Potential Impact of Formulary Restrictions on Anticoagulants in the Post- Maximum Fair Price (MFP) Part D Market

Modeling the effects of access barriers on rates of treatment, non-medical switching, and therapy abandonment among Medicare Part D beneficiaries treated with anticoagulants

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In 2026, the implementation of the Inflation Reduction Act (IRA)'s maximum fair prices on selected anticoagulants, combined with Part D's benefit redesign, may increase net Part D plan financial liabilities and lead to formulary restrictions. Based on historical patient utilization patterns, we modeled scenarios of anticoagulant formulary restrictions on treatment rates, including placement of selected therapies on the non-preferred formulary tier and the introduction of step edits. If implemented, these formulary restrictions could result in high rates of non-medical switching and therapy abandonment, with broader implications for patient care.

Background

IRA'S NEGOTIATION IN 2026 LIKELY TO CHANGE PAYER ECONOMICS FOR ANTICOAGULANTS

The IRA's Part D redesign aims to lower out-of-pocket (OOP) costs on prescription drugs for Medicare Part D beneficiaries. The IRA introduced a "cap" or maximum OOP limit and the ability, for certain beneficiaries, to spread OOP costs throughout the year. The IRA also reduced the government's share of costs incurred in the catastrophic phase to incentivize Part D plans to better manage high costs. Taken together, these provisions are projected to increase Part D plan liabilities. The IRA also includes a provision to institute a maximum price that manufacturers can charge for certain negotiated drugs in the Medicare program, also known as the maximum fair price, or MFP (1). By reducing the price Part D pays for selected drugs, the MFP may also reduce patient OOP for patients when subject to deductibles and coinsurance.

The initial list of negotiated prices, which will go into effect on January 1, 2026, impact 10 drugs selected for price negotiation, including the two highest volume Part D drugs in the anticoagulant class ("selected anticoagulants") (2). Anticoagulants or "blood thinners" are commonly used to prevent and/or treat blood clots. The selected anticoagulants have been associated with high manufacturer rebates, which reduce the liability for Part D plans (3). Part D plans have strong financial incentives for including highly rebated drugs in the preferred formulary tier, even after the IRA's Part D redesign (3). Not surprisingly, 98% of beneficiaries in Part D currently have "preferred" brand formulary tier coverage for the selected anticoagulants, with little to no utilization management in Part D. Drugs covered in the preferred tier (typically indicted as "Tier 3") are associated with lower OOP than those in the "non-preferred" tier ("Tier 4").

The implementation of MFP on the highest-utilized anticoagulants is expected to drastically reduce or eliminate rebates in this class, altering the current dynamics. As rebates for the selected drugs are virtually eliminated, the "net" Part D plan liability (a plan's financial exposure after rebates) could increase, making it less attractive for plans to cover the selected anticoagulants on the preferred tier without utilization management. While all drugs selected for MFP must be included in Part D formularies per Center for Medicare and Medicaid (CMS) guidance (4), a Part D market shift towards non-preferred

tier coverage or step edits for selected anticoagulants could potentially disrupt patient access for the entire class (5).

MFP IMPLEMENTATION MAY INCENTIVIZE FORMULARY RESTRICTIONS ON ANTICOAGULANTS

Part D formulary restrictions have increased over time, and the current MFP environment introduces incentives for more restrictions. A review of utilization restrictions seen in Medicare Part D plans from 2011-2020 determined in 2011, there was an overall "restriction" rate of 31.9%, which was defined as any prior authorizations or plan exclusions. This rate increased to 44.4% in 2020 (6). Increases in formulary restrictions have been shown to be correlated to non-medical switching,[1] therapy abandonment, and a risk of adverse events (7), (8), (9), (10).

CMS has provided limited guidance on the Part D coverage of drugs that were selected for price negotiation. Part D plans must include the selected drugs on their formularies, and CMS will utilize its formulary review process to monitor for policies or practices that "undermine access to negotiated prices for selected drugs (11)." Notably, the guidance does not explicitly require specific tier placement and does not address utilization management requirements, but states CMS may elect to do so in the future, based on how plans react to the legislation (11). The lack of specific guidance and language surrounding formulary access restriction has led to some patient advocacy groups to urge CMS to consider the implementation of specific language that would safeguard patients from non-medical switching in response to changes due to the MFP regulations (12).

As Part D plans attempt to manage their increased financial exposure, they may opt to:

1) Place selected anticoagulants on the non-preferred formulary tier, in an attempt to shift some costs to the patient (as the non-preferred tier has higher patient OOP, typically coinsurance rather than a copay) or
2) Limit utilization of select anticoagulants for patients starting therapy through the adoption of step edits, where a patient must try and fail another drug before the Part D plan pays for the selected drug.[2]

An increase in formulary restrictions would be expected to reduce overall anticoagulant treatment rates and increase the rates of therapy abandonment and non-medical switching, as patients and providers switch to alternative agents with broader formulary coverage and lower OOP costs. This analysis seeks to understand the potential impact of formulary access restrictions that may be imposed in response to the implementation of MFPs on anticoagulant treatment rates among Part D beneficiaries.

Methodology

Using historical data on anticoagulant use from CMS 100% Research Identifiable Part D files, we modeled the potential impact of plans implementing higher cost sharing (through non-preferred tier formulary placement) and step edits on selected drugs.

We first summarized the number of patients on treatment, number of scripts, treatment rates (measured as patients per 1,000 Part D beneficiaries) and treatment adherence (measured as scripts per patient) among patients treated with anticoagulants in 2024. Results were summarized separately for Part D plans with different levels of formulary restrictions: 1) preferred tier placement without step edits, 2) non-preferred tier placement without step edits, and 3) preferred tier placement with step edits.

To model the impact of selected anticoagulants moving from preferred (Tier 3) to non-preferred (Tier 4) status for all Part D plans, we relied on separate observations for existing and new patients to therapy. There is not enough recent experience of formularies moving selected anticoagulants from Tier 3 to Tier 4. However, a study from 2023 described patient choices under such a scenario (13). Results of this study suggest a move from preferred to non-preferred tier may result in 10.3% of patients switching anticoagulants and 17.8% abandoning therapy.

Among patients new to therapy, the inclusion of selected anticoagulants in the non-preferred tier was observed to lead to an overall reduction in the number of patients treated with selected anticoagulants (per 1,000 Part D beneficiaries) from 27.1 to 16.7. This translated into a potential 38% reduction in the number of patients on selected anticoagulants, where 33% of patients initiated treatment with another anticoagulant and 5% did not initiate treatment. Anticoagulant utilization was defined as the observation of one or more scripts in 2024. All patients on anticoagulants were included in this analysis, agnostic of indication. The two scenarios of Part D formulary restrictions we analyzed and modeled were: 1) moving selected anticoagulants from the preferred to the non-preferred tier, and 2) imposing step edits for selected anticoagulants (requiring patients to try and fail a non-selected drug before treatment with ("stepping" into) a selected drug) on patients new-to-therapy.

Based on our retrospective cohort study, we created a model to estimate the potential impact of tier changes and step edits on patient OOP costs, treatment adherence (defined here as

[1] Defined by the American Society of Preventative Cardiology as any changes to a patient's stabilized medication therapy that is brought about by a payor for cost related reasons.

[2] Step edits, are a form of utilization management where a patient must try and fail one therapy before moving onto another

average number of scripts per patient per year), and patterns of therapy switching and abandonment (defined here as observation of treatment discontinuation) patterns. We modeled treatment rates among beneficiaries not eligible for low-income subsidies (LIS) or employer group waiver plans (EGWP). LIS was excluded from this analysis because they have nominal exposure to OOP costs and therefore are less likely to change behavior based on cost sharing alone. EGWP plans were excluded as we do not have information on formulary coverage for these patients.

Results

FORMULARY RESTRICTIONS HAVE A LARGE IMPACT ON UTILIZATION RATES

Overall, we observed 3.4 million beneficiaries in 2024 who filled at least one script for an anticoagulant, of whom 82% used a selected anticoagulant. When selected anticoagulants were covered in the preferred tier, treatment rates per 1000 Part D beneficiaries with selected anticoagulants and with all other anticoagulants were 84.8 and 18.9, respectively. The annual number of 30-day equivalent scripts per patient was 7.4 for those receiving selected anticoagulants, compared to 9.1 for those receiving all other anticoagulants. (Table 1)

When selected anticoagulants were covered in the non-preferred tier, treatment rates decreased to 45.0 per 1000 beneficiaries, with adherence also dropping to 7.2 scripts per patient. Conversely, treatment rates with all other anticoagulants increased to 55.9 per 1000, with no noticeable change in adherence. Moreover, when selected anticoagulants were subject to step edits, treatment rates decreased to 14.1 per 1,000 beneficiaries, with adherence decreasing by about 2 scripts (to 5.4 scripts per patient). Step edits resulted in a three-fold increase in treatment rates with all other anticoagulants, to 78.9 per 1000, with a reduction in adherence of about 1 script (to 8.1 scripts per patient). (Table 1)

TABLE 1: THE CURRENT LANDSCAPE OF ANTICOAGULANT COVERAGE, UTILIZATION, AND PATIENT COST SHARING AMONG NON-LOW INCOME, NON-EGWP PART D BENEFICIARIES (2024)

	Anticoagulant class	Selected anticoagulants	All other anticoagulants
Preferred (Tier 3) Placement for Selected Anticoagulants			
Patients with 1+ Script in 2024	3,385,880	2,768,924	616,955
Patients per 1,000 Part D beneficiaries	103.7	84.8	18.9
Annual Scripts per Patient*	7.7	7.4	9.1
Non-Preferred (Tier 4) Placement for Selected Anticoagulants**			
Patients per 1,000 Part D beneficiaries	101.2	45.0	55.9
Annual Scripts per Patient*	8.3	7.2	9.1
Step Edits on Selected Anticoagulants***			
Patients per 1,000 Part D beneficiaries	93.1	14.1	78.9
Annual Scripts per Patient*	7.7	5.4	8.1

Source: Milliman Analysis of 2024 100% Research Identifiable Part D Files.

** 30-Day Supply Equivalent.*

***We observed that 6% of beneficiaries had non-preferred tier placement of a selected drug in 2024*

****We observed that 2% of beneficiaries had a step edit on selected drugs in 2024. Notably, when we did observe a step edit, it was for one selected drug over another selected drug.*

We note that baseline utilization rates in Table 1 represent an environment where beneficiaries can change Part D plans each year during the open enrollment period to maximize access to therapies and minimize their OOP exposure. Such an environment tends to lead to adverse selection and can result in drastically different treatment rates among the cohorts studied. In our modeling of scenarios of formulary restrictions, we have chosen to assume the entire Part D market implements those restrictions, which would effectively eliminate adverse selection and therefore moderate the impact observed in Table 1. We

believe this assumption illustrates more realistic dynamics in a post-MFP market.

NON-PREFERRED TIER PLACEMENT OF SELECTED ANTICOAGULANTS COULD LEAD TO 30% OF PATIENTS ABANDONING OR SWITCHING THERAPY

We modeled the impact of moving the selected anticoagulants from Tier 3 to Tier 4 using historical patient utilization patterns and assumptions, as described in the methodology section.

Overall, for existing and new-to-therapy patients on selected anticoagulants, we projected about 69% of patients would remain on (or initiate treatment with) the selected drug when covered in the non-preferred tier, compared to the status quo (where 98% of beneficiaries have coverage in the preferred tier). We further estimated there would be a 17% therapy abandonment rate as well as a 14% non-medical switching rate. (Figure 1A).

MODELED SCENARIOS OF TIER 4 PLACEMENT AND STEP EDITS FOR SELECTED ANTICOAGULANTS (2026): IMPACT ON THERAPY ABANDONMENT AND NON-MEDICAL SWITCHING

FIGURE 1A: TIER 4 PLACEMENT FOR SELECTED ANTICOAGULANTS

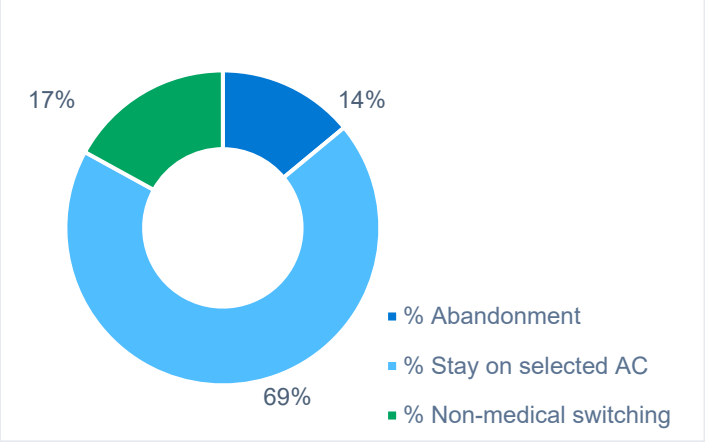
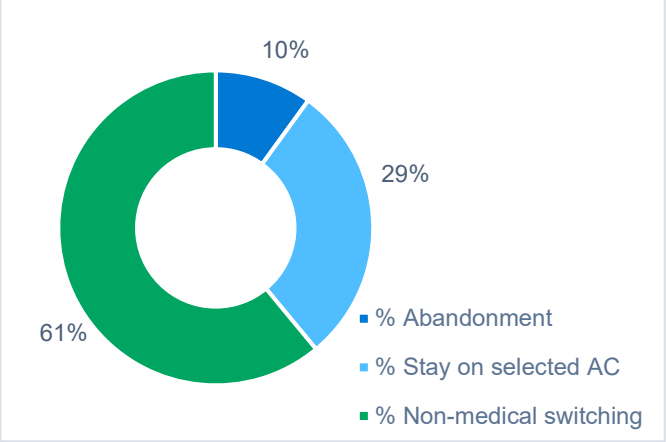


FIGURE 1B: STEP EDITS ON SELECTED ANTICOAGULANTS FOR PATIENTS NEW TO TREATMENT



Source: Milliman Analysis of CMS's 2024 100% Research Identifiable Part D Files; AC = anticoagulant.

THE INTRODUCTION OF STEP EDITS COULD LEAD TO A 70% REDUCTION IN PATIENTS INITIATING THERAPY WITH A SELECTED ANTICOAGULANT

To model the impact of step edits, we relied on historical data as observed in 2024. When selected anticoagulants were modeled to be subject to step edits ("stepping" through generic anticoagulants) for patients new-to-therapy, we estimated a reduction of 71% in the number of new patients treated with selected anticoagulants (per 1,000 Part D beneficiaries), from 27.1 to 8.0. The implementation of step edits on selected anticoagulants was estimated to lead to a 10% abandonment rate and an additional 61% of patients initiating therapy with another anticoagulant (also referred to as non-medical switching in this report). (Figure 1B).

FORMULARY RESTRICTIONS WILL LIKELY INCREASE PATIENT COST SHARING FOR SELECTED ANTICOAGULANTS

In addition to potentially impacting rates of treatment and non-medical switching, changes in formulary access could also impact patient OOP costs. We estimate that a shift from preferred to non-preferred tier could increase patient OOP costs by 80%, from $54.92 for a 30-day script to $98.89 for a 30-day script. This projection relies on an average MFP price of $219 and assumes patient coinsurance of 25% and 45% for preferred and non-preferred tiers, respectively.

Implications for 2026 Formularies

Current CMS guidance does not explicitly require preferred coverage of MFP products and instead relies on its annual formulary review process to assess coverage of MFP-negotiated products. CMS has acknowledged its concern that *"Part D*

sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs." While provisions in the guidance document allow for CMS to take future action based on how plans react to the MFP, appropriate oversight of formulary restrictions are needed prior to implementation to reduce the potential for therapy abandonment and non-medical switching in Part D.

For drugs included in the 2026 negotiated list, plans must submit initial 2026 formularies in the Spring of 2025. CMS will then review bids and formulary submissions during the Summer of 2025. Approved formularies will be released in the Fall 2025. Based on these timelines, we would expect to observe real-world shifts in coverage and/or access by the Fall of 2025. However, the potential impact of formulary restrictions will not be clear until its implementation in 2026.

Conclusion

Our model suggests that barriers to access via non-preferred tier placement or step edits could reduce treatment rates by up to 14% and result in rates of non-medical switching of up to 61%. Other work done evaluating formulary restrictions (via step edits or prior authorizations) in patients with atrial fibrillation has similarly demonstrated reductions in adherence and utilization of anticoagulants as a result (14). Patient OOP costs could also be impacted by access restrictions. We modeled an increase in OOP costs by 80% (from $54.92 to $98.85 per month) when selected anticoagulants are modeled to shift from preferred to non-preferred placement. This could translate to an annual OOP increase of $527 per patient, when calculated using the average MFP price.

While not explored within the scope of this analysis, other studies have quantified the impact of anticoagulant formulary restrictions and discontinuation on the risk of adverse clinical outcomes in patients (14), (15). Published literature summarizes the clinical challenges with non-medical switching of oral anticoagulants leading to over and under coagulation-stasis (16), (17). Since the Medicare program (either fee-for service or Medicare Advantage) is ultimately liable for all medical and pharmacy costs for patients, any potential cost savings must be evaluated in the context of potential increases in healthcare resource utilization that may occur as a result of therapy abandonment or non-medical switching.

The implementation of IRA provisions, including the Part D benefit redesign, is likely to create financial incentives for increased formulary restrictions, particularly on selected drugs (4). CMS acknowledges in their guidance document that plans may disadvantage MFP-selected products based on non-medical factors (11). Formulary restrictions can impact patient affordability and impose further barriers to access, which may result in lower treatment rates, reduced adherence, and the potential for non-medical switching. These results highlight the need to ensure appropriate patient access to therapies.

Caveats and Limitations

The results shown here are based on scenarios of formulary restrictions in Part D based on observations in a national Medicare Part D database among non-low income, non-EGWP patients on anticoagulants. Results for specific Part D subpopulations or other lines of business (or the uninsured) may vary. Only select scenarios of access restriction were modeled in this analysis and they were assumed to be implemented throughout the entire Part D market (we assumed no adverse selection is possible). Partial market implementation of these restrictions may result in lower overall impacts, as patients make informed choices to maximize their access and minimize OOP.

We modeled the implementation of step edits and the formulary tier designation as separate scenarios with no overlap. Other formulary access restrictions may also be implemented but were not modeled, such as prior authorization or step edits where patients may step through one selected product onto another selected product.

The results of this model are based on assumptions and observations of real-world data in 2024, where treatment rates are compared for patients currently enrolled in plans that place the selected anticoagulants on either preferred or non-preferred tiers, and have or do not have step edits. These observations may not demonstrate causality between formulary access restrictions and patient switching or abandonment patterns. We note that patients may switch or discontinued therapy for medically informed reasons. Due to the currently favorable formulary access of selected anticoagulants in 2024, our observations represent adverse selection. To isolate the impact of adverse selection and given the limited recent real-world data on the impact of formulary changes for selected drugs, we relied on assumptions where such data was unavailable. While our assumptions are based on past observations, future patient behavior may not follow these patterns.

Modeled scenarios in this study assumed pre-MFP differences in patient OOP costs for preferred vs non-preferred tier. Note that, under MFP, differences in patient OOP costs between preferred and non-preferred tiers are likely to be less pronounced, and therefore actual dynamics may change from those modeled here. Projected patient OOP cost impacts were based on the list price (MFP) and the cost-sharing percentage (defined by the formulary tier). We assumed the maximum allowable coinsurance percentage by tier stipulated by CMS in our calculations.

We did not determine anticoagulant indication within the scope of this analysis. Additionally, it was not within the scope of this analysis to model rates of clinically significant events that might occur in patients due to therapy abandonment or non-medical switching. Additional research is needed to understand the potential impact of access restriction on clinical outcomes for patients with Part D. The model evaluates patient movement at a class level. However, patient-specific clinical factors play a role in drug selection. These factors were not evaluated in this analysis.

Gabriela Dieguez and Prachi Bhatt are employees of Milliman, Inc. The American Academy of Actuaries requires its members to identify their credentials in their work product. Gabriela Dieguez is a member of the American Academy of Actuaries and meets its relevant qualification requirements.

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