each have unique funding mechanisms:

- **Medicare FFS:** Medicare FFS is fully funded by the federal government through the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trusts. The government pays providers directly for the majority of claim costs, according to an established fee schedule. The only other stakeholders involved in directly paying costs are members, through cost sharing and Part B premiums.
- **Medicare Advantage:** 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. The bid is compared to a risk-adjusted benchmark published by CMS at a county level. If the bid is lower than the benchmark (which is typical), the plan receives a rebate from the government to offer enhanced benefits.
- **Medigap:** Medigap policies are also sold by private insurance companies. Medicare beneficiaries enrolled in Medigap plans still receive traditional FFS benefits, but the Medigap policy serves as supplemental coverage to cover a majority of traditional FFS cost sharing. Prescription drug coverage is excluded. Each insurer

charges premium to cover the costs of this supplemental medical coverage, plus administrative expenses and margin.

- **Medicare Part D:** The Part D program is ultimately funded by members, the federal government, and pharmaceutical manufacturers. Costs are divided into the following components:
  - **Member cost sharing:** The portion of total cost sharing paid out-of-pocket by members (exclusive of government subsidies).
  - **Member premium:** 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 premium, though plans with enhanced benefits also have additional supplemental premium.
  - **National average reinsurance (NAR):** The portion of claims paid by the federal government in the catastrophic phase. The government pays 80% of claims in this phase.
  - **National average direct subsidy (NADS):** 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 (LICS) subsidies:** The portion of total cost sharing subsidized by the federal government for low-income (LI) members.
  - **Low-income premium subsidies (LIPS):** 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 liability:** The portion of claims paid by pharmaceutical manufacturers through the Coverage Gap Discount Program (CGDP).

## PART D FORMULARY COVERAGE

In Part D, formularies include coverage of at least two distinct products within each therapeutic class, unless only a single product is available. Plans must cover all therapeutic classes apart from those that are specifically disallowed, such that a formulary’s design does not specifically discourage the enrollment of any group of beneficiaries.

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.<sup>4</sup> These groups of products are referred to as non-Part D drugs. Plan sponsors are only able to 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 CGDP or reinsurance dollars offsetting those costs as they typically would for a Part D drug, and non-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-Part D drugs is rare due to premium pressures and plan sponsor concerns regarding anti-selection.

Though current regulations exclude coverage of the drug classes mentioned above, changes in required coverage from CMS are not unprecedented. There have been a few significant statutory and regulatory changes in formulary requirements over the history of the program, including:

- Transition to coverage of benzodiazepines and barbiturates (2013)
- Allowance for step therapy between Part B and D for MAPD plans (2019)
- Clarification that products intended to treat AIDS wasting and cachexia are Part D-covered (2008)

One factor that could lead regulatory agencies to consider changing coverage restrictions of the AOM class in the future is that coverage of effective AOM therapies could drive offsets in medical costs. Though additional coverage of new medications in a vacuum produces additional costs to Part D, if AOMs are effective at producing weight loss, and such, weight loss reduces medical and drug costs associated with obesity, then there could be net savings to the Medicare program.

<sup>4</sup> 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>.

## IV. METHODOLOGY AND ASSUMPTIONS

We used Milliman's Part D Analysis and Rating Tool (DART) and Standard Medicare Advantage Rating Tool (SMART) to estimate costs for the Part D and Parts A and B markets, respectively, by stakeholder. These models are designed to project historical claim data forward for the purpose of creating Medicare Advantage and PDP bids. All projection estimates for Part D and Part C were based on individual market data. The results of this report assume members enrolled in employer group waiver plans (EGWPs) have baseline costs and impacts as a result of AOM coverage that are similar to individual members.

### PART D METHODOLOGY

The manual rates, adjustment factors, assumed demographics, and risk scores in the Milliman Medicare Part D pricing models are based on Medicare Part D experience, including over 95 million member months across 34 U.S. regions and Puerto Rico. The underlying data reflects a nationwide, individual market population. Our model relies on separate LI and NLI claim samples, allowing for detailed claim-level adjudication and summaries by product type and distribution channel. All Part D results assume a defined standard benefit design. We estimated the defined standard parameters for years beyond 2022 using the parameters projected in the 2020 Medicare Trustees report.

For 2021, we calibrated to published 2021 national average amounts, using the manual rate data described above with trend and generic pipeline adjustments projected to 2021. We adjusted the data to average contracting non-benefit expense assumptions from Milliman's Medicare Part D Contract Survey, which surveyed Part D plan sponsors on the assumptions underlying 2021 Part D bid development.

For 2022 and future years, we began with our 2021 projection, and we applied annual trends to gross costs and the Part D benefit parameters, using information from the 2020 Medicare Trustees report. To estimate the low-income premium subsidy, we assumed that, on average, 95% of LI premiums are paid by the government through premium subsidies. We projected the mix of NLI and LI members consistent with the 2020 Medicare Trustees report. For all future years, we assume the safe harbor for Part D manufacturer rebates remains as it currently stands under the Anti-Kickback Statute. For all years and in all scenarios, we assume there are no structural changes to the Part D program or benefit design.

For all non-baseline scenarios, overall utilization is projected to increase as a result of members filling AOM prescriptions. We assumed formularies would cover a mix of brand and generic AOMs. The determination of the uptake of AOM use and scripts per utilizer assumptions are discussed below.

The patient profiles of potential AOM patients were developed from a Milliman database, the 2019 CHSD, to model expected AOM utilization. We identified members that may potentially use an AOM if they met the following criteria:

1. Had at least one diagnosis code for obesity on one of their claim records.
2. Had at least one claim for a non-GLP-1 diabetic drug product.
3. Both of the above.

Leveraging the patient profile information summarized from the CHSD and other assumptions (described in more detail below), we modified the baseline projection for all years to integrate the additional costs from AOM coverage for each of the five scenarios. The impact of AOM spend was considered both in the total claim cost development and in the adjudication of member claims throughout the various Part D benefit phases. The ultimate level of additional costs varied depending on the scenario.

In some scenarios, we also assume a savings for pharmacy costs for members projected to use an AOM and also lose weight. The development of the assumptions related to the savings projection are outlined below.

### MEDICAL COST METHODOLOGY

The manual rates, adjustment factors, assumed demographics, and risk scores in the Milliman Medicare medical pricing models are based on Medicare Part C and FFS experience, including over 45 million member months across 34 U.S. regions. The Medicare FFS population is based on members and claim cost data from the 2018 Medicare 5% Sample, while the Medicare Advantage population is based on Milliman's 2019 CHSD database. We segmented the population between members with and without obesity based on diagnosis codes for obesity.

For 2022 and future years, we applied annual trends to gross costs using information from the 2020 Medicare Trustees report, separated by service category. For Medicare FFS members, we assumed a member cost-sharing percentage across all years consistent with the actuarial equivalent cost-sharing percentages published in CMS's Medicare Advantage Part C Bid Pricing Tools (BPTs). For Medicare Advantage members, we based assumed cost sharing on average 2021 Medicare Advantage plan designs, projected forward to future years based on historical cost-sharing trends by service category. For Medigap members, we assumed an average cost sharing based on the mix of members enrolled in each type of Medigap plan. For future years, we assumed membership would gradually shift from Plan F to Plan G, as new members are no longer able to enroll in Plan F.

For overall market results, we assumed membership growth rates in the FFS and Medicare Advantage populations consistent with the 2020 Trustees report. For the Medigap population, we assumed a consistent increase in membership over the projection period in line with historical trends. Medicare Advantage and Medigap projections include an adjustment to member premium for administrative expense and margin of 12.3% and 17.5%, respectively. The impact of administrative expenses and margin extend to the portion of government costs associated with the Part C bid for Medicare Advantage. Medicare Advantage projections also include estimates for projected non-Medicare covered costs consistent with levels reported by the Medicare Payment Advisory Commission (MedPAC) in its 2021 Report to the Congress.<sup>5</sup>

## KEY ASSUMPTIONS

Critical to each of the scenarios presented in this report are key assumptions related to the potential AOM market makeup in Part D and related projected levels of savings for members who lose weight. The following list details these assumptions:

- **AOM class uptake:** We developed assumptions based on research provided by Novo and studies on obesity prevalence from the Centers for Disease Control and Prevention (CDC). Our moderate uptake scenarios assume about 1.6% of Medicare Part D members will use an AOM. We assume a consistent level of uptake in all years of the projection. This estimate relies on an overall obesity assumption in Part D. We assume an obesity prevalence consistent with recent public reports<sup>6</sup> estimating rates of obesity in Medicare aged individuals. We assume about 43% of this population has obesity. The high and low uptake scenarios use an assumption of 4.0% and 0.5% uptake, respectively.
- **AOM class market share distribution:** Based on research from Novo, we assumed the market share consistent with Figure 6 above.
- **AOM price and rebate levels:** We assume an average annual cost of \$755 across all AOMs. For brand products, we assume an average wholesale acquisition cost (WAC) of about \$860 per 30-day script and rebates equal to 31% of WAC in 2022, consistent with the average level for manufacturer rebates observed in Part D. Consistent with historical trends, we project an increase to rebates as a percentage of gross brand costs for both AOM and non-AOM products over the 10-year horizon. For generic products, we assume a unit cost of \$10 per 30-day script and no rebates. For WAC prices, we relied on Medi-Span prices as of April 12, 2021.
- **Distribution of income status among AOM users:** We assume the proportion of LI AOM users is consistent with the overall national percentage of LI members in Part D for each year. It may be that a higher percentage of AOM users would be LI due to differences in the frequency of obesity and diabetes between the income statuses. We conducted a sensitivity test assuming a higher LI percentage of AOM users and ultimately the impact of even a 10% increase in the LI percentage of AOM users would yield very similar results with respect to the changes in Part D costs.
- **AOM scripts per utilizer:** Based on the 2018 CHSD, Milliman research, and discussion with Novo, we observed about three scripts per member using an AOM. Assuming adherence would be similar to the commercial market for AOMs while accounting for higher scripts per utilizer on newer brand products, we assume AOM patients will fill four scripts annually on average. As with most medications, the number of scripts per AOM utilizer would vary, from members who only take a single script to members maintaining adherence until weight loss goals are achieved. Figure 8 below demonstrates a simplified two-point distribution of AOM patients who discontinue therapy after one script versus using an AOM product for six months.

<sup>5</sup> MedPAC (March 2021). Report to the Congress: Medicare Payment Policy. Retrieved May 25, 2021, from [http://medpac.gov/docs/default-source/reports/mar21\\_medpac\\_report\\_to\\_the\\_congress\\_sec.pdf](http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf).

<sup>6</sup> CDC (February 2020). Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017–2018. Retrieved May 25, 2021, from <https://www.cdc.gov/nchs/products/databriefs/db360.htm>.

- **Weight loss for an AOM user:** Among patients who lose weight, we assume an average weight loss of 10%. We observed ranges of 5% to 12% weight loss achieved through the use of AOMs observed in a literature review.<sup>7,8</sup> We assume 50% of patients who use for a treatment duration longer than one or two scripts will achieve weight loss.<sup>9,10</sup>
- **Magnitude and timeframe of average weight regain:** Of the 22% of patients who use an AOM and lose weight, we assume 50% of those patients regain the weight within three years of beginning an AOM treatment, while the other 50% of patients sustain the 10% weight loss.<sup>11</sup>

Figure 8 demonstrates the interaction of the three assumptions detailed above.

Figure 8 Assumed Distribution of AOM Patient Type		
Patient Stay Length	Patient Weight Loss	Regain Weight In Three Years
2 Script (60%)	None (60%)	None (60%)
	None (18%)	None (18%)
7 Script (40%)	10% Loss (11%)	Full Regain (11%)
	10% Loss (11%)	No Regain (11%)

- **Obesity-related conditions (ORC) considered for savings offsets:** We relied on a study funded by Novo reporting one-, two-, and three-year cost relativities by ORC<sup>12</sup> to identify patients who may potentially have changes in their claim costs as the result of weight change. The application of this study to our analysis has two primary limitations: the literature does not specifically address the over 65 population, and the medical costs for patients that lose weight are assumed to decrease in proportion to BMI (as there is limited research available specifically relating weight loss to future healthcare costs). While the average age of the populations in the study are below the average Medicare enrollee, our results consider the frequencies of patients with each ORC specifically within Medicare when considering the magnitude of savings offsets. We assume the cost differential by BMI for ORCs is similar between the commercial and Medicare markets.
- **BMI distribution within ORCs:** We applied weight loss to groups of members using a distribution of members in BMI bands above a BMI of 30.<sup>13</sup> This distribution informs the resulting average BMI of those who use AOMs. In Scenarios where savings offsets are assumed, this BMI distribution when combined with the one-, two-, and three-year cost relativities described above, informs the relative cost changes within each ORC. The BMI distributions within each ORC are based on research from commercial populations. Though we apply these distributions to the Medicare populations as a proxy due to the lack of Medicare-specific data, the distribution among ORCs is ultimately derived using Medicare specific data such that the frequency of members with a given ORC reflect a Medicare population.
- **Magnitude and timeframe of savings offsets due to weight loss:** Any offsets to the costs of covering AOMs will come from medical cost savings due to weight loss. It is difficult to predict how healthcare spending may be impacted by the use of AOMs in the Medicare population, and there is limited research available on the topic. We put a range around total potential impact by assuming no cost offsets at all (Scenario 5), as well as scenarios with high and low potential claim savings (Scenarios 1 and 2, respectively). We base our savings assumptions on the relative percentage change in overall costs for year 1, year 2, and year 3 and beyond by ORC relative to baseline costs. For members who are projected to regain weight by year 3, we assume no savings relative to their baseline costs for year 3 and beyond.

As discussed in the results section, the modeled savings offsets due to weight loss rely on the correlation in healthcare costs for patients with higher and lower BMIs observed in our literature review, rather than a change in healthcare costs for patients who lower their BMI. We assume AOM users who successfully lose weight will have lower future healthcare costs similar to the proportion of costs by BMI band in the study we relied on, as

<sup>7</sup> Chen, F. et al. (October 2019). Ten-year Medicare budget impact of increased coverage for anti-obesity intervention. J Med Econ. Funded by Novo Nordisk. Retrieved May 25, 2021, from <https://pubmed.ncbi.nlm.nih.gov/31378108/>.

<sup>8</sup> Shin, J.H. & Gadde, K.M. (2013). Clinical utility of phentermine/topiramate (Qsymia) combination for the treatment of obesity. *Diabetes Metab Syndr Obes*. Retrieved May 25, 2021, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3626409/>.

<sup>9</sup> Ibid.

<sup>10</sup> Saxenda. Benefits of Saxenda. Retrieved May 25, 2021, from <https://www.saxenda.com/about-saxenda/benefits-of-saxenda.html?campaign=000870211&modal=isi>.

<sup>11</sup> Chen, F. et al. op cit.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.

we were unable to find published research that showed the direct impact of AOM use on healthcare spending in the Medicare market. If weight loss does not produce as large of a cost differential as the reported differentials in costs by BMI group, our savings estimates in Scenarios 1 through 4 would be lower.

- **Service category distribution of savings offsets:** In Scenarios 1 through 4, we leveraged the distribution in savings and additional costs as developed in the “Ten-year Medicare Budget Impact of Increased Coverage for Anti-Obesity Intervention”<sup>14</sup> report to distribute the total savings amount across different service categories. We combine the resulting savings by ORC from the assumed weight loss with the distribution of cost changes by service category as shown in Figure 2a of that report. We did not consider the impact of potential side effects of AOMs or the associated costs of side effects, which we expect to have minimal impact on Medicare claim costs.

Figure 9 shows the total net savings and the distribution of net savings offsets (excluding the cost of the AOM) by service category. These savings are not applicable to Scenario 5, which assumes no change in healthcare spending associated with AOM use.

<b>Figure 9</b>		
<b>Projected PMPM Net Savings Offsets Resulting From AOM Use</b>		
<b>Assumed Monthly Savings Following AOM Use</b>		
<b>All Medicare Members</b>		
	<b>High</b>	<b>Low</b>
IP	-\$17.7	-\$8.5
OP	-\$206.7	-\$98.6
Other - Medical	\$89.2	\$42.5
<b>Total Medical</b>	<b>-\$135.2</b>	<b>-\$64.5</b>
Rx	-\$134.3	-\$63.9
<b>Grand Total</b>	<b>-\$269.4</b>	<b>-\$128.3</b>

<sup>14</sup> Chen, F. et al. op cit.

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## 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 with external parties with Milliman's prior written consent. We do not intend this information to benefit any third party 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 its specific needs. Any releases 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, 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 information provided by Novo, as well as publicly available information, for this purpose and accepted it without audit. 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 and Jake Klaisner 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. The terms of Milliman's Master Services Agreement with Novo Nordisk, effective February 28, 2019, apply to this document and its use.

## APPENDICES

Appendix A1  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes (in billions) - Baseline  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs											
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
<b>Member</b>	\$289.6	\$309.3	\$330.9	\$353.8	\$377.3	\$403.1	\$430.4	\$457.9	\$499.3	\$531.0	\$3,982.6
<b>Federal Government</b>	\$755.6	\$806.5	\$857.0	\$908.2	\$963.5	\$1,022.4	\$1,084.3	\$1,142.5	\$1,193.2	\$1,267.1	\$10,000.2
<b>Manufacturer</b>	\$12.1	\$13.3	\$14.5	\$15.6	\$16.4	\$17.6	\$19.0	\$20.2	\$21.9	\$23.7	\$174.3
<b>Total</b>	\$1,057.3	\$1,129.2	\$1,202.4	\$1,277.5	\$1,357.2	\$1,443.1	\$1,533.7	\$1,620.6	\$1,714.4	\$1,821.8	\$14,157.1
Medical Costs											
<b>Member</b>	\$244.7	\$261.1	\$279.1	\$298.5	\$319.0	\$341.1	\$364.3	\$388.0	\$424.7	\$451.3	\$3,371.8
<b>Federal Government</b>	\$651.4	\$693.7	\$735.6	\$778.6	\$826.5	\$876.2	\$928.2	\$976.6	\$1,015.7	\$1,077.3	\$8,559.9
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$896.2	\$954.9	\$1,014.7	\$1,077.1	\$1,145.5	\$1,217.3	\$1,292.5	\$1,364.6	\$1,440.4	\$1,528.6	\$11,931.7
Pharmacy Costs											
<b>Member</b>	\$44.8	\$48.2	\$51.8	\$55.3	\$58.3	\$62.0	\$66.1	\$69.9	\$74.7	\$79.8	\$610.8
<b>Federal Government</b>	\$104.2	\$112.7	\$121.4	\$129.5	\$137.0	\$146.2	\$156.1	\$165.9	\$177.4	\$189.8	\$1,440.3
<b>Manufacturer</b>	\$12.1	\$13.3	\$14.5	\$15.6	\$16.4	\$17.6	\$19.0	\$20.2	\$21.9	\$23.7	\$174.3
<b>Total</b>	\$161.2	\$174.3	\$187.7	\$200.4	\$211.7	\$225.8	\$241.2	\$256.0	\$274.0	\$293.2	\$2,225.4

Appendix A2  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes (in billions) - Scenario 1  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs											
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
<b>Member</b>	\$289.8	\$309.5	\$330.9	\$353.8	\$377.2	\$402.9	\$430.1	\$457.5	\$498.9	\$530.4	\$3,981.0
<b>Federal Government</b>	\$755.9	\$806.6	\$856.9	\$907.8	\$962.9	\$1,021.6	\$1,083.1	\$1,141.0	\$1,191.3	\$1,264.9	\$9,992.2
<b>Manufacturer</b>	\$12.1	\$13.4	\$14.5	\$15.5	\$16.4	\$17.5	\$18.9	\$20.0	\$21.7	\$23.4	\$173.4
<b>Total</b>	\$1,057.8	\$1,129.4	\$1,202.3	\$1,277.2	\$1,356.5	\$1,442.0	\$1,532.1	\$1,618.6	\$1,711.9	\$1,818.7	\$14,146.5
Medical Costs											
<b>Member</b>	\$244.7	\$261.1	\$279.0	\$298.4	\$318.9	\$341.0	\$364.1	\$387.7	\$424.4	\$450.9	\$3,370.3
<b>Federal Government</b>	\$651.4	\$693.6	\$735.3	\$778.1	\$825.8	\$875.3	\$927.0	\$975.2	\$1,014.0	\$1,075.3	\$8,550.9
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$896.2	\$954.7	\$1,014.3	\$1,076.5	\$1,144.7	\$1,216.2	\$1,291.1	\$1,362.9	\$1,438.4	\$1,526.2	\$11,921.2
Pharmacy Costs											
<b>Member</b>	\$45.0	\$48.4	\$51.9	\$55.4	\$58.3	\$61.9	\$66.0	\$69.7	\$74.5	\$79.5	\$610.7
<b>Federal Government</b>	\$104.5	\$113.0	\$121.6	\$129.7	\$137.1	\$146.3	\$156.2	\$165.8	\$177.4	\$189.6	\$1,441.3
<b>Manufacturer</b>	\$12.1	\$13.4	\$14.5	\$15.5	\$16.4	\$17.5	\$18.9	\$20.0	\$21.7	\$23.4	\$173.4
<b>Total</b>	\$161.7	\$174.8	\$188.0	\$200.7	\$211.8	\$225.8	\$241.0	\$255.6	\$273.5	\$292.5	\$2,225.3

Appendix A3  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes (in billions) - Scenario 2  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs											
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
<b>Member</b>	\$289.8	\$309.5	\$331.0	\$353.9	\$377.4	\$403.1	\$430.4	\$457.8	\$499.3	\$530.9	\$3,983.1
<b>Federal Government</b>	\$755.9	\$806.7	\$857.1	\$908.1	\$963.3	\$1,022.2	\$1,084.0	\$1,142.1	\$1,192.6	\$1,266.4	\$9,998.3
<b>Manufacturer</b>	\$12.1	\$13.4	\$14.5	\$15.6	\$16.4	\$17.6	\$19.0	\$20.2	\$21.8	\$23.6	\$174.2
<b>Total</b>	\$1,057.8	\$1,129.5	\$1,202.6	\$1,277.6	\$1,357.2	\$1,443.0	\$1,533.3	\$1,620.1	\$1,713.7	\$1,820.9	\$14,155.6
Medical Costs											
<b>Member</b>	\$244.7	\$261.1	\$279.0	\$298.5	\$319.0	\$341.1	\$364.2	\$387.9	\$424.5	\$451.1	\$3,371.2
<b>Federal Government</b>	\$651.42	\$693.7	\$735.4	\$778.3	\$826.1	\$875.7	\$927.6	\$976.0	\$1,014.9	\$1,076.4	\$8,555.5
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$896.2	\$954.8	\$1,014.5	\$1,076.8	\$1,145.1	\$1,216.8	\$1,291.8	\$1,363.8	\$1,439.5	\$1,527.5	\$11,926.7
Pharmacy Costs											
<b>Member</b>	\$45.0	\$48.4	\$52.0	\$55.5	\$58.4	\$62.1	\$66.2	\$69.9	\$74.7	\$79.8	\$612.0
<b>Federal Government</b>	\$104.5	\$113.0	\$121.6	\$129.8	\$137.2	\$146.5	\$156.3	\$166.1	\$177.7	\$190.0	\$1,442.7
<b>Manufacturer</b>	\$12.1	\$13.4	\$14.5	\$15.6	\$16.4	\$17.6	\$19.0	\$20.2	\$21.8	\$23.6	\$174.2
<b>Total</b>	\$161.7	\$174.8	\$188.1	\$200.8	\$212.1	\$226.2	\$241.5	\$256.2	\$274.2	\$293.4	\$2,229.0

Appendix A4  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes (in billions) - Scenario 3  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs											
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
<b>Member</b>	\$290.1	\$309.7	\$331.1	\$353.9	\$377.3	\$402.9	\$430.0	\$457.4	\$498.6	\$530.1	\$3,981.1
<b>Federal Government</b>	\$756.4	\$806.9	\$857.0	\$907.7	\$962.6	\$1,021.1	\$1,082.5	\$1,140.1	\$1,190.2	\$1,263.5	\$9,987.9
<b>Manufacturer</b>	\$12.2	\$13.4	\$14.5	\$15.6	\$16.4	\$17.5	\$18.8	\$19.9	\$21.5	\$23.2	\$172.9
<b>Total</b>	\$1,058.6	\$1,130.0	\$1,202.6	\$1,277.2	\$1,356.2	\$1,441.5	\$1,531.3	\$1,617.4	\$1,710.3	\$1,816.8	\$14,142.0
Medical Costs											
<b>Member</b>	\$244.7	\$261.1	\$279.0	\$298.3	\$318.8	\$340.9	\$364.0	\$387.6	\$424.2	\$450.7	\$3,369.2
<b>Federal Government</b>	\$651.4	\$693.5	\$735.0	\$777.6	\$825.1	\$874.4	\$926.0	\$974.0	\$1,012.5	\$1,073.6	\$8,543.1
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$896.2	\$954.5	\$1,013.9	\$1,076.0	\$1,143.9	\$1,215.3	\$1,289.9	\$1,361.5	\$1,436.7	\$1,524.3	\$11,912.3
Pharmacy Costs											
<b>Member</b>	\$45.3	\$48.6	\$52.1	\$55.6	\$58.5	\$62.0	\$66.1	\$69.8	\$74.5	\$79.4	\$612.0
<b>Federal Government</b>	\$105.0	\$113.4	\$122.0	\$130.1	\$137.5	\$146.7	\$156.5	\$166.1	\$177.7	\$189.9	\$1,444.8
<b>Manufacturer</b>	\$12.2	\$13.4	\$14.5	\$15.6	\$16.4	\$17.5	\$18.8	\$19.9	\$21.5	\$23.2	\$172.9
<b>Total</b>	\$162.4	\$175.5	\$188.6	\$201.3	\$212.3	\$226.2	\$241.4	\$255.9	\$273.6	\$292.5	\$2,229.7

Appendix A5  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes (in billions) - Scenario 4  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs											
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
<b>Member</b>	\$289.6	\$309.4	\$330.9	\$353.8	\$377.3	\$403.1	\$430.3	\$457.8	\$499.2	\$530.9	\$3,982.4
<b>Federal Government</b>	\$755.7	\$806.5	\$857.0	\$908.1	\$963.4	\$1,022.3	\$1,084.1	\$1,142.2	\$1,192.8	\$1,266.6	\$9,998.7
<b>Manufacturer</b>	\$12.1	\$13.3	\$14.5	\$15.6	\$16.4	\$17.6	\$19.0	\$20.2	\$21.8	\$23.6	\$174.1
<b>Total</b>	\$1,057.5	\$1,129.3	\$1,202.4	\$1,277.5	\$1,357.1	\$1,442.9	\$1,533.4	\$1,620.2	\$1,713.9	\$1,821.2	\$14,155.2
Medical Costs											
<b>Member</b>	\$244.7	\$261.1	\$279.0	\$298.5	\$319.0	\$341.1	\$364.3	\$387.9	\$424.6	\$451.2	\$3,371.4
<b>Federal Government</b>	\$651.4	\$693.7	\$735.6	\$778.5	\$826.3	\$876.0	\$927.9	\$976.3	\$1,015.3	\$1,076.8	\$8,557.8
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$896.2	\$954.8	\$1,014.6	\$1,077.0	\$1,145.3	\$1,217.1	\$1,292.2	\$1,364.2	\$1,439.9	\$1,528.0	\$11,929.3
Pharmacy Costs											
<b>Member</b>	\$44.9	\$48.3	\$51.8	\$55.3	\$58.3	\$62.0	\$66.1	\$69.9	\$74.6	\$79.7	\$610.9
<b>Federal Government</b>	\$104.3	\$112.8	\$121.5	\$129.6	\$137.1	\$146.3	\$156.2	\$165.9	\$177.5	\$189.8	\$1,440.9
<b>Manufacturer</b>	\$12.1	\$13.3	\$14.5	\$15.6	\$16.4	\$17.6	\$19.0	\$20.2	\$21.8	\$23.6	\$174.1
<b>Total</b>	\$161.3	\$174.4	\$187.8	\$200.5	\$211.8	\$225.9	\$241.2	\$256.0	\$274.0	\$293.1	\$2,225.9

Appendix A6  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes (in billions) - Scenario 5  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs											
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
<b>Member</b>	\$289.8	\$309.5	\$331.1	\$354.0	\$377.6	\$403.3	\$430.6	\$458.1	\$499.6	\$531.3	\$3,985.1
<b>Federal Government</b>	\$755.9	\$806.8	\$857.3	\$908.5	\$963.8	\$1,022.8	\$1,084.7	\$1,142.9	\$1,193.6	\$1,267.5	\$10,003.8
<b>Manufacturer</b>	\$12.1	\$13.4	\$14.5	\$15.6	\$16.5	\$17.7	\$19.1	\$20.3	\$22.0	\$23.8	\$175.2
<b>Total</b>	\$1,057.8	\$1,129.7	\$1,202.9	\$1,278.1	\$1,357.8	\$1,443.8	\$1,534.4	\$1,621.4	\$1,715.2	\$1,822.7	\$14,164.0
Medical Costs											
<b>Member</b>	\$244.7	\$261.1	\$279.1	\$298.5	\$319.0	\$341.1	\$364.3	\$388.0	\$424.7	\$451.3	\$3,371.8
<b>Federal Government</b>	\$651.4	\$693.7	\$735.6	\$778.6	\$826.5	\$876.2	\$928.2	\$976.6	\$1,015.7	\$1,077.3	\$8,559.9
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$896.2	\$954.9	\$1,014.7	\$1,077.1	\$1,145.5	\$1,217.3	\$1,292.5	\$1,364.6	\$1,440.4	\$1,528.6	\$11,931.7
Pharmacy Costs											
<b>Member</b>	\$45.0	\$48.4	\$52.0	\$55.5	\$58.5	\$62.2	\$66.3	\$70.2	\$75.0	\$80.1	\$613.3
<b>Federal Government</b>	\$104.5	\$113.0	\$121.7	\$129.9	\$137.3	\$146.6	\$156.5	\$166.3	\$177.9	\$190.2	\$1,443.9
<b>Manufacturer</b>	\$12.1	\$13.4	\$14.5	\$15.6	\$16.5	\$17.7	\$19.1	\$20.3	\$22.0	\$23.8	\$175.2
<b>Total</b>	\$161.7	\$174.9	\$188.2	\$201.0	\$212.3	\$226.5	\$241.9	\$256.8	\$274.8	\$294.1	\$2,232.3

Appendix B1  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes PMPM - Baseline  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs										
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
<b>Member</b>	\$383.4	\$399.6	\$417.2	\$435.7	\$453.9	\$474.7	\$496.6	\$518.7	\$555.2	\$578.6
<b>Federal Government</b>	\$995.5	\$1,036.9	\$1,076.1	\$1,114.1	\$1,155.2	\$1,200.5	\$1,247.8	\$1,291.7	\$1,326.4	\$1,380.4
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.7	\$24.4	\$25.6	\$27.0	\$28.3	\$29.9	\$31.5
<b>Total</b>	\$1,398.8	\$1,457.9	\$1,515.8	\$1,573.4	\$1,633.5	\$1,700.9	\$1,771.4	\$1,838.7	\$1,911.5	\$1,990.5
Medical Costs										
<b>Member</b>	\$309.53	\$322.3	\$336.5	\$351.6	\$367.4	\$384.6	\$402.6	\$421.0	\$453.4	\$472.4
<b>Federal Government</b>	\$823.8	\$856.3	\$887.0	\$917.1	\$951.7	\$987.9	\$1,025.8	\$1,059.8	\$1,084.4	\$1,127.7
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$1,133.4	\$1,178.6	\$1,223.5	\$1,268.7	\$1,319.1	\$1,372.5	\$1,428.4	\$1,480.8	\$1,537.7	\$1,600.1
Pharmacy Costs										
<b>Member</b>	\$73.8	\$77.3	\$80.7	\$84.1	\$86.6	\$90.1	\$93.9	\$97.7	\$101.8	\$106.2
<b>Federal Government</b>	\$171.6	\$180.7	\$189.1	\$197.0	\$203.5	\$212.7	\$222.0	\$231.9	\$242.0	\$252.6
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.7	\$24.4	\$25.6	\$27.0	\$28.3	\$29.9	\$31.5
<b>Total</b>	\$265.4	\$279.3	\$292.3	\$304.8	\$314.4	\$328.4	\$343.0	\$357.9	\$373.7	\$390.3

Appendix B2  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes PMPM - Scenario 1  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs										
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
<b>Member</b>	\$383.7	\$399.8	\$417.3	\$435.7	\$453.8	\$474.5	\$496.2	\$518.3	\$554.6	\$577.9
<b>Federal Government</b>	\$995.9	\$1,037.2	\$1,076.0	\$1,113.8	\$1,154.6	\$1,199.6	\$1,246.5	\$1,290.1	\$1,324.4	\$1,378.1
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.6	\$24.3	\$25.5	\$26.8	\$28.0	\$29.5	\$31.1
<b>Total</b>	\$1,399.7	\$1,458.4	\$1,515.9	\$1,573.1	\$1,632.7	\$1,699.6	\$1,769.6	\$1,836.4	\$1,908.6	\$1,987.0
Medical Costs										
<b>Member</b>	\$309.53	\$322.3	\$336.4	\$351.5	\$367.2	\$384.4	\$402.4	\$420.7	\$453.1	\$472.1
<b>Federal Government</b>	\$823.8	\$856.1	\$886.6	\$916.5	\$950.9	\$986.8	\$1,024.5	\$1,058.2	\$1,082.5	\$1,125.6
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$1,133.4	\$1,178.4	\$1,223.1	\$1,268.0	\$1,318.1	\$1,371.2	\$1,426.9	\$1,478.9	\$1,535.6	\$1,597.7
Pharmacy Costs										
<b>Member</b>	\$74.2	\$77.6	\$80.9	\$84.2	\$86.6	\$90.0	\$93.8	\$97.5	\$101.6	\$105.8
<b>Federal Government</b>	\$172.1	\$181.1	\$189.4	\$197.3	\$203.7	\$212.8	\$222.1	\$231.9	\$241.9	\$252.5
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.6	\$24.3	\$25.5	\$26.8	\$28.0	\$29.5	\$31.1
<b>Total</b>	\$266.3	\$280.0	\$292.8	\$305.1	\$314.6	\$328.4	\$342.7	\$357.4	\$373.0	\$389.4

Appendix B3  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes PMPM - Scenario 2  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs										
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
<b>Member</b>	\$383.7	\$399.9	\$417.4	\$435.9	\$454.1	\$474.8	\$496.6	\$518.7	\$555.1	\$578.5
<b>Federal Government</b>	\$995.9	\$1,037.3	\$1,076.2	\$1,114.1	\$1,155.1	\$1,200.3	\$1,247.5	\$1,291.3	\$1,325.8	\$1,379.7
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.7	\$24.4	\$25.6	\$27.0	\$28.2	\$29.8	\$31.4
<b>Total</b>	\$1,399.7	\$1,458.5	\$1,516.2	\$1,573.7	\$1,633.6	\$1,700.8	\$1,771.1	\$1,838.2	\$1,910.8	\$1,989.5
Medical Costs										
<b>Member</b>	\$309.53	\$322.3	\$336.5	\$351.5	\$367.3	\$384.5	\$402.5	\$420.9	\$453.2	\$472.3
<b>Federal Government</b>	\$823.8	\$856.2	\$886.8	\$916.8	\$951.3	\$987.3	\$1,025.1	\$1,059.0	\$1,083.5	\$1,126.8
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$1,133.4	\$1,178.4	\$1,223.2	\$1,268.3	\$1,318.6	\$1,371.9	\$1,427.7	\$1,479.9	\$1,536.8	\$1,599.0
Pharmacy Costs										
<b>Member</b>	\$74.2	\$77.6	\$80.9	\$84.3	\$86.8	\$90.3	\$94.1	\$97.8	\$101.9	\$106.2
<b>Federal Government</b>	\$172.1	\$181.1	\$189.5	\$197.4	\$203.8	\$213.0	\$222.3	\$232.3	\$242.3	\$252.9
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.7	\$24.4	\$25.6	\$27.0	\$28.2	\$29.8	\$31.4
<b>Total</b>	\$266.3	\$280.1	\$293.0	\$305.4	\$315.0	\$328.9	\$343.4	\$358.3	\$374.0	\$390.5

Appendix B4  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes PMPM - Scenario 3  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs										
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Member	\$384.2	\$400.2	\$417.6	\$435.9	\$454.0	\$474.5	\$496.2	\$518.1	\$554.4	\$577.6
Federal Government	\$996.7	\$1,037.7	\$1,076.3	\$1,113.8	\$1,154.4	\$1,199.2	\$1,245.9	\$1,289.2	\$1,323.3	\$1,376.6
Manufacturer	\$20.1	\$21.5	\$22.6	\$23.7	\$24.3	\$25.5	\$26.8	\$27.9	\$29.3	\$30.8
<b>Total</b>	<b>\$1,400.9</b>	<b>\$1,459.3</b>	<b>\$1,516.4</b>	<b>\$1,573.4</b>	<b>\$1,632.6</b>	<b>\$1,699.2</b>	<b>\$1,768.8</b>	<b>\$1,835.2</b>	<b>\$1,907.0</b>	<b>\$1,985.0</b>
Medical Costs										
Member	\$309.5	\$322.2	\$336.4	\$351.4	\$367.1	\$384.3	\$402.2	\$420.6	\$452.8	\$471.8
Federal Government	\$823.8	\$855.9	\$886.2	\$915.9	\$950.2	\$985.9	\$1,023.4	\$1,056.9	\$1,081.0	\$1,123.8
Manufacturer	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	<b>\$1,133.4</b>	<b>\$1,178.1</b>	<b>\$1,222.6</b>	<b>\$1,267.3</b>	<b>\$1,317.3</b>	<b>\$1,370.2</b>	<b>\$1,425.6</b>	<b>\$1,477.4</b>	<b>\$1,533.8</b>	<b>\$1,595.6</b>
Pharmacy Costs										
Member	\$74.6	\$78.0	\$81.2	\$84.5	\$86.8	\$90.2	\$93.9	\$97.6	\$101.5	\$105.8
Federal Government	\$172.9	\$181.8	\$190.0	\$197.9	\$204.2	\$213.3	\$222.5	\$232.3	\$242.3	\$252.8
Manufacturer	\$20.1	\$21.5	\$22.6	\$23.7	\$24.3	\$25.5	\$26.8	\$27.9	\$29.3	\$30.8
<b>Total</b>	<b>\$267.5</b>	<b>\$281.2</b>	<b>\$293.8</b>	<b>\$306.1</b>	<b>\$315.3</b>	<b>\$329.0</b>	<b>\$343.2</b>	<b>\$357.7</b>	<b>\$373.2</b>	<b>\$389.4</b>

Appendix B5  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes PMPM - Scenario 4  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs										
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
<b>Member</b>	\$383.5	\$399.6	\$417.2	\$435.7	\$453.9	\$474.7	\$496.5	\$518.6	\$555.1	\$578.5
<b>Federal Government</b>	\$995.6	\$1,037.0	\$1,076.1	\$1,114.0	\$1,155.1	\$1,200.4	\$1,247.6	\$1,291.4	\$1,326.0	\$1,379.9
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.7	\$24.4	\$25.6	\$27.0	\$28.2	\$29.8	\$31.4
<b>Total</b>	\$1,399.1	\$1,458.1	\$1,515.9	\$1,573.4	\$1,633.4	\$1,700.7	\$1,771.0	\$1,838.2	\$1,910.9	\$1,989.8
Medical Costs										
<b>Member</b>	\$309.5	\$322.3	\$336.5	\$351.6	\$367.3	\$384.6	\$402.6	\$420.9	\$453.3	\$472.3
<b>Federal Government</b>	\$823.8	\$856.2	\$886.9	\$916.9	\$951.5	\$987.6	\$1,025.5	\$1,059.4	\$1,084.0	\$1,127.3
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$1,133.4	\$1,178.5	\$1,223.4	\$1,268.5	\$1,318.9	\$1,372.2	\$1,428.0	\$1,480.4	\$1,537.3	\$1,599.6
Pharmacy Costs										
<b>Member</b>	\$73.9	\$77.4	\$80.8	\$84.2	\$86.6	\$90.1	\$93.9	\$97.7	\$101.8	\$106.1
<b>Federal Government</b>	\$171.8	\$180.8	\$189.2	\$197.1	\$203.6	\$212.8	\$222.1	\$232.0	\$242.1	\$252.6
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.7	\$24.4	\$25.6	\$27.0	\$28.2	\$29.8	\$31.4
<b>Total</b>	\$265.7	\$279.6	\$292.5	\$304.9	\$314.6	\$328.5	\$343.0	\$357.9	\$373.7	\$390.2

Appendix B6  
 Novo Nordisk Inc.  
 2022 - 2031 Total Stakeholder Costs and Changes PMPM - Scenario 5  
 Medicare FFS and Medicare Advantage Members

Total Stakeholder Costs										
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
<b>Member</b>	\$383.7	\$399.9	\$417.5	\$436.0	\$454.3	\$475.1	\$496.9	\$519.1	\$555.6	\$579.0
<b>Federal Government</b>	\$995.9	\$1,037.4	\$1,076.6	\$1,114.6	\$1,155.7	\$1,201.1	\$1,248.3	\$1,292.2	\$1,327.0	\$1,381.0
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.8	\$24.5	\$25.8	\$27.2	\$28.4	\$30.1	\$31.7
<b>Total</b>	\$1,399.7	\$1,458.8	\$1,516.7	\$1,574.4	\$1,634.5	\$1,701.9	\$1,772.4	\$1,839.8	\$1,912.6	\$1,991.6
Medical Costs										
<b>Member</b>	\$309.5	\$322.3	\$336.5	\$351.6	\$367.4	\$384.6	\$402.6	\$421.0	\$453.4	\$472.4
<b>Federal Government</b>	\$823.8	\$856.3	\$887.0	\$917.1	\$951.7	\$987.9	\$1,025.8	\$1,059.8	\$1,084.4	\$1,127.7
<b>Manufacturer</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total</b>	\$1,133.4	\$1,178.6	\$1,223.5	\$1,268.7	\$1,319.1	\$1,372.5	\$1,428.4	\$1,480.8	\$1,537.7	\$1,600.1
Pharmacy Costs										
<b>Member</b>	\$74.2	\$77.6	\$81.0	\$84.5	\$86.9	\$90.5	\$94.3	\$98.1	\$102.2	\$106.6
<b>Federal Government</b>	\$172.1	\$181.1	\$189.6	\$197.5	\$204.0	\$213.2	\$222.5	\$232.5	\$242.6	\$253.2
<b>Manufacturer</b>	\$20.0	\$21.4	\$22.6	\$23.8	\$24.5	\$25.8	\$27.2	\$28.4	\$30.1	\$31.7
<b>Total</b>	\$266.3	\$280.2	\$293.2	\$305.7	\$315.4	\$329.4	\$344.0	\$359.0	\$374.9	\$391.5

**Appendix C2**  
**Novo Nordisk Inc.**  
**Annual Claim Costs for Potential AOM Patients**  
**Medicare Advantage Members**  
**2019 Consolidated Health Cost Guidelines Source Database**

	<b>Medical Claim Costs</b>	<b>Pharmacy Claim Costs</b>
<b>10th Percentile</b>	\$738	\$51
<b>25th Percentile</b>	\$1,565	\$233
<b>50th Percentile</b>	\$3,825	\$1,035
<b>75th Percentile</b>	\$11,489	\$4,144
<b>90th Percentile</b>	\$31,157	\$8,324
<b>Average</b>	\$12,059	\$3,912

**Appendix C1**  
**Novo Nordisk Inc.**  
**Annual Claim Costs for Potential AOM Patients**  
**Medicare FFS Members**  
**2018 Medicare 5% Sample Database**

	<b>Medical Claim Costs</b>
<b>10th Percentile</b>	\$960.35
<b>25th Percentile</b>	\$2,239.72
<b>50th Percentile</b>	\$6,051.26
<b>75th Percentile</b>	\$19,151.28
<b>90th Percentile</b>	\$46,691.33
<b>Average</b>	\$17,733.64

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