Original Work

Impact of Insulin Copay Cap Legislation on Savings, Adherence, and Utilization Among Health Plan Medicare Beneficiaries

by Darryl K. Monroe II, PharmD, MBA, Agata Siwak, PharmD, MSBA, Marleen K. Wickizer, PharmD, AE-C, CDCES, Robert Topp, PhD, RN

Abstract

Purpose: The purpose of this study was to determine the effect of the Inflation Reduction Act (IRA) on member copayments for insulin between 2022 and 2023, while also identifying relationships between copayments for insulin and adherence, average income, gender, and utilization of insulin and GLP-1 agonists.

Methods: A retrospective claims analysis was conducted for Medicare beneficiaries of a single health plan; members were included if they had at least two paid insulin claims between the periods of January 1, 2022, to June 30, 2022, and January 1, 2023, to June 30, 2023. Adherence was measured using proportion of days covered. Members were categorized into an income range by their zip code based on the 2020 US Census data.

Results: There were 71 members in the 2022 cohort and 59 in the 2023 cohort. After implementation of the IRA, there was a statistically significant decrease in the average of member copayments for insulin between 2022 ($68.15) and 2023 ($54.34) ($p < 0.001$). Although the overall ANOVA model was not significant, post hoc comparisons indicated a trend in which adherence in the ≤ $60,000 income group was lower than both the $70,000-$79,999 ($p = 0.01$) and $80,000-$89,999 ($p = 0.04$) income groups. Between the years, GLP-1 utilization significantly increased ($p = 0.03$).

Conclusions: The insulin copay legislation significantly lowered insulin copayments for Medicare beneficiaries of the studied health plan, and a trend was identified between members' income and their level of adherence. Despite IRA implementation, GLP-1 agonist utilization continued to increase.

Currently, 28 million Americans have a diagnosis of diabetes.[1] Of these, approximately 7.4 million adults use insulin to regulate their glucose levels in management of this condition. Although insulin plays a vital role in diabetes management, insulin costs have continued to rise between 2012 and 2021, with the price of a 30-day supply of insulin increasing by 184 percent over this ten-year interval.[2] Many individuals diagnosed with diabetes often incur out of pocket costs associated with obtaining their insulin prescriptions, despite the status of their insurance coverage. From 2007 to 2022, member out-of-pocket spending on insulin for Medicare Part D enrollees quadrupled from $236 million to $1.03 billion.[3] More specifically, the average copay per insulin fill was around $63 in 2020 for Medicare beneficiaries.[4] Exceedingly high costs of insulin can create a barrier to affordability and members' adherence to their treatment regimens, leading to further complications that increase overall health care costs.

When members are not able to afford their insulin prescriptions, it can contribute to poor adherence to their prescribed treatments and to an exacerbation of their diabetes and associated comorbidities. Poor adherence can be characterized by members not taking their medications or rationing their insulin doses, which can lead to further complications.[5] A survey report from the American Diabetes Association (ADA) revealed that 1 in 4 insulin users have said that the cost of insulin has impacted their insulin use by requiring them to cut back or skip doses.[6] Improper use of insulin can lead to complications that include ketoacidosis, neuropathy, kidney disease, amputations, and even death. Many of these complications can lead to increased patient costs through medical treatment, hospitalizations, and additions to medication regimens while also negatively impacting quality of life.[7,8]

In August of 2022, the Inflation Reduction Act (IRA) was enacted to fight inflation, invest in domestic energy production and manufacturing, and reduce carbon emissions by an estimated 40 percent by 2030.[9] This new legislation allowed Medicare to negotiate for prescription drug prices and extend the expanded Affordable Care Act program through 2025. Specifically, the IRA legislation capped insulin copayments at $35 for each 30-day supply of insulin for Medicare beneficiaries.[4] This legislation brought the potential to create meaningful savings for Medicare beneficiaries while also potentially increasing their adherence to insulin treatment regimens. It was estimated that 1.5 million Medicare beneficiaries would benefit from the legislation. If this had been implemented in the year 2020,

the cost savings of beneficiaries in Part D plans would have amounted to around $734 million, with an average of $500 in savings per beneficiary.[4] This legislation could potentially greatly impact member adherence rates, especially for those who may have concerns with affordability.

A previous survey study on insulin copayments in Medicare Part D members revealed a positive correlation between lowered copayments and patient satisfaction, adherence, and affordability. Members with copayments greater than $35 per 30-day supply were more likely to not fill their prescriptions.[10] The purpose of this study will further address this problem by examining cost savings for members after IRA implementation in 2023. This study will also identify trends between member adherence, average income, and gender. A key focus of the IRA is to increase the affordability of insulin by reducing copayments, and this study will investigate decreases in member copayment for insulin, along with the anticipated increase in medication adherence for insulin utilizers.

Methods

Study Design

The proposed study is a retrospective claims analysis design in which members of a Northwest region health plan were identified by having at least two paid claims for the targeted medications within the defined pre- and post-intervention periods. The target medications in this study include short-acting and long-acting types of insulin. Glucagon-like-peptide 1 (GLP-1) agonists indicated for type 2 diabetes were included for the utilization trend analysis, for members who met the target medication criteria. The pre- and post-intervention periods were January 1, 2022, to June 30, 2022, and January 1, 2023, to June 30, 2023, respectively. The dates for the intervention period were selected to capture pre- and post-implementation of IRA and investigate equivalent periods of time, while also intending to avoid claims affected by the coverage gap and subsidies. Paid claims from the chosen health plan were retrieved from a pharmacy benefits manager claims database. Pharmacy claims were utilized to identify the total each member paid as a copayment for insulin in both intervention periods, medication adherence, and utilization trends for included medications.

Medicare beneficiaries of the health plan were included in the claims analysis if they had at least two paid claims for insulin on different days during the pre- and post-intervention study periods. Beneficiaries who had only one paid insulin claim or lived in a zip code where there was no average income reported during the 2020 US Census were excluded from the analysis. All reversed or rejected claims during the study periods were also excluded from the analysis. This study was exempted from review by the Institutional Review Board as it met the requirements of secondary research and did not require patient consent.

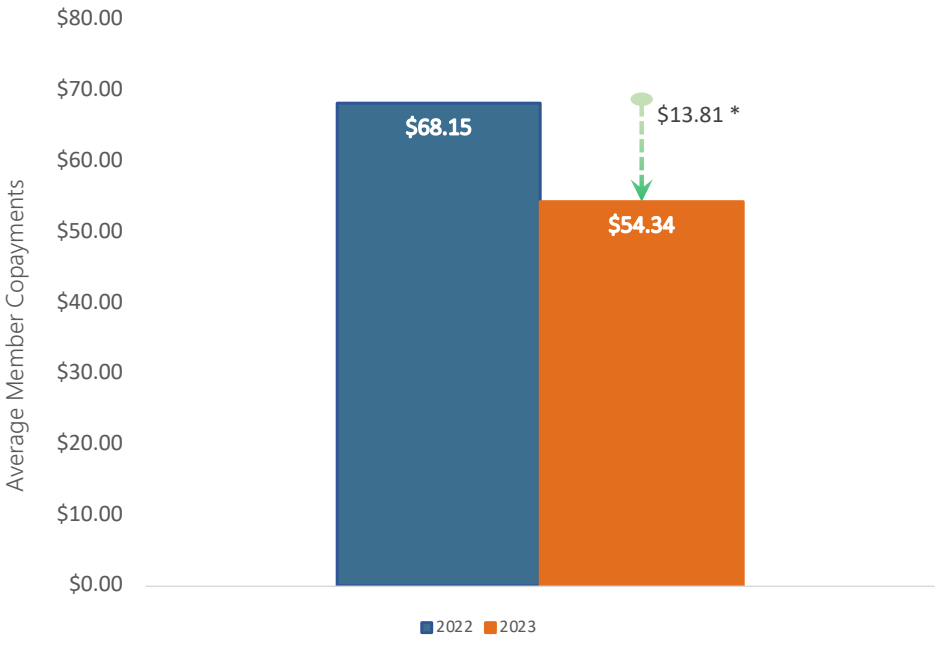
The primary outcome of this study was to determine the difference in the average amount of member insulin copayments during the pre- and post-intervention periods of 2022 and 2023, representing the implementation of the reduction of insulin copayments. To compare member copayments between the pre- and post-intervention periods, the total amount of member paid claims was calculated for each year. The sum of member copayments was then divided by the number of claims in the specified period to reach the average member copayment for each intervention period, respectively.

Additional secondary outcomes examined adherence pre- and post-IRA implementation, proportions of member adherence by their income, and gender. The utilization of insulin and GLP-1 agonists was also compared between study periods. Adherence was defined by proportion of days covered (PDC), calculated by utilizing data from pharmacy claims and excel formulas. PDC was calculated by the total number of days covered divided by the total number of days in the member-specific treatment period.[11] The treatment period was defined as the first fill date of the target medication through the projected end date of the last fill within the lookback period. Members were considered adherent to their treatment regimens if they had a PDC of 80% or greater. According to the Pharmacy Quality Alliance, a benchmark of 80% is the point at which the medication is likely to provide a clinically relevant benefit.[12,13] To categorize members by their average income,

TABLE 1. Baseline Demographics

	2022	2023
Mean Age, years (SD)	77.1 (6.6)	76.6 (6.3)
Female, n (%)	33 (46.5%)	26 (44.1%)
Male, n (%)	38 (53.5%)	33 (55.9%)
Average Income	$71,004.38	$71,682.56

FIGURE 1. Average Member Copayments Pre- and Post-IRA Implementation



*Indicates statistical significance ($p < 0.05$)

average income values were included from the 2020 US Census, and members were matched by their zip codes provided from both pharmacy claims and US Census data. Members were divided into six different income ranges when measuring member adherence by average income. Utilization was defined as the number of insulin and GLP-1 agonist claims, for members who had claims for both insulin and GLP-1-agonist during the intervention period.

For the statistical analysis, independent t-test samples were calculated to determine differences in average member copayments, member adherence measured as PDC, and utilization of insulin and GLP-1 agonists between pre- and post-intervention periods. A chi square analysis was performed to determine if there was a difference in the proportion of males versus females who achieved a PDC threshold of 80%. Finally, an ANOVA model was used to determine differences in adherence between six average income ranges across the pre- and post-intervention periods.

Results

A total of 71 members and 59 members were included in the claims analysis for the 2022 and 2023 cohorts, respectively. Cohorts were similar in the proportions of gender and age, and the baseline demographics of members included in the analysis are in Table 1. After the implementation of the IRA, there was a statistically significant decrease in the average of member copayments for insulin between 2022 ($68.15) and 2023 ($54.34) (see Figure 1). Post-IRA implementation claims in the data set reflected an insulin copayment of $35 for a 30-day supply, $70 for a 60-day supply, and $105 for a 90-day supply. Of the insulin claims included in the analysis, 34% were filled for greater than a 30-day supply. Of those claims that were filled for greater than 30 days, 71% were for a 90-day supply of insulin. The average day supply of insulin was 53 and 51 in 2022 and 2023, respectively.

There was a non-statistically significant increase in member average PDC between 2022 (87.82%) and 2023 (88.62%) (p = 0.44) (see Figure 2). While females were consistently more adherent compared to males in the pre- and post-IRA cohorts, adherence in both groups demonstrated a non-statistically significant increase after experiencing a reduction in copayments for insulin (p = 0.169) (see Figure 3). The overall 1-way ANOVA model comparing adherence measured by PDC over the six income categories among the combined pre- and post-IRA cohorts approached statistical significance (p = 0.08). Post hoc comparisons indicated a trend in which adherence in the ≤ $60,000 income group was lower than both the $70,000-$79,999 (p = 0.01) and $80,000-$89,999 (p = 0.04) income groups (see Figure 4). Post-IRA implementation, insulin utilization decreased (p = 0.071) while utilization of GLP-1 agonists significantly increased (p = 0.03) (see Figure 5).

FIGURE 2. Overall Member Average Proportion of Days Covered (PDC) Pre- and Post-IRA Implementation

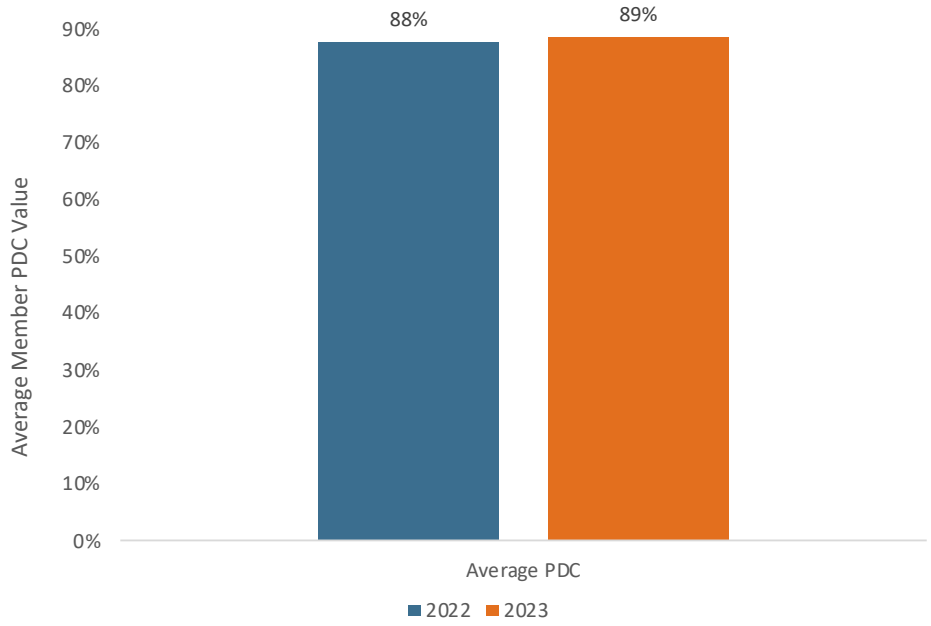
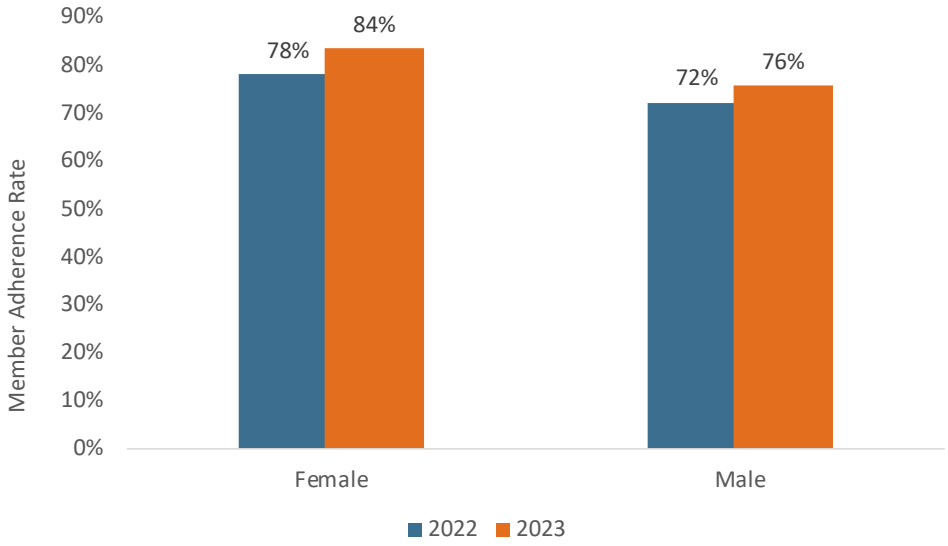


FIGURE 3. Proportion of Adherent (PDC ≥ 80%) Members Stratified by Gender



Discussion

Patient adherence to medication treatment regimens is related to health outcomes, and it is important to recognize all the barriers that may negatively impact one's adherence. This study observed the impact of decreased out-of-pocket copayments and changes in adherence to insulin after implementation. After reducing insulin copayments to $35 per 30-day supply, the analysis demonstrated a

statistically significant decrease in average member copayments for insulin. As insulin copayments were reduced, there was a non-statistically significant increase in adherence post-IRA implementation. Members with a PDC value of ≥ 80% are considered adherent, and in this study, patients demonstrated adherence to their insulin regimen at a value of 87.82% in 2022 before IRA implementation, with a slight increase to 88.62% in 2023 post-IRA implementation. Based on prior studies, males are typically more adherent to their medications.[14-16] In this study population, females demonstrated higher adherence (PDC) to their insulin treatment regimens than males.

After implementation of the IRA, it was hypothesized that capped insulin copayments would cause a significant decrease in out-of-pocket expenses for insulin, and lead to an increase in medication adherence. This study identified that members' copayments for insulin were significantly decreased post-IRA and saved approximately $14 on average per insulin claim. While copayments were decreased, adherence to insulin also increased and a trend was identified regarding members' average income. Previous studies that analyzed adherence and medication affordability indicate that higher adherence is correlated to greater affordability. Within this study, this belief was confirmed, as members who were in higher average income ranges demonstrated greater adherence than those in lower income ranges. As members in lower income ranges would be impacted most by a reduction in insulin copayments, a statistically significant increase was not identified, but larger studies may be adequately powered to detect such differences. Post-IRA implementation, insulin utilization trended lower while utilization of GLP-1 agonists significantly increased. With decreased insulin copayments following IRA implementation, an increase in insulin utilization may have been expected due to increased affordability through lower copayments; however, the smaller sample size in the 2023 cohort may have diluted statistical power, contributing to the non-significant decrease in insulin. Additionally, recent clinical guideline updates to treating type 2 diabetes indicate that GLP-1 agonists are now first line of therapy treatment options.[17] When considering the findings of this study, this may have also impacted the increase in GLP-1 utilization within the health plan, as patients may be initiated on GLP-1 agonists to begin treatment or switch from insulin to GLP-1 agonists if they're an appropriate candidate.

Some limitations of this study include the small sample size, unreliability of insulin quantity and day supply on pharmacy claims, and the limited information on social determinants of health (e.g., race, ethnicity, education status) that was omitted from health plan and pharmacy claims. The small sample size threatens the study's internal and external validity. Future studies may approach this limitation by analyzing multiple health plans in various geographical

FIGURE 4. Proportion of Adherent (PDC ≥ 80%) Members by Average Income Ranges Pre- and Post-IRA Implementation

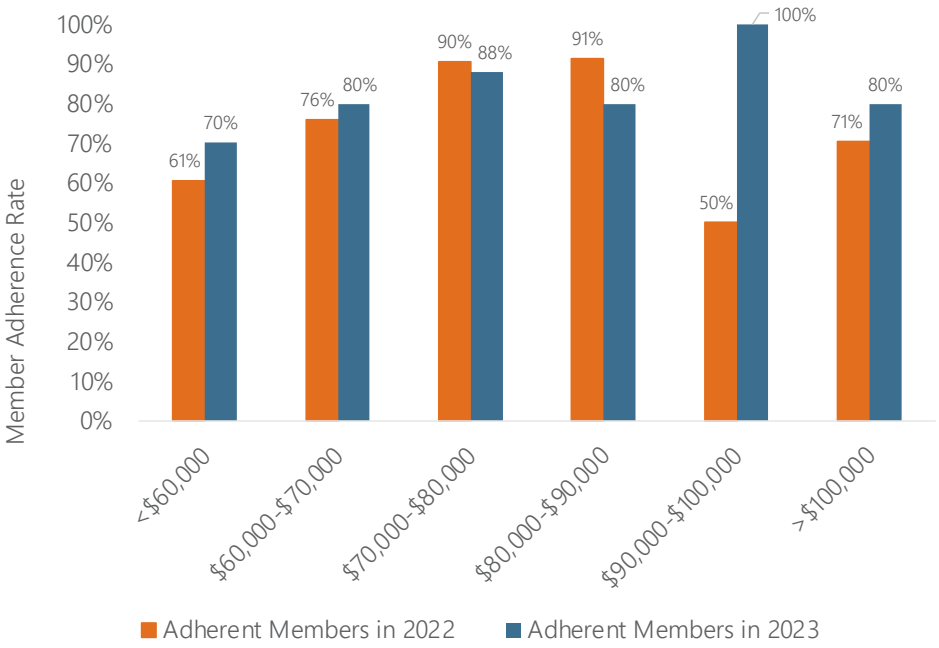
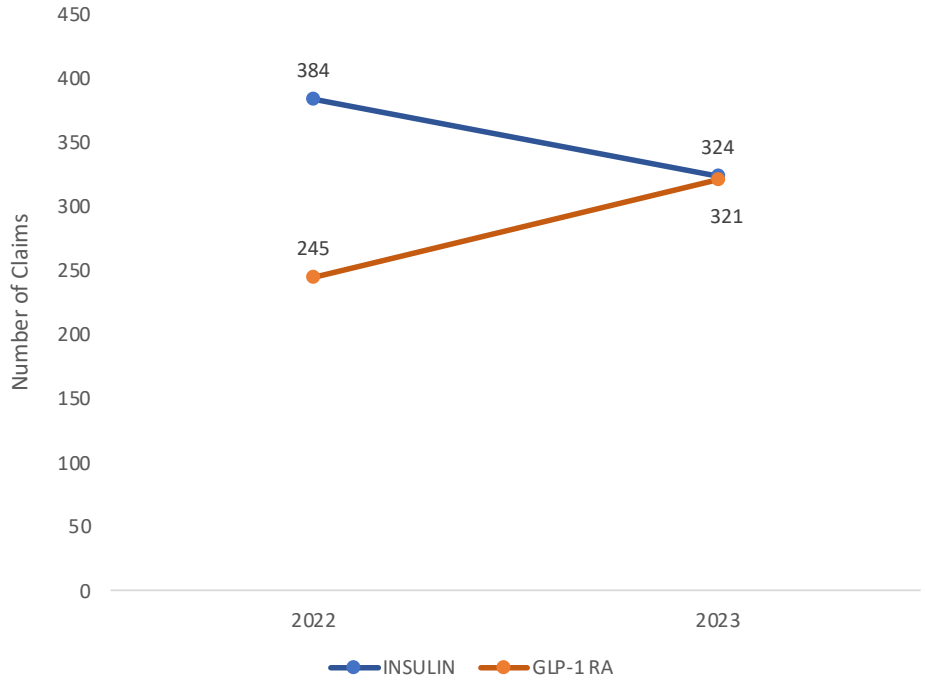


FIGURE 5. Insulin vs. Glucagon-like peptide-1 (GLP-1) Member Utilization



regions. Using PDC to measure adherence to insulin and relying on day supply values may provide limited insight into the true level of adherence. Quantity and day supply values submitted from pharmacy claims do not capture varying dosing regimens with insulin in response to variations in the individual's blood glucose. Persistence may be a greater measure to track adherence or a gap in therapy when analyzing insulin treatment, and future studies may wish to measure members' persistence to determine the impact of the IRA.

Conclusion

The insulin copay legislation significantly lowered insulin copayments for Medicare beneficiaries of the studied health plan. Respective beneficiaries experienced a significant decrease of between $13 and $14 on average for their insulin copayments. A trend was also identified between members' income and their level of adherence, where members with higher average incomes had higher adherence rates (PDC) to their insulin treatment regimen. Post hoc comparisons after statistical modeling indicated that members' adherence in the ≤ $60,000 income group was lower than both the $70,000-$79,999- and $80,000-$89,999-income groups. Despite IRA implementation, GLP-1 agonist utilization continued to increase, while insulin utilization decreased. Further research will be needed to assess the impact of the IRA on persistence to insulin and studies with larger samples may also wish to examine differences in adherence between average income groups.

Darryl Monroe is a Rebate Account Executive at Navitus Health Solutions in Madison, WI. Agata Siwak is a Manager of Clinical Outcomes Analysis at Navitus Health Solutions in Madison, WI. Marleen Wickizer is a Director of Clinical Services at Navitus Health Solutions in Madison, WI. Robert Topp is a Professor at the University of Kentucky, Lexington, KY.

Corresponding Author:
Darryl Monroe - Darryl.Monroe@navitus.com

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