

Impact of the Inflation Reduction Act on Medicare Part D:
Changes in Spending on the First 10 Selected Drugs and
Beneficiary Out-of-Pocket Costs

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A dissertation

submitted in partial fulfillment of the
requirements for the degree of

Doctor of Philosophy

University of Washington

2026

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Abstract

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Changes in Spending on the First Ten Selected Drugs and Beneficiary Out-of-Pocket Costs

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Background

The Inflation Reduction Act (IRA) introduced several provisions to lower prescription drug spending for Medicare Part D program and its beneficiaries. These included price negotiation for selected high-spending drugs, a Part D benefit redesign with an out-of-pocket cap and a new manufacturer discount program, and broader low-income subsidy (LIS) eligibility. Whether they achieve their intended savings depends on how market conditions evolve. When a selected drug faces generic or biosimilar entry, its price and volume decline regardless, reducing negotiation savings. The redesign increased Part D plans' financial risk, incentivizing plans to shift beneficiaries' cost-sharing from fixed copayments to percentage-based coinsurance. Unlike prior analyses, this study accounted for market dynamics while estimating the effect of negotiation on Medicare spending, and of the broader Part D provisions on beneficiaries' out-of-pocket costs.

Methods

For Aim 1, we projected 2026 Part D net spending for the first ten drugs under three scenarios. The first assumed no IRA, with net prices after the coverage gap discounts the IRA replaced. The second applied the negotiated prices, which exempt selected drugs from the new manufacturer discounts. The third assumed the ten drugs were not selected, with manufacturer discounts applied instead. All scenarios accounted for expected generic and biosimilar entry in volumes and the first and third also adjusted net prices. The negotiated prices were used as announced. For Aim 2, we applied the 2023 and 2026 benefit and cost-sharing rules to all 2023 prescription drug claims for beneficiaries with full-year enrollment in a Medicare Advantage prescription drug plan (MA-PD) or a stand-alone prescription drug plan (PDP), matched to the formulary files. We simulated a baseline under the 2023 rules at 2026 prices, then added each provision in sequence: the benefit redesign with the expanded LIS, the updated rules for out-of-pocket cost accumulation, and price negotiation.

Results

Projected 2026 Part D net spending for the ten drugs was \$26.1 billion without the IRA and \$23.8 billion under negotiation, a \$2.3 billion (8.8%) reduction. Spending was \$26.2 billion when the manufacturer discounts applied instead. Savings were larger for drugs with low prior rebates and longer periods without competition, and smaller for drugs facing generic or biosimilar entry. Without accounting for such entry, the reduction increased to \$4.7 billion. Mean annual out-of-pocket costs fell by \$129 per beneficiary, from \$524 to \$395. The benefit redesign with the LIS expansion contributed \$55, negotiated prices \$43, and the updated accumulation rule \$31. These savings were unevenly distributed with 36% of beneficiaries paying more and 14% experiencing no change. Higher out-of-pocket costs were concentrated among moderate-to-high spenders and MA-PD beneficiaries, whom the copayment-to-coinsurance shift affected most. These increases persisted for the ten selected drugs.

Conclusion

The IRA lowered Medicare spending on the ten drugs and reduced beneficiaries' out-of-pocket costs overall. Generic and biosimilar entry, however, reduced negotiation savings, while the copayment-to-coinsurance shift increased the out-of-pocket spending for more than a third of beneficiaries. Ignoring these market dynamics would have doubled the projected Medicare savings and masked beneficiary-level cost increases behind the mean reduction. Future policy should account for market responses in design and assessment.

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ACKNOWLEDGEMENTS

This dissertation may bear my name, but the journey was never mine alone.

To my dissertation committee, Kristi Martin, Ryan Hansen, and John Coster, I could not have hoped for a better group of mentors to guide me along the way. I still find it remarkable that I had the privilege of receiving so much of your time, thought, and generous counsel.

To my chair, Sean Sullivan, I owe a special debt of gratitude. I have been fortunate to meet many wonderful mentors, but you were the first who truly tried to understand me as I am, while sincerely wanting me to become not only a better researcher, but also a better person. Your trust, patience, and guidance have meant more to me than I can put into words.

Inma Hernandez, Sean Dickson, and Nico Gabriel, Thank you for your guidance and for generously sharing your thoughts on this work.

Josh Carlson, thank you for helping me find my way through some of the darkest periods of my life. Your belief in me and your patience carried me farther than you may ever know.

Lou Garrison, thank you for always seeing possibility in me. Your perspective always taught me to look beyond what was immediately in front of me and see the bigger picture.

To the CHOICE family, thank you for your generosity, friendship, and support which made a difficult road lighter.

To my husband, Eunho, thank you so much for being my loving and steadfast partner through better and worse, for richer and poorer, in sickness and in health. Thank you for loving and cherishing me through every version of myself, and for building this life with me.

Roy and Leon, you are the reason I want to become a better person and leave behind a world a little better than the one I found. Thank you for making me a mother and for giving everything I do a deeper sense of purpose.

And finally, to my family and friends, especially my parents, my parents-in-law, and my one-and-only sister, thank you for always showing up when I needed you, sometimes from across the world, and for carrying me forward when I could not carry myself. Thank you. [Proverbs 16:9]

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INTRODUCTION

The Inflation Reduction Act (IRA) introduced several provisions to lower prescription drug spending for the Medicare Part D program and its beneficiaries. The IRA authorized the Centers for Medicare and Medicaid Services (CMS) to negotiate Maximum Fair Prices (MFPs) for selected high-spending, single-source drugs. The IRA also expanded the low-income subsidy (LIS), extending full-subsidy eligibility to partial-subsidy beneficiaries. It further redesigned the Part D benefit by introducing an annual out-of-pocket (OOP) cap, updating OOP cost accumulation rules, eliminating the coverage gap phase, and replacing the Coverage Gap Discount Program (CGDP) with a new Manufacturer Discount Program (MDP). The redesigned benefit removed beneficiaries' cost-sharing above the OOP cap. Under the updated accumulation rules, MDP discounts do not count toward the cap, whereas CGDP discounts previously did. These rules also count the greater of what beneficiaries paid or what they would have paid under the standard benefit ("greater-of" rule).

Whether these provisions deliver their intended savings depends on how market dynamics evolve. When a selected drug faces generic or biosimilar entry, its price and volume decline regardless of negotiation, attenuating the spending impact of price negotiation. The Part D redesign, in turn, redistributed financial liability above the OOP cap, increasing Part D plans' share and exposing them to greater financial risk. This greater risk contributed to plans shifting beneficiaries' cost-sharing from fixed copayments to percentage-based coinsurance. These market responses may alter the spending impact of the Part D provisions. Hence, this dissertation estimated the effect of the IRA's Part D provisions on what Medicare and beneficiaries spend on prescription drugs, while accounting for concurrent market dynamics.

Aim 1 estimated the effect of Medicare Drug Price Negotiation Program for the first ten selected drugs, accounting for the CGDP replacement with the MDP and expected biosimilar and generic

entry. These factors can change net prices to Medicare, while generic or biosimilar can also shift volume away from drugs selected for negotiation but were not captured in prior analyses.

CMS reported \$6.0 billion in aggregate savings assuming the MFPs had applied to 2023 spending, and the Brookings Institution estimated \$6.37 billion at the drug level, both holding utilization fixed and excluding generic or biosimilar entry. The Congressional Budget Office projected \$3.7 billion at the aggregate level without modeling such entry. None of these analyses examined what spending would have been had the selected drugs not been negotiated and instead received the MDP discounts, a counterfactual that requires modeling the exemption of negotiated drugs from the MDP.

Aim 2 examined the effect of broader Part D provisions on beneficiaries' OOP costs by adding each provision in sequence and accounting for changes in cost-sharing rules between 2023 and 2026. The included provisions were the Part D redesign with the expanded LIS, the updated rule for out-of-pocket accumulation, and the MFP. The year 2023 was selected as the baseline in that it was the last year before these major Part D provisions took effect. No prior analyses considered these provisions and market responses together.

The Office of Assistant Secretary for Planning and Evaluation (ASPE) projected \$7.4 billion in 2025 OOP reductions across 18.7 million beneficiaries expected to save, using 2021 claims.¹ ASPE updated the analysis using 2023 claims and reported \$7.2 billion across 11.3 million beneficiaries expected to reach the cap.² These analyses considered multiple Part D provisions but excluded price negotiation and cost-sharing changes, both of which directly affect beneficiaries' OOP costs. Other claims-based studies examined individual provisions.³⁻¹²

By comprehensively incorporating multiple provisions and market responses, this dissertation provides more accurate estimates of the IRA's effect on Medicare and beneficiary spending for prescription drugs covered under Part D plans and inform future policy.

CHAPTER 1: SPENDING IMPACT OF THE FIRST TEN DRUGS SELECTED FOR MEDICARE DRUG PRICE NEGOTIATION IN THE US

Abstract

Objectives

The Inflation Reduction Act (IRA) introduced Medicare Drug Price Negotiation Program (MDPNP) for selected high-cost, single-source drugs, and replaced the Part D Coverage Gap Discount Program (CGDP) with the Manufacturer Discount Program (MDP). In 2024, negotiated prices, Maximum Fair Prices (MFPs), were announced for the first ten drugs, effective in 2026. We evaluated the impact of negotiation on 2026 Medicare spending.

Methods

We modeled three scenarios: (1) 'Historical Benchmark', no negotiation and no changes to the CGDP; (2) 'Negotiation under the IRA', negotiation implemented, and the selected drugs exempt from the MDP; and (3) 'No Negotiation under the IRA', no negotiation and the MDP applied to selected drugs. Spending in scenarios (1) and (3) was estimated as net prices multiplied by projected volumes. In scenario (2), spending was estimated using MFPs and projected volumes. Volumes and net prices were adjusted for expected generic and biosimilar entry through 2026.

Results

Projected 2026 Medicare Part D net spending for the ten drugs was \$26.1 billion in scenario (1) and \$23.8 billion in scenario (2), a \$2.3 billion (8.8%) reduction with negotiation. Scenario (3) projected \$26.2 billion in spending, \$2.4 billion (9.0%) higher than scenario (2). Savings were larger for drugs with low pre-negotiation rebates and longer market exclusivity, whereas smaller reductions occurred for the drugs facing generic or biosimilar entry.

Conclusions

MDPNP is projected to reduce Part D spending, with greater reductions among drugs with low prior rebates and longer exclusivity. These findings clarify the policy impact and inform anticipated effects from subsequent negotiation rounds.

This chapter was previously published as:

Jeon YK, Hansen RN, Gabriel N, Martin K, Sullivan SD. *Spending Impact of the First 10 Drugs Selected for Medicare Drug Price Negotiation in the United States. Value in Health.* 2026;29(7):1228–1234. doi:10.1016/j.jval.2026.03.010.

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Introduction

The Inflation Reduction Act (IRA) introduced significant changes to Medicare Part D aimed at reducing prescription drug spending and improving affordability for beneficiaries. The IRA authorized the Centers for Medicare and Medicaid Services (CMS) to negotiate directly with manufacturers the prices of selected high-cost, single-source drugs paid for under Part B and D. Drugs are selected based on their Medicare gross drug costs and other eligibility criteria.¹³ For the Initial Price Applicable Year (IPAY) 2026, CMS selected the first ten Part D drugs using the total gross covered drug costs from June 2022 to May 2023.¹⁴ In August 2024, CMS announced the Maximum Fair Prices (MFP) agreed to with manufacturers, effective January 1, 2026.⁵ The MFP set the maximum price a manufacturer of a selected drug may charge a physician or pharmacy that dispenses a drug to an eligible beneficiary under Medicare Part B and Part D, respectively.¹⁵

In January 2025, CMS announced an additional 15 Part D drugs selected for the second round (IPAY 2027).¹⁶ Beginning in 2028, the negotiation program will expand to physician-administered Part B drugs, and starting in 2029, CMS may negotiate prices for up to 20 additional drugs annually across Part B and D.¹⁷

Beginning in 2025, the IRA also eliminated the Part D coverage gap phase and its associated discount program, which required manufacturers to provide discounts on brand-name drugs and biosimilars.¹⁸ Before the Coverage Gap Discount Program (CGDP) was created under the Affordable Care Act in 2011, beneficiaries paid their full drug costs while in the coverage gap phase.¹⁹ The CGDP introduced 50% manufacturer discounts for branded drugs, which later increased to 70%.¹⁸ The IRA replaced CGDP with a new Manufacturer Discount Program (MDP). The MDP requires manufacturers to provide a 10% discount in the initial coverage phase and a 20% discount in the catastrophic phase. As the final phase of Part D coverage, the catastrophic phase has no upper limit on the amount owed by manufacturers in discounts paid. These changes in manufacturer discounts affected net prices to Medicare. Under the MDP, the selected

drugs under negotiation with effectuated MFPs are exempt from those discounts, with CMS assuming financial responsibility through selected drug subsidy and reinsurance.²⁰

Several analyses have estimated spending reductions from negotiation relative to a counterfactual scenario without negotiation, but none have provided drug-level estimates that incorporate drug-specific utilization and price trajectories for 2026.³⁻⁶ Assuming the MFPs had applied in 2023, CMS reported aggregate savings of \$6.0 billion after rebates, fees, and other concessions to Part D plans.⁵ This estimate used 2023 spending under the standard benefit design and did not incorporate market changes, such as generic or biosimilar entry. Five selected drugs may face such competition by the end of 2026, potentially reducing price and volume independent of negotiation. Brookings Institution produced drug-level estimates totaling \$6.37 billion.⁶ Similar to CMS, their analysis held 2023 utilization fixed and excluded generic or biosimilar competition. Their net prices were estimated by combining several data sources, including average pre-IRA Medicare Part D rebates at the therapeutic class-level from Medicare Payment Advisory Commission (MedPAC).⁶

The Congressional Budget Office (CBO) projected a direct Part D spending reduction of \$3.7 billion in 2026, assuming the MFP was set at about a 50% of average net prices across all Part D plans. CBO reported savings at the aggregate level rather than at the individual drug level and also did not explicitly model generic or biosimilar entry.^{3,4} To our knowledge, no prior analysis has examined what spending would have been for the selected drugs had they *not* been negotiated under the IRA, and were only subject to the new MDP. This requires incorporating the direct interaction with the MDP, which does not apply to the selected drugs during the period in which their MFP is in effect.¹⁹⁻²¹ We compared projected 2026 Medicare spending for the ten selected drugs under three scenarios: (1) 'Historical Benchmark', with no changes to the CGDP and no price negotiation; (2) 'Negotiation under the IRA', in which the selected drugs were negotiated and exempted from MDP, and (3) 'No Negotiation under the IRA', where MDP was applied but negotiation was not.

Methods

Spending under the scenarios (1) and (3) was estimated as net price multiplied by volume. The scenario (1) used net prices after CGDP discounts, and the scenario (3) used net prices after MDP discounts. Under scenario (2), spending was estimated as the product of MFP and volume (Table 1 - 1). Volume and net prices, except MFP, were adjusted for generic and biosimilar entry for all scenarios, treated as a background market dynamic. The volume and net price erosion were modeled to begin at the timing of generic or biosimilar entry.

Table 1 - 1: Assumptions for Estimating 2026 Medicare Spending for the Ten Drugs under the Scenarios

Scenarios	Scenario (1) Historical Benchmark	Scenario (2) Negotiation under the IRA	Scenario (3) No Negotiation under the IRA
Description	No Negotiation and CGDP unchanged	Negotiation Implemented and MDP exempted	No negotiation and MDP applied
Price	2026 Net Price After CGDP Adjusted for Biosimilar and Generic Entry	2026 Maximum Fair Price	2026 Net Price After MDP Adjusted for Biosimilar and Generic Entry
Volume	2026 Volume Adjusted for Biosimilar and Generic Entry		

ABBREVIATIONS: CGDP, Coverage Gap Discount Program; MDP, Manufacturer Discount Program

Generic and Biosimilar Entry

We identified the drugs expected to face competition and the anticipated market entry dates of their generic or biosimilar competitors through a structured review of publicly available information. Predicting the launch date is inexact, as market entry may be delayed by patent disputes, settlement negotiations, commercial strategies, or Part D formulary placement. To inform these estimates, we reviewed companies' Form 10-K filings with the U.S. Securities and Exchange Commission, patent and exclusivity data from the U.S. Food and Drug Administration's Orange Book and Purple Book, and press releases on litigation status.²²⁻²⁴ (See Table 1A - 1 and Table 1A - 2 in the Supplementary Appendix)

When only a month was reported without a specific launch date, beneficiary access was assumed to begin on the first day of the reported month.²⁵ If neither a date nor a month was available, particularly for drugs not facing imminent competition, the latest expiration date of

the drug substance, drug product and method-of-use patents, as well as regulatory exclusivity was used as a proxy for small-molecule drugs.^{26,27} For biologics, the later of the 12-year reference product exclusivity period or the latest patent expiration in the relevant territory was used.^{28,29} The assumption that the beneficiary access coincides with generic or biosimilar entry may be conservative. The time required for formulary placement and, in case of biosimilars, placement in higher cost-sharing tiers may delay the access.²⁵

Among the ten selected drugs, three small-molecule and two biologic products are expected to face generic or biosimilar competition before or during 2026. Except for sitagliptin (Januvia), anticipated to face generic entry in 2026, the remaining two small-molecule and two biologic products launched in 2025. As of September 1, 2025, both sacubitril/valsartan (Entresto) and rivaroxaban (Xarelto) each had eight marketed generic alternatives, while ustekinumab (Stelara) and insulin aspart (Novolog) each had at least two biosimilars available (Table 1 - 2).

Table 1 - 2: Expected Generic and Biosimilar Entry Timing

Generic Name (Brand Name)		Expected Generic and Biosimilar Entry ^a	Deselected in 2027, as CMS determined a bona fide marketing between August 2, 2024, and March 31, 2026
Apixaban (Eliquis)		2028 or later ³⁰⁻³²	No
Etanercept (Enbrel)		2029 or later ^{33,34}	No
Sacubitril/Valsartan (Entresto)		Jul 22, 2025 ³⁵⁻³⁷	Yes
Dapagliflozin (Farxiga) ^b		2028 or later ³⁸⁻⁴⁰	No
Ibrutinib (Imbruvica)		2029 or later ⁴¹⁻⁴³	No
Sitagliptin (Januvia) ^c		May 1, 2026 ⁴⁴	No
Empagliflozin (Jardiance)		2028 or later ⁴⁵	No
Insulin aspart (NovoLog) ^{b, d}		Jan 1, 2026 ^{22,46}	No
Insulin aspart (Fiasp)		2029 or later ⁴⁷	No
Ustekinumab (Stelara)		Jan 1, 2025 ⁴⁸	Yes
Rivaroxaban (Xarelto) ^e	2.5 mg	Mar 7, 2025 ⁴⁹⁻⁵¹	Yes
	10 mg, 15 mg, 20 mg	2029 or later ⁵¹⁻⁵³	

NOTE

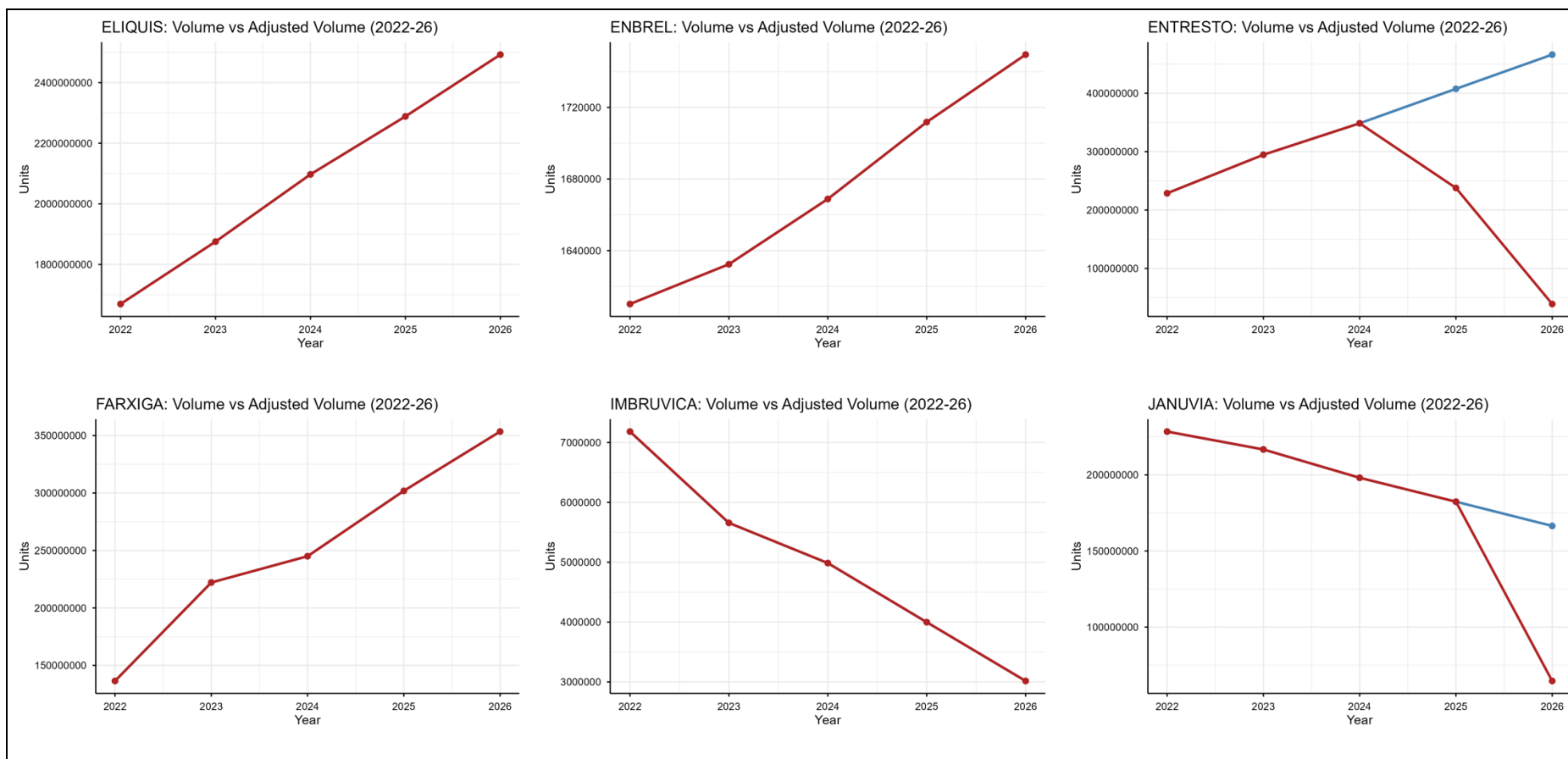
- We assumed that sales start accruing on the exact date of market entry. If the specific entry release date was unknown, it is assumed to be the first day of the month.
- NovoLog (2020) and Farxiga (2024) have authorized generics; however, under CMS's interpretation of section 1192(e)(2)(A), these authorized generics are not treated as separate drugs, but instead are included as part of the same qualifying single source drug as their brand-name counterparts.
- Zituvio released in Dec 2023, which contains the same active ingredient, sitagliptin, despite being approved through the alternative 505(b)(2) pathway and not deemed therapeutically interchangeable. CMS did not consider Zituvio as a generic to Januvia and selected Januvia for the price negotiation.
- Sanofi confirmed the commercial launch of Merilog, a biosimilar to NovoLog, through correspondence with the authors; however, during the deselection process, CMS did not determine that Merilog was being actively marketed.
- Generic entry for rivaroxaban has occurred only for the 2.5 mg strength in the US.

If CMS determines that a generic or biosimilar product is approved and actively marketed, the selected drug is removed from selection, with the effective date of deselection tied to when CMS makes that determination.⁵⁴ CMS determined as of December 2025 that active marketing had occurred for sacubitril/valsartan, rivaroxaban and ustekinumab. These drugs retain MFP applicability for 2026 but are no longer selected drugs beginning in 2027.⁵⁵ Although insulin aspart-szjj (Merilog), a biosimilar to Novolog, was launched in July 2025, CMS did not remove Novolog from selection, indicating a lack of bona fide marketing. We confirmed Merilog's launch through communication with its manufacturer and its appearance on wholesaler brochures indicating that the product was ready to order. Based on this information, we conservatively assumed Merilog uptake as an analog, beginning in January 2026.

Volume Projection

We projected 2026 volumes using extended-unit data between 2022 and 2024 from IQVIA's National Sales Perspectives (NSP) database.⁵⁶ We limited the analysis to the recent, shorter time series to better capture current utilization trends, as several selected drugs underwent major market changes in recent years. For instance, the label of empagliflozin (Jardiance) was expanded in 2022 to include heart failure regardless of diabetes status.⁵⁷ We calibrated the IQVIA NSP data to utilization levels reported in the 2022-2023 Medicare Part D Drug Spending Dashboard.⁵⁸ This approach effectively isolated the Part D component, while incorporating more recent 2024 utilization trends into projecting 2026 volumes, beyond what is reflected in the 2023 Medicare dashboard.

Baseline volume estimates for 2026 were generated by fitting a Prais-Winsten linear regression to quarterly utilization data from 2022 through 2024 and extrapolating to 2026. The Prais-Winsten method corrects for serial autocorrelation and reduces to a linear regression when autocorrelation is absent.⁵⁹ Given the short time series and the implausible forecasts produced by higher-order models, we assumed linearity, and robustness was assessed through sensitivity analysis using predictive intervals.



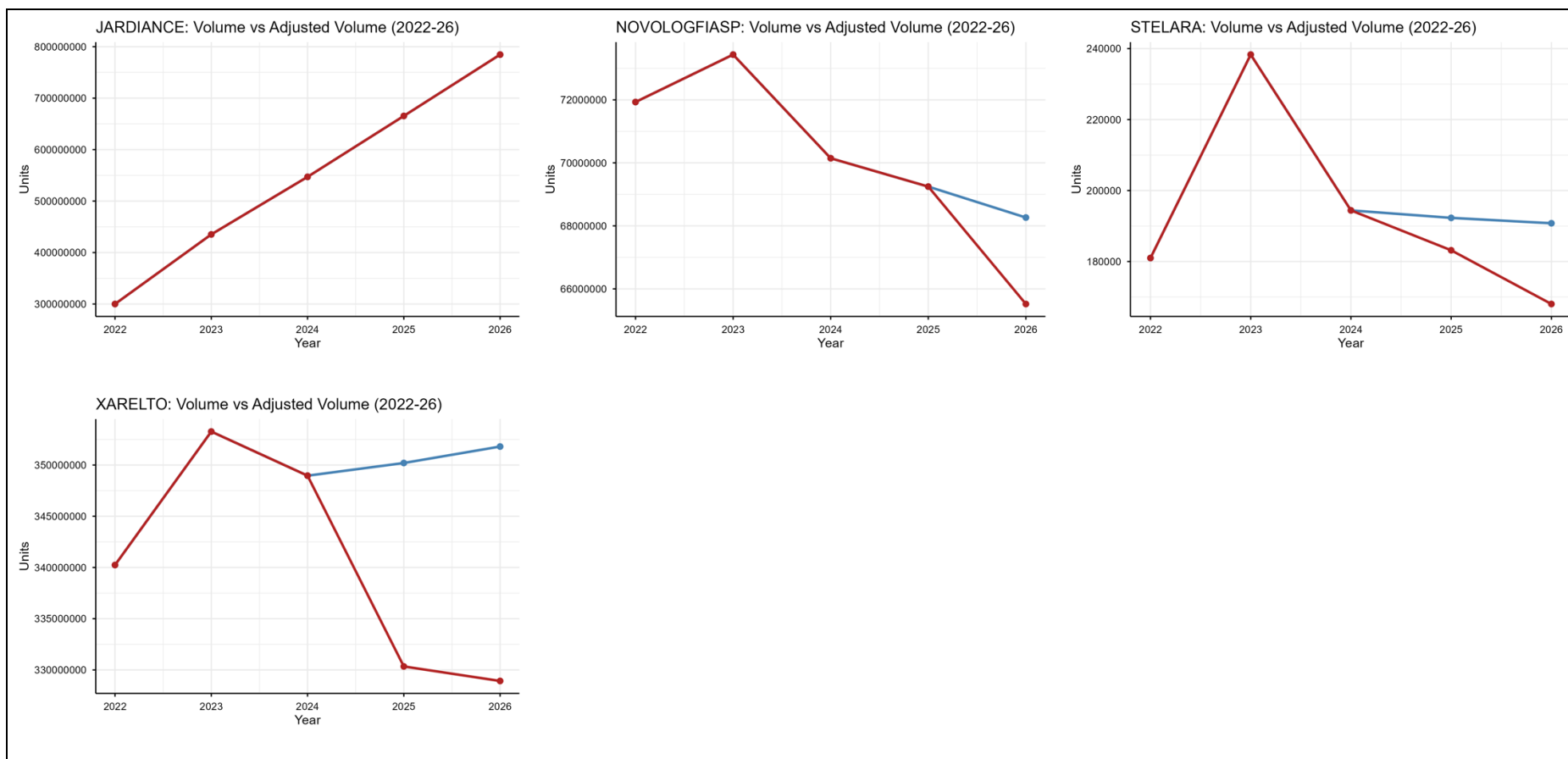


Figure 1 - 1: Drug-Level 2026 Projected Volume for the Ten Selected Drugs

For the three small-molecule drugs, expected or already facing generic competition, volume declines were modeled using published estimates following generic entry.⁶⁰ For the two biologics, we applied drug-specific assumptions informed by historical analogs sharing clinical and practice characteristics reported as key determinants of biosimilar uptake.^{61,62} Insulin lispro (Humalog) and adalimumab (Humira) were used as analogs for insulin aspart and ustekinumab, respectively. (Figure 1 - 1)

Net Price Projection

In the scenarios (1) and (3), net prices served as the price basis for spending estimation. We extrapolated 2021 net prices derived using the published algorithm of Dickson and Hernandez to their 2026 values.^{63,64} To accurately estimate future net prices under these scenarios, we accounted for the replacement of the CGDP with the MDP and anticipated generic and biosimilar entry where applicable.

When extrapolating net prices through 2026, we applied secular trends based on manufacturer-reported average net price changes across their entire portfolios.⁶⁵ For the baseline analysis, we used the net price changes reported by companies marketing the selected drugs, whereas for the sensitivity analysis we applied trends aggregated across all manufacturers with reported data.⁶⁵ (Table 1 - 3)

Table 1 - 3: Annual Change by rebate type

Drugs	Annual Growth Rate
Base case analysis	-1.22%
Sensitivity analysis	+0.22%

The extrapolated net prices did not inherently account for the MDP transition or the effects of generic and biosimilar entry. We therefore adjusted them by first adding historical per-unit CGDP discounts in 2026 back to the net prices, and then subtracting the newly estimated per-unit CGDP in the scenario (1) and per-unit MDP discounts in the scenario (3) for 2026, both adjusted for expected generic and biosimilar entry.

We estimated 2026 CGDP discounts that would have applied under the pre-IRA benefit design in the scenario (1) for non-low-income subsidy (non-LIS) beneficiaries with at least one claim for any of selected drugs.^{66,67} Using a 5% random sample of 2022 Medicare Part D Prescription Drug Event (PDE) data, we modeled coverage phase trajectory across all drugs used by each beneficiary.⁶⁸

To project full-year results, we restricted the sample to beneficiaries with continuous enrollment in a Standalone Prescription Drug Plans (PDPs) for the entire year. All 2022 cost components were inflated to 2026 dollars by applying the chained annual percentage increase.⁶⁹ All estimates derived from the sample were scaled to represent the full Medicare population. (See Figure 1A - 1 in the Supplementary Appendix)

For MDP discounts in the scenario (3), we additionally included low-income subsidy (LIS) beneficiaries. Unlike CGDP, MDP discounts apply to LIS beneficiaries and do not count toward True Out-of-Pocket (TrOOP) spending, which determines phase progression.²⁰ We applied 10% and 20% discounts to gross drug costs in the initial coverage and catastrophic phases, respectively.

Net price changes following generic or biosimilar entry cannot be directly observed. For three small-molecule drugs expected or already facing generic entry, we modeled net price erosion as the lower of the projected brand-name net price or the estimated generic acquisition cost to avoid overestimating drug costs. The estimated generic acquisition cost was calculated by applying generic-to-brand price ratios to the National Average Drug Acquisition Cost (NADAC).⁷⁰ For ustekinumab and insulin aspart, net prices were adjusted using published reductions observed after biosimilar entry for infliximab (Remicade) and insulin glargine (Lantus).^{71,72}

The net prices, combined with predictive intervals for projected volumes, formed a two-way sensitivity analysis addressing uncertainty in volume extrapolation and variation in net price trajectories.

Maximum Fair Price (MFP)

The MFP for the ten selected drugs will remain in effect through 2026.⁵⁴ In the scenario (2), we used the published per-unit MFPs at the 9-digit National Drug Code (NDC-9) level to construct drug-level prices.⁷³ For each product, we calculated a weighted average MFP using 2022 NDC-9 volumes from the 5% sample of Medicare Part D PDE data as weights.⁶⁸ Manufacturer liability under the MDP is exempt for the selected drugs and we did not adjust MFP for MDP. Further methodological details are provided in the Supplementary Appendix.

Result

In the ‘Historical Benchmark’ scenario (1), 2026 spending on the ten drugs was estimated at \$26.1 billion after adjusting volumes and net prices for potential biosimilar or generic entry. In the ‘Negotiation under the IRA’ scenario (2), spending was \$23.8 billion at the MFP with similar volume adjustment, representing a \$2.3 billion (8.8%) reduction relative to the scenario (1). Under the ‘No Negotiation under the IRA’ scenario (3), projected spending was \$26.2 billion after the volume and price adjustment. Spending in the scenario (2) was \$2.4 billion (9.0%) lower than the scenario (3). (Table 1 - 4)

Table 1 - 4: Drug-Level Estimated 2026 Medicare Spending for the Ten Drugs (\$ million)

Generic Name (Brand Name)	Scenario (1) ^{a, b}	Scenario (2) ^{a, b}	Scenario (3) ^{a, b}
Apixaban (Eliquis)	\$10,853	\$10,331	\$12,483
Etanercept (Enbrel)	\$1,434	\$1,021	\$897
Sacubitril/Valsartan (Entresto) ^c	\$201	\$204	\$209
Dapagliflozin (Farxiga) ^c	\$1,996	\$2,140	\$1,958
Ibrutinib (Imbruvica)	\$1,090	\$665	\$263
Sitagliptin (Januvia) ^c	\$407	\$253	\$391
Empagliflozin (Jardiance)	\$5,815	\$5,330	\$5,851
Insulin aspart (NovoLog/Fiasp) ^c	\$754	\$543	\$560
Ustekinumab (Stelara) ^c	\$1,835	\$1,124	\$1,206
Rivaroxaban (Xarelto) ^c	\$1,724	\$2,200	\$2,348
TOTAL	\$26,109	\$23,812	\$26,167

ABBREVIATIONS: CGDP, Coverage Gap Discount Program; IRA, Inflation Reduction Act; MFP, Maximum Fair Price; MDP, Manufacturer Discount Program

NOTE

- a. Numbers are rounded to the nearest \$1,000,000.
- b. Negotiated price between plans and manufacturers or pharmacies may be lower than the MFP, but we assumed to be equal to the MFP
- c. Under section 1192(c)(1) of the IRA, a selected drug remains in the negotiation program for the initial year and each following year until at least nine months have passed since CMS determines that a generic or biosimilar meets the statutory criteria for substitution.

The two-way sensitivity analysis showed that Part D spending was consistently lower under the scenario (2) than under the scenarios (1) and (3). Aggregate reductions ranged from \$1.6 billion to \$5.1 billion compared with the scenario (1), and from \$2.4 billion to \$4.5 billion compared with the scenario (3). These ranges were driven by apixaban (Eliquis) and empagliflozin, the highest-spending drug, and ustekinumab, which had wide predictive intervals for volume projections. (Table 1 - 5)

The relative reduction compared with the scenario (1) was greater for drugs with longer market exclusivity, consistent with the statutory ceiling for the MFP.^{16,54} Etanercept, insulin aspart, sitagliptin, and ustekinumab had been on the market for more than 16 years by 2026, making them subject to the 40% ceiling and projected to have 28% to 43% net spending reduction. (Figure 1 - 2)

The reduction was also greater for drugs with low pre-negotiation rebates. For ibrutinib which showed 39% to 43% net spending reduction, the estimated prior rebate was 9% to 9.5%.^{74,75} Prior research reported a 2021 net price of \$11,571 for a 30-day equivalent supply, compared with an estimated 2021 non-Federal Average Manufacturer Price (non-FAMP), the average manufacturer price to non-federal purchasers, of \$10,236.⁶³ Ibrutinib was subject to a 75% ceiling of non-FAMP.⁷⁴ This highlights how statutory ceiling can drive down prices effectively in drugs with low prior rebates.

Table 1 - 5: Two-way Sensitivity Analysis (\$ millions)

Generic Name (Brand Name)		Lower bound a			Base case b			Upper bound c		
		Scenario (1)	Scenario (2)	Scenario (3)	Scenario (1)	Scenario (2)	Scenario (3)	Scenario (1)	Scenario (2)	Scenario (3)
Apixaban (Eliquis)		\$10,498	\$9,993	\$12,074	\$10,853	\$10,331	\$12,483	\$12,143	\$10,669	\$13,826
Etanercept (Enbrel)		\$1,324	\$943	\$828	\$1,434	\$1,021	\$897	\$1,654	\$1,099	\$1,076
Sacubitril/valsartan (Entresto)		\$193	\$196	\$201	\$201	\$204	\$209	\$208	\$212	\$217
Dapagliflozin (Farxiga)		\$1,601	\$1,716	\$1,571	\$1,996	\$2,140	\$1,958	\$2,584	\$2,563	\$2,539
Ibrutinib (Imbruvica)		\$677	\$413	\$163	\$1,090	\$665	\$263	\$1,616	\$917	\$475
Sitagliptin (Januvia)		\$374	\$232	\$360	\$407	\$253	\$391	\$453	\$273	\$437
Empagliflozin (Jardiance)		\$5,485	\$5,027	\$5,518	\$5,815	\$5,330	\$5,851	\$6,637	\$5,633	\$6,675
Insulin aspart (Novolog/Fiasp)		\$737	\$532	\$546	\$754	\$543	\$560	\$829	\$554	\$631
Ustekinumab (Stelara)		\$593	\$363	\$390	\$1,835	\$1,124	\$1,206	\$3,310	\$1,885	\$2,256
Rivaroxaban (Xarelto)		\$1,576	\$2,010	\$2,146	\$1,724	\$2,200	\$2,348	\$1,873	\$2,389	\$2,551
Total		\$23,057	\$21,428	\$23,798	\$26,109	\$23,812	\$26,167	\$31,309	\$26,195	\$30,684
ΔSpendin g	Scenario (1) vs (2)	\$1,629			\$2,297			\$5,114		
	Scenario (2) vs (3)		\$2,370			\$2,355			\$4,489	

NOTE

- Lower-bound scenario: Volume based on the lower predictive interval; net prices adjusted using manufacturer-reported net price changes for manufacturers of the selected drugs only.
- Base-case scenario: Volume estimated via Prais–Winsten regression; net prices adjusted using manufacturer-reported net price changes for manufacturers of the selected drugs only.
- Upper-bound scenario: Volume based on the upper predictive interval; net prices adjusted using net price changes aggregated across all manufacturers with reported data.

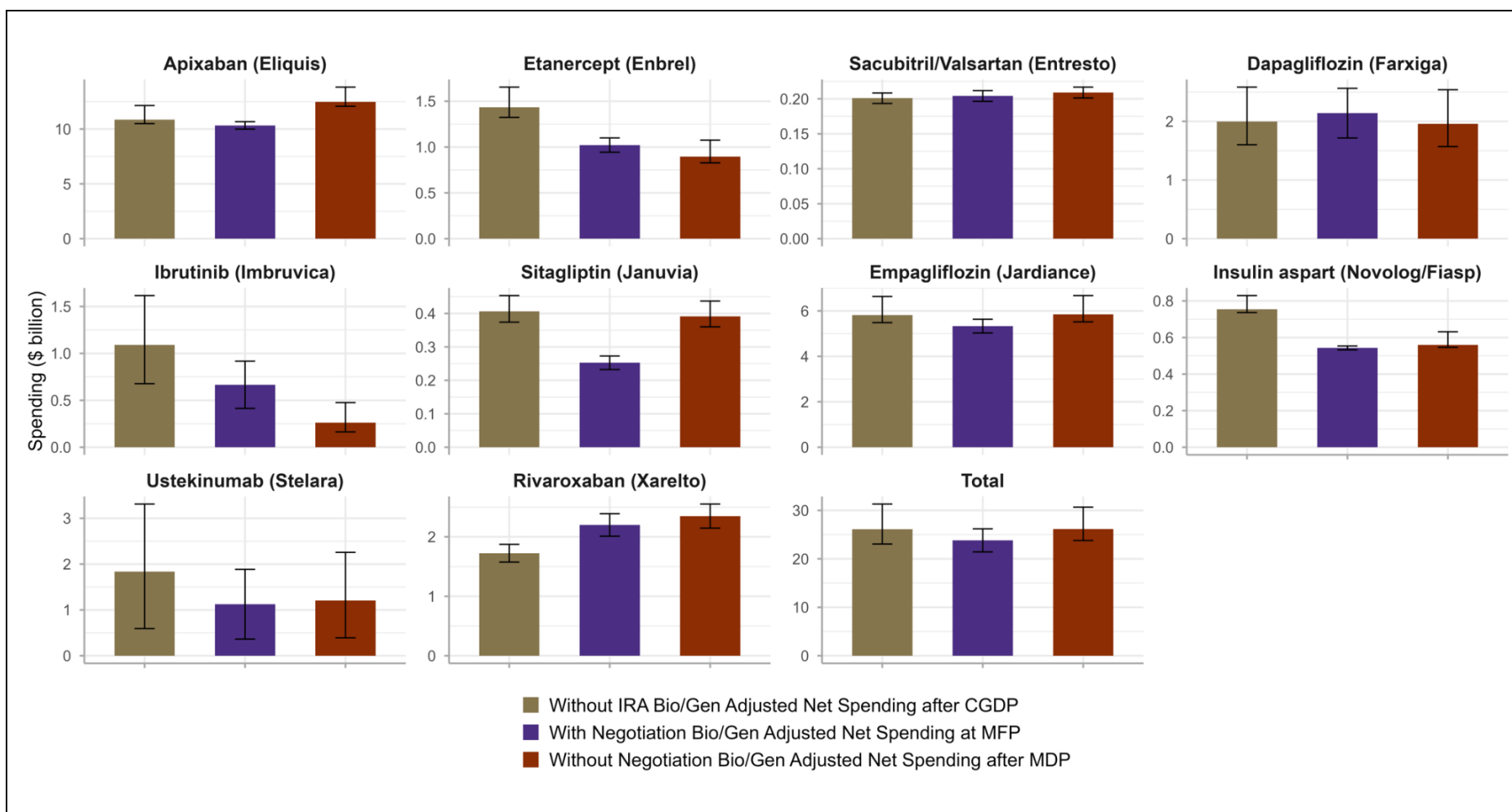


Figure 1 - 2: Drug-Level 2026 Spending for the Ten Selected Drugs under 'Historical Benchmark', 'Negotiation under the IRA' and 'No Negotiation under the IRA' Scenarios

ABBREVIATIONS: Bio, Biologics; CGDP, Coverage Gap Discount Program; Gen, Generic drugs; IRA, Inflation Reduction Act; MFP, Maximum Fair Price; MDP, Manufacturer Discount Program
 NOTE: Error bars represent the range of projected spending from the two-way sensitivity analysis

Despite its relatively low rebate, sacubitril/valsartan showed similar spendings between scenarios (1) and (2). Without adjusting for generic entry, the projected reduction was 23%. (Table 1 - 6) The unadjusted reduction may reflect the statutory ceiling and the lower net prices of therapeutic alternatives, although it has demonstrated greater clinical effectiveness.^{63,76} In determining the initial price offer, CMS is required to consider the net prices and comparative clinical benefit of alternatives.¹⁶

Table 1 - 6: Drug-Level Estimated 2026 Medicare Spending for the Ten Drugs Without and With Biosimilar and Generic Entry Adjustment (\$ million)

Generic Name (Brand Name)	Without Biosimilar and Generic Entry Adjustment			With Biosimilar and Generic Entry Adjustment		
	Scenario (1)	Scenario (2)	Spending Reduction Scenario (1) vs (2)	Scenario (1)	Scenario (2)	Spending Reduction Scenario (1) vs (2)
Apixaban (Eliquis)	\$10,853	\$10,331	\$521	\$10,853	\$10,331	\$521
Etanercept (Enbrel)	\$1,434	\$1,021	\$412	\$1,434	\$1,021	\$412
Sacubitril/Valsartan (Entresto)	\$3,167	\$2,436	\$731	\$201	\$204	-\$3
Dapagliflozin (Farxiga)	\$1,996	\$2,140	-\$143	\$1,996	\$2,140	-\$143
Ibrutinib (Imbruvica)	\$1,090	\$665	\$425	\$1,090	\$665	\$425
Sitagliptin (Januvia)	\$1,122	\$651	\$472	\$407	\$253	\$154
Empagliflozin (Jardiance)	\$5,815	\$5,330	\$485	\$5,815	\$5,330	\$485
Insulin aspart (Novolog/Fiasp)	\$785	\$566	\$219	\$754	\$543	\$211
Ustekinumab (Stelara)	\$2,801	\$1,277	\$1,525	\$1,835	\$1,124	\$711
Rivaroxaban (Xarelto)	\$2,388	\$2,353	\$35	\$1,724	\$2,200	-\$475
TOTAL	\$31,451	\$26,770	\$4,681	\$26,109	\$23,812	\$2,297

ABBREVIATIONS: MDP, Manufacturer Discount Program

As would be expected, the largest absolute spending reductions relative to the scenario (1) were observed for drugs with either the largest relative reductions or highest baseline Part D spending. Ustekinumab and ibrutinib, which experienced the largest relative reductions,

represented \$711 million (30.9%) and \$425 million (18.5%) of the \$2.3 billion total reduction, respectively.

Apixaban and empagliflozin, despite smaller relative reductions of 4.8% and 8.3%, generated large absolute reductions in spending. Apixaban and empagliflozin accounted for \$521 million (22.7%) and \$485 million (21.1%) of the total reductions. Both drugs were highly rebated before negotiation and launched in 2012 and 2014, which contributed to their smaller relative reductions.^{63,77} Their large beneficiary bases and high baseline spending translated into substantial absolute reductions.^{5,14}

If the MDP had applied in the scenario (3), manufacturers would have paid \$8.1 billion for the ten drugs. Although total discounts under the CGDP and MDP appeared comparable, drug-level comparisons revealed a shift in discount toward high-cost specialty drugs, such as etanercept, ustekinumab, and ibrutinib. For these drugs, most beneficiary spending occurred in the catastrophic phase, quickly bypassing the coverage gap where CGDP applied, and only a small share of their spending was subject to CGDP. Under the MDP, manufacturer liability continues through the catastrophic phase without an upper limit. (Table 1 - 7)

Table 1 - 7: Drug-Level Estimated 2026 Manufacturer Discounts for the Ten Drugs (\$ million)

Generic Name (Brand Name)	Scenario (1)	Scenario (2)	Scenario (3)
	CGDP Discount a (% of Gross Spending at Ingredient costs)	Selected Drug Subsidy and Reinsurance a, b, c (% of Gross Spending at MFP)	MDP Discount a, c (% of Gross Spending at Ingredient costs)
Cost-bearing entity	Manufacturers	CMS	Manufacturers
Apixaban (Eliquis)	\$4,194 (23%)	\$1,129 (11%)	\$2,563 (11%)
Etanercept (Enbrel)	\$71 (6%)	\$206 (19%)	\$608 (19%)
Sacubitril/Valsartan (Entresto)	\$48 (26%)	\$18 (13%)	\$40 (13%)
Dapagliflozin (Farxiga)	\$417 (23%)	\$140 (14%)	\$455 (14%)
Ibrutinib (Imbruvica)	\$118 (3%)	\$604 (19%)	\$946 (19%)
Sitagliptin (Januvia)	\$231 (24%)	\$52 (12%)	\$247 (12%)
Empagliflozin (Jardiance)	\$1,072 (24%)	\$347 (14%)	\$1,036 (14%)

Generic Name (Brand Name)	Scenario (1)	Scenario (2)	Scenario (3)
	CGDP Discount a (% of Gross Spending at Ingredient costs)	Selected Drug Subsidy and Reinsurance a, b, c (% of Gross Spending at MFP)	MDP Discount a, c (% of Gross Spending at Ingredient costs)
Cost-bearing entity	Manufacturers	CMS	Manufacturers
Insulin aspart (Novolog/Fiasp)	\$407 (22%)	\$136 (14%)	\$601 (14%)
Ustekinumab (Stelara)	\$54 (3%)	\$229 (19%)	\$683 (19%)
Rivaroxaban (Xarelto)	\$1,579 (23%)	\$358 (10%)	\$955 (10%)
Total	\$8,191	\$3,220	\$8,134

ABBREVIATIONS: CGDP, Coverage Gap Discount Program; IRA, Inflation Reduction Act; MFP, Maximum Fair Price; MDP, Manufacturer Discount Program

NOTE

- a. Numbers are rounded to the nearest \$1,000,000.
- b. The effect of lower MFP on phase progression was not reflected.
- c. Manufacturer liabilities under the CGDP and MDP are netted out from estimated spending for the ten drugs to Medicare program, while CMS liability of \$3.2 billion is included in the estimate based on the product of the MFP and dispensed volume.

Discussion

Our analysis showed that IPAY 2026 price negotiation could directly lower Medicare spending on the ten selected drugs by \$2.3 billion (8.8%) compared to the scenario (1). This estimate was lower than the CBO's projection of \$3.7 billion and CMS's estimate of \$6.0 billion, largely because our analysis explicitly incorporated the effect of generic and biosimilar entry. When this competition was excluded, the estimated reduction in spending increased from \$2.3 billion to \$4.7 billion. The remaining difference likely reflects variations in the underlying assumptions about volume and prices. For example, CMS relied on utilization in 2023.

Rome et al. (2025) examined manufacturer discounts by comparing actual CGDP discounts in 2022 with the amounts that would have applied had the MDP been implemented that year.⁷⁸

While our analysis focused on isolating the impact of price negotiation, their analysis incorporated TrOOP expansion. Following the IRA, TrOOP was expanded in 2025 to include Part D plan payments made on behalf of beneficiaries, accelerating phase progression. This shift moves more spending into catastrophic phase, where a 20% discount applies without an upper

limit. This explains why Rome et al (2025) estimated total MDP discounts of \$34.5 billion, more than twice the CGDP discounts of \$16.8 billion in 2022.

Our analysis reported comparable aggregate discounts under the CGDP in scenario (1) and the MDP in scenario (3) in 2026, totaling \$8.2 billion and \$8.1 billion, respectively. Drug-level findings indicated that replacing the CGDP with the MDP does not necessarily increase the total level of manufacturer discounts and, in turn, lead to larger spending reductions. Rather, the MDP redistributes discounts across benefit phases following the elimination of the coverage gap and total manufacturer discounts can be smaller under the MDP for certain drugs. These drugs include rivaroxaban and apixaban, which were not extremely high-cost but used chronically at high volume and frequently reached the coverage gap under CGDP.

This study has several limitations. Reliance on a limited dataset and historical patterns may not precisely capture future shifts in utilization, especially with generic and biosimilar entry, including private labeling of high-cost biologics such as ustekinumab. Entry timing was inherently uncertain and often we could not reliably infer it from publicly available information, which adds uncertainty into our analysis. Although we attempted to incorporate these dynamics using drug-specific adjustments, this approach assumed future trajectories will mirror past experiences of the closest available agents, which may not hold if market conditions, payer strategies, or regulations diverge. We also used Prais-Winsten linear regression to address autocorrelation in volume projection. This assumes continuation of past linear trend and may not fully capture changes in market dynamics.

Another source of uncertainty was the estimation of historical per-unit CGDP amounts, which were highly sensitive to volume. Our approach, which scaled IQVIA data to Part D volumes and projected to 2026, may have introduced extrapolation error. After adjusting for CGDP amounts and generic and biosimilar entry, the projected net prices for dapagliflozin and rivaroxaban fell below the MFP.

Our net price estimates followed peer-reviewed methods that explicitly accounted for 340B discounts and Part D manufacturer discounts. However, these methods could not distinguish between commercial and Medicare net prices.⁶⁴ In the absence of segment-specific net prices, our approach represented the best available estimate and was consistent with prior literature.

Our analysis was limited to beneficiaries enrolled in the PDPs and excluded Medicare Advantage prescription drug (MA-PD) plans. Unlike MA-PD coverage, PDPs provide Part D benefits administered separately from medical benefits provided through original fee-for-service Medicare. This separation makes their spending patterns easier to interpret without the influence of integrated benefit management.⁷⁹ Although PDP enrollees represent a more homogenous coverage structure, they accounted for 43% of total Medicare Part D population in 2024 and exhibited higher risk-standardized gross plan costs than the MA-PD enrollees.^{79,80} These differences may limit the interpretation of our estimated savings.

We focused on the direct impact of price negotiation and its interaction with replacing CGDP with MDP, but we did not model potential utilization changes from other IRA provisions and their interactions. For example, while the OOP cap could increase demand by lowering patient costs, the MFP may delay reaching the cap, potentially dampening demand. These offsetting effects were not incorporated into our analysis.

We also assumed that Part D plan behavior would remain constant across scenarios, while plan sponsors may leverage the MDP exemption for the selected drugs to secure additional rebates from manufacturers. In addition to the MDP, the IRA restructured cost-sharing responsibilities for plans and federal reinsurance in the catastrophic phase to reduce federal spending. Plan liability increased from 15% in 2023 to 20% in 2024, and then to 60% in 2025. Federal reinsurance liability decreased substantially from 80% to 20% for brand-name and biosimilar drugs and to 40% for generic drugs. How plans will respond to the IRA remains uncertain. They may alter formulary placement and cost-sharing structures or adopt stricter utilization management policies.

Lastly, we did not consider the potential impact of policy developments such as the American Rescue Plan Act (ARPA) which eliminated the statutory cap on Medicaid inflationary rebates, allowing Medicaid rebates to exceed a drug's Average Manufacturer Price. This increases manufacturers' rebate liabilities and may alter pricing strategies across markets by further eroding net revenues.⁸¹ We also did not consider how published MFP might impact entry pricing for generics or biosimilars.⁸²

Despite these limitations, our findings highlight several important considerations for future negotiations. Negotiation is likely most effective for drugs with low prior rebates or long market exclusivity.

Conclusion

In 2026, price negotiation is projected to reduce Medicare Part D spending for the first ten drugs by \$2.3 billion (8.8%) compared with the 'Historical Benchmark' scenario. Under the 'Negotiation under the IRA' scenario, spending was \$2.4 billion (9.0%) lower than if the drugs had not been selected for negotiation but subject to MDP. Larger reductions occurred for drugs with low prior rebates and long market exclusivity, whereas smaller reductions were observed for those affected by generic or biosimilar entry. These findings provide important lessons for estimating the spending impact of future negotiations.

CHAPTER 2: OUT-OF-POCKET COSTS FOR MEDICARE BENEFICIARIES UNDER THE INFLATION REDUCTION ACT'S PART D PROVISIONS AND PLAN COST-SHARING CHANGES

Abstract

Objectives

The Inflation Reduction Act (IRA) redesigned the Medicare Part D benefit, expanded the low-income subsidy (LIS), and authorized the Medicare Prescription Drug Price Negotiation Program. These changes contributed to Part D plan sponsors shifting many high-spending drugs from fixed copayments to percentage-based coinsurance, and it is unclear whether the intended out-of-pocket (OOP) cost reductions reached all beneficiaries. This study estimated the impact of the IRA's Part D provisions and cost-sharing changes on beneficiaries' annual Part D OOP costs and decomposed the changes by individual provision.

Methods

The Part D provisions and the 2023 and 2026 cost-sharing rules were applied to the full sample of eligible 2023 Part D prescription drug event (PDE) claims for covered drugs. These claims came from beneficiaries with full-year enrollment in either a Medicare Advantage prescription drug plan (MA-PD) or a stand-alone Prescription Drug Plan (PDP). Each claim was matched to its plan's formularies for tier and cost-sharing terms and used to simulate a 2023 counterfactual baseline. The simulation sequentially added the benefit redesign with low-income subsidy (LIS) expansion, the updated OOP cost accumulation rule, and the negotiated prices.

Results

Mean annual OOP fell from \$524 to \$395 per beneficiary, a reduction of -\$129 (95% CI, -129.51 to -128.81). Part D benefit redesign with OOP cap and LIS expansion contributed the largest share of the reduction at -\$55 (95% CI, -54.94 to -54.25), followed by Medicare price negotiation (-\$43; 95% CI, -43.13 to -43.01) and the "greater-of" rule at list prices (-\$31; 95% CI, -31.53 to -31.46).

Despite these overall reductions, 36% of beneficiaries, particularly moderate-to-high spenders, experienced increased OOP costs, while 14% experienced no change. These increases were likely driven by copayment-to-coinsurance shifts and were concentrated in high-spending Tier 3 drugs. The increase persisted even for negotiated drugs. This pattern was more pronounced in MA-PD than PDP with mean OOP savings of -\$55 (95% CI, -55.35 to -54.59) and -\$235 (95% CI, -235.32 to -234.03), respectively.

Conclusions

The IRA provisions were estimated to reduce Medicare Part D beneficiaries' total OOP costs by \$6.6 billion in 2026, yet the savings did not reach half of beneficiaries. For these beneficiaries, plan sponsor copayment-to-coinsurance shifts offset the savings, and the price negotiation yet restored them. Savings were smaller in MA-PD than PDP, where the offsetting shifts were more pronounced. Extending these savings to all beneficiaries would require discouraging coinsurance shifts.

Introduction

The Inflation Reduction Act (IRA) restructured the Medicare Part D benefit to reduce beneficiaries' financial burden and restore plan sponsor incentives to manage Part D drug spending.^{21,83} As part of this redesign, the IRA eliminated the coverage gap phase ("donut hole") and redistributed the associated manufacturer discounts across the remaining phases, requiring a 10% discount in the initial coverage phase and a 20% discount in the catastrophic phase.²¹

The Part D benefit redesign also introduced a fixed out-of-pocket (OOP) cap, above which beneficiaries owe no further cost-sharing. Progress toward this cap is determined by true out-of-pocket (TrOOP) costs, which historically included beneficiary payment, low-income cost-sharing subsidy (LICS), certain third-party payments, such as support from State Pharmaceutical Assistance Programs, Coverage Gap Discount Program (CGDP) amounts. Under the redesign, the definition of TrOOP was revised and accumulation toward the cap changed. TrOOP-eligible costs now accrue based on the greater of the defined standard benefit cost-sharing amount and the beneficiary's actual payment ("greater-of" rule). That is, the cost-sharing amounts paid by plans on behalf of their beneficiaries accrue toward the cap, while that supplemental coverage lowers what beneficiaries actually pay.²¹ The actual OOP payment required to reach the cap is therefore lower than the cap value.⁸⁴ Under the updated definition, new Manufacturer Discount Program which replaced CGDP do not count toward the cap.

The redesign shifted the dominant federal financing mechanism for Part D plan sponsors away from Medicare reinsurance toward the direct subsidy, thereby giving plan sponsors a direct financial stake in managing drug spending.²¹ Reinsurance retrospectively reimbursed 80% of catastrophic spending, whereas the direct subsidy is a fixed monthly per-enrollee payment determined through each plan's bid.⁸⁵ Under this shift, Medicare reinsurance in the catastrophic phase fell from 80% to 20%, while the plan share of brand-drug liability increased from 15% to 60%.²¹ This change exposes plan sponsors to financial risk arising from the potential gap

between the revenue a plan locks in through its bid and premium and the costs it actually incurs.⁸⁶

This added risk prompted plans to reshape their cost-sharing structures. A copayment-to-coinsurance shift, observed among stand-alone prescription drug plans (PDPs) by 2019, has appeared among Medicare Advantage prescription drug plans (MA-PDs).¹⁰ Between 2024 and 2025, mean MA-PD deductibles rose from \$66 to \$228, and the share of MA-PD enrollees facing coinsurance for preferred brand-name drugs rose from roughly 2.5% to 27.7%.¹¹

The IRA also expanded the low-income subsidy (LIS) eligibility, extending full subsidy to partial-subsidy population.²¹ It also authorized Medicare to negotiate prices for selected high-spending, single-source drugs, with the first maximum fair prices (MFPs) taking effect in 2026.⁵⁴

Accurately estimating how these IRA provisions affect Part D OOP costs requires capturing changes in beneficiary cost-sharing, the LIS expansion, and the negotiated prices, while simulating phase progression as those payments accumulate toward the cap under the “greater-of” rules. To our knowledge, no analysis has incorporated these elements together to estimate beneficiary-level OOP change.

The Office of Assistant Secretary for Planning and Evaluation (ASPE) projected \$7.4 billion in 2025 OOP reductions across 18.7 million beneficiaries expected to save, using 2021 claims.¹

ASPE updated the analysis using 2023 claims and reported \$7.2 billion across 11.3 million beneficiaries expected to reach the cap.² These analyses considered multiple Part D provisions but excluded price negotiation and cost-sharing changes, both of which directly affect beneficiaries’ OOP costs.

Both CMS and the Congressional Budget Office (CBO) modeled multiple IRA provisions including Part D redesign and Medicare price negotiation, but for federal budgetary impact rather than enrollees’ OOP costs.^{87,88} Other studies measured OOP costs but examined individual provisions. One estimated the OOP a beneficiary pays before reaching the cap under the “greater-of” rule.⁸ Another measured OOP per fill through 2025, before the MFP took effect, without separating the

contributions of the individual IRA provisions.⁹ Formulary reviews analyzed plan benefit designs rather than claims, reporting rising deductibles and the movement of brand drugs to coinsurance, and estimated per-prescription cost-sharing for the ten drugs selected for negotiation.¹⁰⁻¹² Studies of price negotiation estimated the reduction in Medicare spending under negotiated prices rather than the change in beneficiary payments.³⁻⁷

We address this gap by applying, in sequence, the redesigned Part D benefit with the expanded LIS, the “greater-of” rule, and the MFPs, while accounting for changes in cost-sharing rules between 2023 and 2026.

Method

We anchored the baseline to 2023, the last year before these Part D IRA provisions took effect.²¹ Holding 2023 utilization constant allows differences in simulated OOP costs to be attributed to the exposures of interest. The \$35 monthly insulin OOP cap and zero cost-sharing for ACIP-recommended vaccines in Part D were already in effect in 2023 and therefore do not contribute to the estimated change.

We built the simulation in five steps. Step (A) is the counterfactual baseline, applying the 2023 benefit design and cost-sharing rules. The 2023 benefit ran through four phases, namely the deductible, initial coverage, coverage gap, and catastrophic phases. Step (B) replaces these with the 2025 redesigned benefit, with parameters adjusted for 2026 coverage year, and 2026 cost-sharing and added LIS expansion. The 2026 redesigned benefit removed the coverage gap and retained the deductible, initial coverage, and catastrophic phases. Steps (C) and (D) each add one element to Step (B). Step (C) adds the “greater-of” rule and Step (D) adds price negotiation. Step (E) applies both. For all steps, we inflated 2023 prices to 2026 using the annual percentage increase, the factor CMS applies to update Part D defined standard benefit parameters each year.^{21,89} For Step (A), we applied the same factor to the hypothetical 2026 thresholds that define the pre-redesign benefit phases. (Table 2 - 1)

Table 2 - 1: Simulation Steps A to E

Simulation steps	
Step A:	2023 Benefit Design and Cost-Sharing
Step B:	2026 Benefit Design and Cost-Sharing + LIS Expansion
Step C:	2026 Benefit Design and Cost-Sharing + LIS Expansion + “Greater-of” Rule
Step D:	2026 Benefit Design and Cost-Sharing + LIS Expansion + Price Negotiation
Step E:	2026 Benefit Design and Cost-Sharing + LIS Expansion + “Greater-of” Rule + Price Negotiation

ABBREVIATION: LIS, Low-income subsidy

Study population

The study used 100% sample of eligible prescription drug event (PDE) claims incurred by beneficiaries with full-year enrollment in either MA-PD or PDP. The full-year enrollment is required to simulate phase progression, which tracks each beneficiary's TrOOP accumulation throughout the year. This restriction excludes beneficiaries with partial-year enrollment, who tend to differ in health and drug use.⁹⁰ Our estimates therefore may not generalize to those with partial-year coverage. Given the systematic differences in cost-sharing structure and LIS composition between MA-PD and PDP, we reported both pooled and separate outcomes. We excluded all other contract types and employer group waiver plans (EGWPs), whose cost-sharing are set outside the standard Part D benefit and would not reflect the statutory design under study.⁹¹

Tier and Cost-Sharing Assignment

We assigned each 2023 PDE claim a formulary tier and its corresponding cost-sharing, using the beneficiaries' plan formulary, and modeled the actual mix of plan designs. For the 2023 baseline (Step A), we used the Chronic Conditions Warehouse (CCW) Part D formulary, the most direct record of the terms each beneficiary actually faced. The CCW formulary carries a drug identifier (FRMLRY_RX_ID) derived from the Health Plan Management System (HPMS) and PDE files, which allows direct matching to PDE claims. For the 2026 steps (Steps B through E), CCW formulary was not available yet. We therefore applied the published 2026 HPMS formularies to the same 2023 claims, matching on National Drug Code (NDC) with the RxNorm Concept Unique

Identifier (RxCUI) as the fallback. When a claim matched neither on NDC nor RxCUI, we assigned the drug's most common tier across plans.

We then attached cost-sharing to each claim from a cost-sharing grid defined by tier, contract identifier, plan identifier, benefit phase, and supply duration. In certain phases, cost-sharing follows program rules when plan terms are not specified. Under the 2023 standard benefit, this is 25% coinsurance in the coverage gap and 5% coinsurance subject to a minimum copay in the catastrophic phase. The 2026 benefit removes the coverage gap and charges no cost-sharing above the cap. For claims that could not be matched the grid, we imputed cost-sharing based on the tier in the same plan. If still unmatched, we widened the search to the same contract, then to any contract that covered the drug.

LIS Cohort

LIS beneficiaries do not draw cost-sharing from the plan's tier structure. Each drug fill instead carries a statutory copay set by the beneficiary's cost-share group. Step (A) used the 2023 groups as enrolled, inflated to 2026, keeping the partial-subsidy groups distinct. Steps (B) to (E) merged the partial-subsidy groups into the full-subsidy schedule under the LIS expansion. The beneficiary paid the lesser of the copay and the drug's cost. The low-income cost-sharing subsidy (LICS) covered the remainder, defined as the plan cost-sharing minus the copay, bounded at zero. The copay, the LICS, and any other TrOOP-eligible spending advanced the beneficiary's TrOOP.

Medicare Drug Price Negotiation Program

We modeled the MFP as a price adjustment applied to the ten selected drugs that participated in the first year of negotiations with Medicare and agreed to a negotiated price for Initial Price Applicability Year (IPAY) 2026. Each IPAY 2026 selected drug carried a factor that scaled its 2026 gross cost to the MFP level, matched to claims at the NDC level. The MFP steps (Steps D and E) applied this factor, and the other steps used the unadjusted prices.

OOP simulation

We ordered each beneficiary's claims by date of service and simulated their progression through the benefit phases one claim at a time. Each claim drew its cost-sharing from the phase the beneficiary occupied, and its TrOOP-eligible payment advanced the year-to-date TrOOP total that set the next phase. This running total fixed each beneficiary's phase and the point of entry into the catastrophic phase.

The "greater-of" rule changed how the beneficiary component of TrOOP-eligible payment is accumulated. Without it (Steps B and D), this component increased by the beneficiary's actual payment. With it (Steps C and E), it rose by the greater of the defined standard benefit cost-sharing and the actual payment. This rule moved the beneficiary with enhanced coverage into the catastrophic phase sooner, which lowered the OOP they paid over the rest of the year.

Outcome Measures

The primary outcome was simulated mean annual OOP cost per beneficiary. We decomposed the OOP change from Step (A) to Step (E), which combines the benefit redesign, the "greater-of" rule, LIS expansion, and price negotiation. We isolated the MFP by comparing Step (C) with Step (E) at a common "greater-of" setting. We isolated the "greater-of" rule at two price levels, comparing Step (B) with Step (C) before the MFP and Step (D) with Step (E) after it. The lower MFP slows TrOOP accumulation, which attenuates the effect of the "greater-of" rule.

We examined OOP differences across gross drug spending deciles, ranking beneficiaries by total annual gross drug costs and dividing them into ten equal groups. This separated beneficiaries whose spending stayed in the early phases from those who reached the catastrophic phase, where the redesign and the OOP cap act most directly.

Although the analysis used the full sample of eligible PDE claims, we calculated 95% confidence intervals from the standard error of the paired mean difference. The intervals reflect within-beneficiary variability and thus yields narrow intervals.

Result

Matching quality

Of 1.6 billion drug-level claims, we included 1.3 billion claims of covered drugs among beneficiaries with full-year enrollment in either a MA-PD or a PDP. In Step A, 94.7% to 98.3% of 2023 PDE claims were directly matched to the 2023 formulary, depending on the benefit phase. After imputation, only 1.7% to 1.8% remained unmatched. In subsequent steps, 21.9% to 61.7% of 2023 PDE claims were directly matched to the 2026 formulary. After cost-sharing imputation, 1.7% to 2.6% remained unmatched.

Cost-sharing changes between 2023 and 2026

We examined which drugs plans moved to a different tier and cost-sharing rule between 2023 and 2026 and how many claims were affected. The shift was most prominent on Tiers 3 and 4. 61.8% of Tier 3 and 59.9% of Tier 4 claims moved from copayment to coinsurance. Tiers 3 and 4 accounted for the highest gross spending, with Tier 3 alone accounting for \$54.7 billion, more than any other tier. (Table 2 - 2).

Table 2 - 2: Cost-Sharing Changes by Tier, Step A to Step E

Tier ^a	Claim No.	Step A Total Gross Spending (\$ million)	Step E Total Gross Spending (\$ million)	Copay to Coins (% of Claims)	Coins to Copay (% of Claims)	Coins to Coins (% of Claims)	Copay to Copay (% of Claims)	Δ Total OOP
All Beneficiaries								
1	573M	\$168,016	\$14,377	6.5%	1.6%	1.1%	90.7%	-39.5%
2	339M	\$9,943	\$9,270	5.5%	3.0%	2.0%	89.3%	-26.8%
3	234M	\$111,564	\$54,651	61.8%	0.7%	13.7%	22.1%	+3.1%
4	70M	\$15,837	\$13,650	59.9%	0.1%	35.4%	1.3%	11.5%
5	12M	\$84,206	\$40,203	7.6%	1.9%	71.1%	1.9%	83.7%
6	24M	\$1,818	\$776	0.0%	0.2%	0.1%	99.5%	57.5%
7	0.2M	\$69	\$45	0.0%	25.0%	38.3%	20.5%	56.9%
All	1,252M	\$240,239	\$132,972	16.0%	10.7%	11.9%	60.4%	23.9%

NOTE

- Definition of Drug Tiers: Tier 1 - Preferred, low-cost generic drugs; Tier 2 - Non-preferred and other low-cost generic drugs; Tier 3 - Preferred brand-name and some higher-cost generic drugs; Tier 4 - Non-preferred brand-name and higher-cost generic drugs; Tier 5 - Specialty drugs, which CMS limits to products exceeding a monthly cost threshold; Tier 6 - Select care drugs offered at reduced cost-sharing; and Tier 7 - An additional tier permitted since 2021, used for non-preferred specialty or select diabetic drugs. Plans assign drugs to tiers at their own discretion, so placement may vary across plans

All beneficiaries

The combined effect of IRA provisions in 2026, including the Part D benefit redesign with the OOP cap, the “greater-of” rule, the LIS expansion, and the Medicare drug price negotiation, lowered mean annual OOP cost per beneficiary by -\$129.16 (95% CI, -129.51 to -128.81). (Table 2 - 3) This corresponds to an estimated -\$6.6 billion reduction in total Medicare Part D beneficiaries OOP costs. This estimate extrapolated the savings from full-year enrollees to beneficiaries with partial-year enrollment.

The benefit redesign and LIS expansion (Step A to B) were the largest drivers, lowering mean annual OOP by -\$54.60 (95% CI, -54.94 to -54.25). At list prices, the “greater-of” rule further reduced mean OOP by -\$31.49 (95% CI, -31.53 to -31.46) (Step B to C). Once the MFP applied, the same rule lowered OOP by -\$15.12 (95% CI, -15.14 to -15.09), resulting from the lower MFP slowing TrOOP accumulation and dampening the rule's effect. Price negotiation with the “greater-of” rule in place (Step C to E) yielded additional savings of -\$43.07 (95% CI, -43.13 to -43.01) (Table 2 - 3).

Despite these reductions in mean OOP costs, 36% of beneficiaries paid, on average, +\$176 more under the Step E (Median +\$78), while 14% experienced no change. The increases concentrated among beneficiaries in the 7th and 8th deciles (“moderate-to-high” spenders). These moderate-to-high spenders were heavy users of Tier 3 drugs but did not spend enough to reach the OOP cap (Table 2 - 4).

We decomposed mean OOP costs of these moderate-to-high spenders by benefit phase. While the initial coverage limit (ICL) phase narrowed from \$615-\$5,690 in 2023 to \$615-\$2,100 in 2026, mean OOP incurred during this phase rose from \$203 to \$223 in the 7th decile and \$330 to \$418 in the 8th decile. The ICL is the only phase where cost-sharing applied in 2026. These findings suggest that the increased OOP costs were driven by plan sponsors’ decisions related to cost-sharing changes rather than IRA benefit redesign.

Table 2 - 3: Mean Annual OOP Cost per Beneficiary by Step and by Plan Type

Steps	All	MA-PD	PDP
Mean Beneficiary-Level Annual OOP ^a			
Step A: 2023 Benefit Design and Cost-Sharing	\$524	\$381	\$728
Step B: 2026 Benefit Design and Cost-Sharing + LIS Expansion	\$470	\$397	\$574
Step C: 2026 Benefit Design and Cost-Sharing + LIS Expansion + “Greater-of” Rule	\$438	\$366	\$542
Step D: 2026 Benefit Design and Cost-Sharing + LIS Expansion + Price Negotiation	\$410	\$342	\$507
Step E: 2026 Benefit Design and Cost-Sharing + LIS Expansion + “Greater-of” Rule + Price Negotiation	\$395	\$326	\$493
OOP Change			
From 2026 Benefit Design and Cost-Sharing + LIS Expansion (A vs B) [95% CI] ^b	-\$55 [-54.94 to -54.25]	+\$15 [+15.01 to +15.78]	-\$154 [-154.78 to -153.50]
From “Greater-of” Rule at List Price (B vs C) [95% CI] ^b	-\$31 [-31.53 to -31.46]	-\$31 [-31.10 to -31.01]	-\$32 [-32.17 to -32.05]
From Price Negotiation (C vs E) [95% CI] ^b	-\$43 [-43.13 to -43.01]	-\$39 [-39.38 to -39.23]	-\$48 [-48.52 to -48.33]
Baseline vs Full IRA provisions (A vs E) [95% CI] ^b	-\$129 [-\$129.51 to -\$128.81]	-\$55 [-55.35 to -54.59]	-\$235 [-235.32 to -234.03]

NOTE

- a. Positive values denote higher OOP under the Step E than baseline Step A; negative values denote savings
- b. Although the analysis used the full sample of eligible PDE claims, 95% confidence intervals are calculated from the standard error of the paired mean difference between Step A and Step E. Their narrowness reflects cohort size, not low dispersion.

ABBREVIATIONS: CI, Confidence Interval; LIS, Low-Income Subsidy; MA-PD, Medicare Advantage Prescription Drug Plan; MFP, Maximum Fair Price; OOP, Out-of-pocket costs; PDP, Stand-Alone Prescription Drug Plan

Table 2 - 4: Total Annual OOP Cost (\$ million) by Gross Spending Decile and by Plan Type

	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
All Beneficiaries										
Tier 3	\$1.7	\$4.8	\$19	\$117	\$158	\$128	\$203	\$387	-\$36	-\$717
Other Tiers	-\$26	-\$111	-\$177	-\$174	-\$178	-\$200	-\$169	-\$175	-\$394	-\$3,285
Sum	-\$25	-\$106	-\$158	-\$57	-\$19	-\$73	+\$33	+\$211	-\$429	-\$4,002
MA-PD Beneficiaries										
Tier 3	\$1.0	\$3	\$17	\$70	\$90	\$105	\$196	\$329	\$92	-\$246
Other Tiers	-\$10	-\$33	-\$53	-\$44	-\$39	-\$54	-\$26	-\$13	-\$106	-\$1,360
Sum	-\$9	-\$30	-\$35	+\$25	+\$50	+\$51	+\$170	+\$316	-\$14	-\$1,606
PDP Beneficiaries										
Tier 3	\$0.7	\$1.5	\$1.6	\$47	\$69	\$23	\$7.0	\$57	-\$128	-\$470
Other Tiers	-\$16	-\$77	-\$125	-\$130	-\$138	-\$146	-\$143	-\$162	-\$287	-\$1,925
Sum	-\$15	-\$76	-\$123	-\$82	-\$69	-\$123	-\$136	-\$105	-\$415	-\$2,396

NOTE

Positive values denote higher OOP under the Step E than baseline Step A; negative values denote savings

The cost-sharing changes were concentrated in Tier 3 drugs, which accounted for \$54.7 billion in gross spending. Among Tier 3 claims, 61.8% moved from copayment to coinsurance, and total OOP costs increased by 3.1% (Table 2 - 2). This increase was greatest among moderate-to-high spenders, where the Tier 3 OOP increase offset reductions in all other tiers, since many did not reach the OOP cap and bore the higher coinsurance without benefiting from the cap (Table 2 - 4). These patterns were more pronounced in MA-PD than PDPs.

MA-PD beneficiaries

MA-PD beneficiaries saved -\$55 on average (95% CI, -\$55.35 to -\$54.59) (Table 2 - 3). The 2026 cost-sharing, benefit redesign and LIS expansion (Step A to B), however, increased mean OOP by +\$15 (95% CI, 15.01 to 15.78), despite the expected OOP reductions from the benefit redesign and LIS expansion. This increase likely reflects the plan sponsors change from copayment-to-

coinsurance and not the specific provisions themselves. The “greater-of” rule and the MFP in later steps outweighed this increase. Those in the 4th through 8th deciles paid +\$11 to +\$127 more, while the highest decile paid -\$770 less.

Tier 3 drugs drove the increase in total annual OOP costs, and Medicare price negotiation did not reverse this increase. Across all deciles, total OOP costs for tier 3 drugs rose 3.4% for non-selected drugs and 2.6% for selected drugs. This increase was larger among moderate-to-high spenders, reaching 21.6% for non-selected drugs and 27.5% for selected drugs (Table 2 - 5).

Table 2 - 5: Total Annual OOP Cost (\$ million) by Tier and by Drug Type

Tier	Drug Type	All Gross Spending Deciles			Moderate-to-High Spenders (7 th and 8 th deciles)		
		Step A: Total OOP	Step E: Total OOP	Δ Total OOP %	Step A: Total OOP	Step E: Total OOP	Δ Total OOP %
1	MFP Selected	\$19	\$9.0M	-52.9%	\$1.0M	\$2.1M	115.4%
	Non-Selected	\$2,754M	\$1,668M	-39.5%	\$563M	\$365M	-35.2%
2	MFP Selected	\$2.4M	\$2.3M	-3.7%	\$1.1M	\$1.2M	3.2%
	Non-Selected	\$2,580M	\$1,890M	-26.8%	\$734M	\$551M	-24.9%
3	MFP Selected	\$2,546M	\$2,611M	+2.6%	\$655M	\$835M	+27.5%
	Non-Selected	\$5,915M	\$6,115M	+3.4%	\$1,892M	\$2,300M	+21.6%
4	MFP Selected	\$1.9M	\$2.1M	+14.4%	\$0.2M	\$0.4M	+128.4%
	Non-Selected	\$2,031M	\$1,797M	-11.5%	\$713M	\$769M	+7.9%
5	MFP Selected	\$275M	\$36M	-86.9%	\$0.2M	\$0.2M	-8.8%
	Non-Selected	\$3,030M	\$504M	-83.4%	\$49M	\$45M	-7.5%
6	MFP Selected	\$0.2M	\$0.3M	+28.7%	\$0.05M	\$0.1M	+101.4%
	Non-Selected	\$143M	\$61M	-57.6%	\$28M	\$16M	-44%
7	MFP Selected	\$0M	\$0M	-	\$0M	\$0M	-
	Non-Selected	\$14M	\$6.0M	-56.9%	\$4.9M	\$2.6M	-46.5%

ABBREVIATIONS: MFP, Maximum Fair Price; OOP, Out-of-pocket costs

PDP beneficiaries

PDP beneficiaries saved -\$235 on average (95% CI, -235.32 to -234.03), substantially more than MA-PD beneficiaries. Unlike in MA-PD, the benefit redesign and LIS expansion lowered PDP OOP from the first step, by -\$154 (95% CI, -154.78 to -153.50) from Step A to B, with the “greater-of” rule and the MFP contributing further reductions of -\$32 (95% CI, -32.17 to -32.05) from Step B to C and -\$48 (95% CI, -48.52 to -48.33) from Step C to E. These reductions narrowed the OOP

gap between PDP and MA-PD from \$347 (\$728 versus \$381, under Step A) to \$167 (\$493 versus \$326, under Step E). (Table 2 - 3)

The larger saving resulted from a higher baseline OOP in PDP than MA-PD (\$728 versus \$381), which left more room for the redesign to lower it. This higher baseline also traced in part to the LIS composition of each cohort. LIS beneficiaries made up 34.4% of our MA-PD sample compared with 24.4% of our PDP sample. Both were above the national shares of 29.6% and 17.3%.⁹²

As in MA-PD, the copay-to-coinsurance shift concentrated among negotiated drugs in PDP, at 56.0% of negotiated drug claims compared with 23.6% of non-negotiated claims. In 2023, all three negotiated oral antidiabetics sat on Tier 6, a Select Care tier that carries a \$0 or very low copayment for chronic-disease drugs. Under the 2026 benefit, many plan sponsors moved these drugs to Tier 3, which raised cost-sharing for the beneficiaries who had filled them on Tier 6.

Discussion

We estimated beneficiary-level changes in annual Part D OOP spending by applying IRA provisions, including the redesigned Part D benefit, the LIS expansion, the “greater-of” rule, and Medicare Drug Price Negotiation Program’s MFPs for IPAY 2026, together with changes in plan cost-sharing between 2023 and 2026.

Despite the Part D plan sponsors’ copayment-to-coinsurance shift for high-spending drugs, the broader Part D provisions together lowered mean annual OOP by \$129.16. This reduction, however, did not reach beneficiaries evenly due to the plan sponsors’ changes to plans. Among moderate-to-high spenders, the coinsurance shift outweighed the IRA-driven reductions, raising their OOP. For moderate-to-high spenders, Medicare price negotiation lowered gross spending on eight Tiers 3 negotiated drugs by 64.0%, yet OOP for those drugs rose by 27.5% because of plan sponsors’ tier placement, as coinsurance applied to the lowered price exceeded the copayment it replaced.

Our results are consistent with external plan-level evidence. Studies of plan benefit designs report that MA-PD plans moved brand drugs to coinsurance after the redesign, while PDPs had long relied on coinsurance.^{10,11,93} Claims analyses of realized spending, report that OOP per fill rose sharply at the start of the year and fell as more beneficiaries reached the cap later in the year.⁹ Neither approach decomposed the sources of the beneficiary's annual OOP increase.

The redesign itself created the incentive behind the coinsurance shift. Reinsurance once retrospectively reconciled 80% of catastrophic spending. The redesign cut this to 20% for brand-name drugs and biosimilars and moved financing to the prospectively fixed direct subsidy. Plan liability in the catastrophic phase also increased from 15% to 60%. These changes leave plans at risk when actual costs exceed bid revenue.²¹

Plan sponsors neutralized the greater risk by shifting costs to beneficiaries through cost-sharing changes from fixed copayment to percentage-based coinsurance. Policy should discourage this shift for the intended savings to reach all beneficiaries. In MA-PD, where more beneficiaries experienced increases in OOP costs, policymakers could consider policy that directs MA-PD rebates be specifically toward supplemental drug coverage.

This study has several limitations. By holding utilization fixed at its 2023 level, our estimates did not capture beneficiaries' behavioral response to the OOP changes they faced. Our results showed 51% of Medicare Part D beneficiaries experienced reduced OOP costs, and lower costs may lead them to fill more. CBO identified increased prescription drug use in response to lower OOP costs as an important contributor to higher Part D spending. CBO noted that plan sponsor reported a 35% increase in per-beneficiary annual costs, far exceeding CBO's prior estimate of 5%.⁸⁷ Cai et al. reported that Medicare use rose relative to commercial plans after the 2025 cap, with the largest increase among very-high-cost drugs at 22.7%.⁹⁴ Our simulation does not capture this added use and therefore understates the redesign's full effect on drug utilization.

Our simulation also did not capture other plan responses such as adding utilization management or narrowing their preferred pharmacy networks, concerns raised in the CY2027 rulemaking.⁹⁵

Recent data showed that prior authorization on covered brand drugs rose about three percentage points for PDPs and two for MA-PDs between 2025 and 2026, following a similar increase the year before.⁹³ The share of regional PDPs with a preferred network fell from a 2023 peak of 98% to 79% in 2026.⁹⁶ Any of these changes could leave prescriptions unfilled, which our OOP estimates do not reflect.

Our attribution of the cost-sharing shift to the redesign is based on timing and incentive alignment rather than causal identification. Plan sponsors set cost-sharing in response to multiple factors, including rising drug prices, generic and biosimilar availability, new drug introductions, pharmacy network economics, and rebate strategies, operating alongside the redesign.^{10,97,98} The shift observed between 2023 and 2026 therefore reflects the combined influence of these forces.

A 2023 fill does not always appear on the 2026 formulary, since plans revise their drug lists every year. If a fill had no direct match, we imputed its cost-sharing from other plans and contracts. That is, the 2026 estimates rest partly on imputed rather than observed terms. This affects the 2026 steps more than the 2023 baseline. In 2023, most fills matched the beneficiary's own formulary directly.

We restricted the sample to beneficiaries with full-year enrollment and scaled the estimates to the full Part D population. Beneficiaries with partial-year enrollment differ from this sample in ways that could bias savings in either direction. For instance, those entering Medicare at age of 65 years tend to have lower spending, while those entering Medicare midway due to disability tend to have high spending.⁹⁹ The direction and magnitude of the resulting bias in total savings are therefore unknown.

Conclusion

The IRA provisions were estimated to reduce Medicare Part D beneficiaries' total OOP costs by \$6.6 billion in 2026, yet the savings may not have reached half of beneficiaries. For these beneficiaries, plan sponsor copayment-to-coinsurance shifts offset the savings, and the price

negotiation yet restored them. Savings were smaller in MA-PD than PDP, where the offsetting shifts were more pronounced. Extending these savings to all beneficiaries would require discouraging coinsurance shifts.

CONCLUSION

Summary of Findings

This dissertation estimated the effect of the IRA's Part D provisions on what Medicare and beneficiaries spend on prescription drugs, while accounting for concurrent market dynamics.

In 2026, Medicare prescription drug price negotiation program is projected to reduce Medicare Part D spending for the first ten drugs by \$2.3 billion (8.8%) compared with the 'Historical Benchmark' scenario. Under the 'Negotiation under the IRA' scenario, spending was \$2.4 billion (9.0%) lower than if the drugs had not been selected for negotiation but subject to MDP. Larger reductions occurred for drugs with low prior rebates and long market exclusivity, whereas smaller reductions were observed for those affected by generic or biosimilar entry. These findings inform both more accurate assessments of the spending impact of future negotiations and policy design to enhance negotiation effectiveness as market conditions change.

The IRA's broader Part D provisions were estimated to reduce beneficiaries' total OOP costs by \$6.6 billion in 2026, yet the savings did not reach half of beneficiaries. For these beneficiaries, plan sponsor copayment-to-coinsurance shifts offset the savings, and the price negotiation yet restored them. Savings were smaller in MA-PD than PDP, where the offsetting shifts were more pronounced. Extending these savings to all beneficiaries would require discouraging coinsurance shifts.

Together, this dissertation may contribute more accurate estimates of the IRA's effect on Medicare and beneficiary spending for prescription drugs covered under Part D plans and inform future policy.

Implications for Policy and Research

Our findings showed that market dynamics altered whether the IRA's Part D provisions deliver their intended savings. Aim 1 showed that the spending impact of price negotiation depended not only on the negotiated MFP but also on factors that determine the counterfactual net price, such as manufacturer discounts and generic or biosimilar competition. These findings suggest that future statutory framework may need to account for changing market conditions throughout the negotiation program.

At the selection stage, this need is more apparent for drugs facing imminent generic or biosimilar entry. For biologics, the statute allows deferral of selection when biosimilar entry is expected within two years after selection and imposing rebates when expected entry does not occur.¹⁰⁰ This mechanism could be extended to small molecule drugs preserving negotiation program for those less likely to face the competition and maximizing the negotiation impact.

At the negotiation stage, the statutory ceiling for MFP could reflect the MDP liability that would apply if the drug were not selected. This would capture the net prices that Medicare would have paid and reflect counterfactual savings under the MDP. MDP savings would be particularly substantial for drugs whose costs are concentrated in catastrophic phase. This adjustment would retain other benefits of the negotiation, such as greater price transparency at the point of sale and a lower price basis for beneficiary cost-sharing.¹⁰¹

After the MFP takes effect, MDP liability could be restored during the lag between a bona fide marketing determination and formal deselection. Deselection takes effect only on the 1st day of January that falls at least 9 months after the determination and 'selected-drug' status can last for up to 21 months, during which the MDP exemption remains in effect.¹⁰⁰

In Aim 2, plan cost-sharing changes, particularly copayment-to-coinsurance shift, attenuated the intended beneficiary savings and even increase the OOP costs for certain enrollees. This was more pronounced in MA-PDs.^{10,11,93} The MA-PDs had long used rebate dollars to offer zero

deductibles and fixed copayments for preferred brands, keeping OOP lower than in PDPs.⁷⁹ After the redesign, MA-PD plans converged toward the PDP pattern, replacing fixed copayments with coinsurance.^{10,11,93} A fixed copayment is independent of price, whereas coinsurance is a share of it. Hence, the replacement itself moved cost from the plan to the patient.^{10,11,79,93} The transferred amount scaled with price, and the conversion therefore concentrated in Tier 3, where gross spending was largest at \$54.7 billion. For the OOP reductions from the IRA provisions to reach all patients, plan sponsors must not offset them through cost-sharing changes. This will require policies that discourage copayments-to-coinsurance shifts.

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SUPPLEMENTAL APPENDICES

Chapter 1: Technical Appendix

A. Generic and Biosimilar Entry

Table 1A - 1: Public Information Used to Determine Expected Generic and Biosimilar Entry Timing

A. Patent and Exclusivity Barriers		
Assess structural constraints on near-term generic entry and Paragraph IV challenge requirements		
Exclusivity	Active Exclusivity	FDA may not approve an ANDA, regardless of patent status Generic entry blocked until exclusivity expiry
	Expired Exclusivity	Generic company can submit ANDA Paragraph IV requirement depends on remaining patent status
Patent status	Drug Substance (DS) active	Near-term generic entry unlikely Entry requires Paragraph IV challenge, settlement, or patent expiry
	Drug Product (DP) only active	Near-term generic entry possible, often partial/strength-specific Paragraph IV required only if the DP patent cannot be avoided
	Method of Use (MOU) only active	Near-term generic entry possible, if skinny labeling is feasible Paragraph IV only if skinny label not feasible
B. Regulatory Status		
Assess whether an ANDA has been approved, regardless of launch		
Generic appears in the Orange Book		ANDA approved Approval does not necessarily imply commercial launch
Generic not appear in the Orange Book		- ANDA may not have been submitted, or - ANDA under FDA review or tentative approval
C. Paragraph IV, Litigation, and Market Signals		
Infer ANDA submission, legal status, and likely launch timing by searching 10-K / annual reports / press releases / court dockets to infer ANDA status		
Paragraph IV notice or patent litigation		ANDA submitted, and under FDA review or tentative approval
Settlement		- Generic entry timing governed by settlement terms - Use the earliest possible generic entry date disclosed
No evidence of Paragraph IV activity		Generic entry depends on patent/exclusivity expiry or non-infringing ANDA design
Press release announcing generic launch		ANDA approved and possibly launched

Table 1A - 2: Expected Generic and Biosimilar Entry Timing and Rationale

Generic Name (Brand Name)	Expected Entry	Rationale
Apixaban (Eliquis)	2028 or later	Active Exclusivity until April 2028 ³⁰⁻³²
Etanercept (Enbrel)	2029 or later	Enbrel was first approved in November 1998. Amgen subsequently secured exclusive rights to later-filed drug substance patents, including U.S. Patent No. 8,163,522. Through a combination of patent enforcement and litigation outcomes, these patents have effectively extended protection for etanercept in the U.S. until 2029. ^{33,34}
Sacubitril/Valsartan (Entresto)	Jul 22, 2025	Although the key drug substance patent expires in May 2027 and is extended to November 2027 by pediatric exclusivity, Novartis entered settlement agreements that allowed generic launch prior to patent expiry. The FDA approved the first generic Entresto in May 2024, and it has been commercially available since July 2025. ³⁵⁻³⁷
Dapagliflozin (Farxiga)	2028 or later	NPP exclusivity runs through June 2027, extending to December 2027 with pediatric exclusivity. Taken together with Orange Book-listed DS and DP patents, the combined protection makes commercial generic entry before late 2027 unlikely. ³⁸⁻⁴⁰
Ibrutinib (Imbruvica)	2029 or later	NP/NPP exclusivity expires February 2026, while ODE extends to August 2029 or February 2030, with pediatric extensions. When paired with Orange Book patents for drug substances (2033-2034) and drug products (2036-2039), these protections make full-label generic entry unlikely before late 2029. ⁴¹⁻⁴³
Sitagliptin (Januvia)	May 1, 2026	Although the DS patent expires in November 2026, extending to May 2027 with pediatric exclusivity, Merck successfully defended the patent in Paragraph IV litigation and subsequently entered into settlement agreements allowing generic entry in May 2026. ⁴⁴
Empagliflozin (Jardiance)	2028 or later	NPP exclusivity runs through June 2026, extending to December 2026 with pediatric exclusivity. Its primary DS patent remains a barrier until August 2028 (February 2029, with pediatric exclusivity). Coupled with MOU patents extending into 2034, these protections make full-label generic entry unlikely before late 2028. ⁴⁵
Insulin aspart (Novolog)	Jan 1, 2026	Novolog was first licensed in 2000. Merilog and Kristy were approved in 2025, with Merilog confirmed as commercially launched by Sanofi in July 2025; however, as of December 2025, CMS did not find bona fide marketing for either Merilog or Kristy and therefore did not treat their entry as alternative entry sufficient to trigger deselection. ⁴⁶
Insulin aspart (Fiasp)	2029 or later	Fiasp was first licensed in September 2017, and accordingly, any 351(k) biosimilar approval cannot become effective before September 2029. ⁴⁷
Ustekinumab (Stelara)	Jan 1, 2025	Stelara was first licensed in September 2009. Johnson & Johnson maintained market control through a portfolio of DP, MOU, and manufacturing patents, enforced through litigation and settlement agreements, successfully delaying U.S. biosimilar market entry until January 2025. ⁴⁸
Rivaroxaban 2.5 mg (Xarelto)	Mar 7, 2025	FDA approved the first 2.5 mg generics in March 2025, with Lupin launching commercially on March 7, 2025, with a full CAD/PAD label. The launch occurred prior to final resolution of remaining MOU patent litigation. ⁴⁹⁻⁵¹

Generic Name (Brand Name)	Expected Entry	Rationale
Rivaroxaban 10 mg, 15 mg, 20 mg (Xarelto)	2029 or later	While higher-strength generic ANDAs received FDA approvals beginning in May 2025, no broad commercial launches have been announced as of early 2026, likely reflecting ongoing DS patent protection through February 2029 and multiple MOU patents extending into 2034 ⁵¹⁻⁵³

B. Volume Projection and Adjustment

(1) Data Preparation

We projected 2026 drug volumes using IQVIA extended-unit data for 2022 to 2024, calibrated to Part D utilization levels using drug-specific scaling factors from Medicare Part D Spending Dashboard.^{56,58} For each drug, we calculated a scaling factor defined as the ratio of total annual Part D units to total annual IQVIA units in 2022 or 2023. For a given drug d , the scaling factor was defined as:

$$\text{Scaling Factor}_d^y = \frac{\text{Total Annual Part D Dashboard Units}_d^y}{\text{IQVIA's Aggregated Extended Units}_d^y} \text{ where } y = 2022 \text{ and } 2023$$

(2) Projection into 2026

For each drug, we modeled quarterly volume from 2022 Q1 through 2024 Q4. All selected drugs are indicated for chronic diseases, and we suspect that residual autocorrelation exists. We applied Ljung-Box test to assess residual autocorrelation, which was present for all drugs except etanercept (Enbrel), ustekinumab (Stelara), and rivaroxaban (Xarelto).

For consistency and reliability, we used Prais-Winsten regression for all drugs specified as below:

$$V_t = \beta_0 + \beta_1 t + u_t, \quad u_t = \rho u_{t-1} + \varepsilon_t$$

where V_t denotes the Medicare Part D volume in quarter t with $t = 1$ for 2022 Q1 up to $t = 12$ for 2024 Q4. When residual autocorrelation was absent, the model yielded $\rho = 0$, reducing

to an ordinary least squares linear regression. The fitted model was then used to project volumes for $t = 17$ through $t = 20$, corresponding to 2026 Q1 through 2026 Q4.

(3) Biosimilar and Generic Entry Adjustment

Small Molecule Drugs (Entresto, Januvia, and Xarelto)

Grabowski et al. (2016) reported monthly percentage reduction in brand-name volume up to 12 months following generic entry.⁶⁰ We extracted those 12-month declines and expressed them as adjustment factors relative to the quarter immediately preceding generic entry. For sitagliptin (Januvia), expected face generics in 2026, we fitted an exponential decay model to the observed adjustment factors and used the fitted curve to extrapolate the adjustment factor beyond one year. When a generic drug was expected to enter the market in the middle of a quarter, we computed a weighted average of the two adjacent quarterly factors according to the exact number of days before and after the entry. We then multiplied the corresponding factor by each drug's projected volume to produce the forecast adjusted for generic entry. A generic entered the market for *rivaroxaban* (*Xarelto*) at the 2.5 mg strength only, not for other strengths. We weighted the adjustment rate based on the share of 2.5 mg volume among all strengths from 2022 Medicare PDE data.

We did not incorporate the 180-day exclusivity for the first small-molecule generic entrant as we identified no successful patent challenge or demonstration of non-infringement, which are required for Paragraph IV certification and the associated exclusivity.¹⁰² As of September 1, 2025, the two small-molecule drugs with 2025 entry already have multiple (eight each) marketed generic alternatives and the two biologics have at least two available biosimilars, supporting our approach.

Biologic Drugs (Novolog and Stelara)

Biosimilar adoption was modeled analogously to reference biologics, Insulin lispro (Humalog) for insulin aspart (Novolog) and adalimumab (Humira) for ustekinumab (Stelara). The pool of agents with prior biosimilar experience was limited and exact matches were not possible. We assumed that insulin aspart (Novolog) and ustekinumab would follow post-biosimilar entry

volume trends observed for their respective analogs. Only insulin aspart (Novolog) is expected to face biosimilar entry, and no adjustment was applied to insulin aspart (Fiasp).

We collected the observed quarterly volume after biosimilar entry for each reference drug and calculated the shares of volumes relative to the quarter immediately before the entry. We then fitted those shares with an exponential decay model. Whenever a biosimilar launch occurred partway through a quarter, we prorated between the two adjacent quarterly factors based on the exact days before and after launch. Finally, we multiplied the baseline linear-trend projections by these adjustment factors to generate biosimilar-adjusted forecasts for insulin aspart (Novolog) and ustekinumab (Stelara).

C. Net Price Projection and Adjustment

We extrapolated 2021 net prices derived using the published algorithm of Dickson and Hernandez to their 2026 values.^{63,64} To accurately estimate future net prices under these scenarios, we accounted for the replacement of the CGDP with the MDP, as well as anticipated biosimilar and generic entry where applicable.

(1) Projections into 2026

We applied secular trends based on manufacturer-reported average net price changes across their entire portfolios.⁶⁵ We applied the average annual growth rate reported by the manufacturers of the selected drugs (-1.22%) to each drug's 2021 net price ($Net\ Price_{2021}^{unadj}$) as derived from the algorithm published by Dickson et al. (2022).⁶⁴ In a sensitivity analysis, we used the average across all manufacturers (+0.22%).

$$P_y = P_{2021}^{unadj} \times (1 + r)^{y-2021}$$

D. Manufacturer Discount Program Adjustment

(1) Coverage Gap Discount Program (Scenario 1)

Prior to the implementation of the IRA, the Medicare Part D benefit included a Coverage Gap Discount Program (CGDP), in which a 70% discount applied to total gross covered drug cost (TGCD) incurred during the coverage gap phase for brand-name drugs.

Benefit Design

We estimated the Initial Coverage Limit (ICL) and the Out-of-Pocket Cost Threshold (OOP) under a counterfactual scenario in which the IRA had not implemented the Out-of-Pocket Cost (OOP) cap. To project these thresholds, we applied the Annual Percentage Increase (API) published by CMS, which is used to update Medicare Part D benefit parameters annually.

$$Deductible_{25}^{TrOOP} = 615$$

$$ICL_{25}^{TrOOP} \times API_{25 \rightarrow 26} = 5,690$$

$$OOP_{25}^{TrOOP} \times API_{25 \rightarrow 26} = 9,050$$

Phase Progression

This CGDP discount, along with beneficiary payments and third-party contributions, was included in the calculation of true out-of-pocket spending (TrOOP). By its definition, TrOOP also included low-income subsidy (LIS) payments but not considered as CGDP only applies to non-LIS beneficiaries.

In the pre-IRA design, CGDP discounts determined entry into the catastrophic phase, while earlier phase progression was based on TGCD. Since TGCD and TrOOP accumulate differently, tracking both introduces complexity into modeling phase progression. To address this, we adopted a two-step approach: (1) determining whether a beneficiary's TrOOP exceeded the OOP, and (2) if not, applying a TGCD-based equivalent of the OOP, enabling the use of TGCD alone to determine progression across all phases.

To convert the TrOOP-based OOP into a TGCD-based equivalent, we divided the amount of TrOOP required during the coverage gap to reach the catastrophic phase by 0.95. This reflects the pre-IRA benefit design for brand-name drugs, under which 25% of TGCD was paid by the

beneficiary and 70% was covered by CGDP, both of which counted toward TrOOP, while the remaining 5% paid by the plan did not.

If a beneficiary's TrOOP exceeded the OOPT, the entire TGCDL associated with the claim was allocated to the catastrophic phase. Otherwise, the TGCDL-based OOPT, along with the published deductible and estimated ICL, was applied to the beneficiary's cumulative TGCDL to identify the current phase, and TGCDL amounts were distributed across phases according to the benefit design. For claims that straddled the thresholds, TGCDL amounts were proportionally allocated across two or more phases according to the applicable limits.

Including the coverage gap discount in TrOOP, while also using TrOOP to determine progression from the coverage gap into the catastrophic phase complicates phase classification. To address this, converted the API-adjusted, TrOOP-based OOPT into its TGCDL-based equivalent and inferred benefit phases by applying it to TGCDL. We divided the TrOOP amount a beneficiary is expected to incur to reach the catastrophic phase by 0.95 to estimate the TGCDL equivalent of the OOPT. This adjustment reflects that both the 25% paid by the beneficiary and the 70% manufacturer discount count toward TrOOP, while the remaining 5% paid by the plan sponsor does not. To fully capture TGCDL, we increased the result by 4% to account for dispensing fees and sales tax, which are excluded from TrOOP but included in TGCDL. The 4% adjustment is based on the average share of these costs between 2019 and 2023. This method aligns with the approach outlined in Chronic Conditions Data Warehouse guidance.

Under the CGDP, claims were chronologically ordered, and cumulative TGCDL were computed for each beneficiary. We defined the TGCDL range, $[S_i^{TGCDL}, E_i^{TGCDL}]$, for each claim and computed its overlaps of with each benefit phase interval:

$$S_i^{TGCDL} = CumTGCDL_i - TGCDL_i$$

$$E_i^{TGCDL} = CumTGCDL_i$$

For phase ϕ and claim i , allocation fraction (f_i^ϕ) were obtained by dividing the overlap in that phase by total TGCD.

Total amount of CGDP discounts

We compared the adjusted volume (V_{2026}^{adj}) , which incorporates expected uptake of biosimilars or generics, against the unadjusted forecast (V_{2026}^{unadj}) . The entry substitution ratio measures the proportional reduction in brand-name volume attributable to market entry of biosimilar or generic drugs.

$$V_{entry} = \frac{V_{2026}^{adj}}{V_{2026}^{unadj}}$$

Total amount of CGDP discounts was calculated as:

70% of TGCD at ingredient costs $(TGCD_i^{ing})$ in the coverage gap phase; and

$$\text{For claim } i, CGDP_i^{without\ IRA} = (0.70 \times f_i^{cov} \times TGCD_i^{ing})$$

$$CGDP^{without\ IRA} = \left(\sum_i CGDP_i^{without\ IRA} \right) \times V_{entry} \times Multiplier$$

Per-Unit CGDP discounts

Spending in the scenario (1) was calculated as projected 2026 spending at the net price. Since the 2021 net price already reflected CGDP discounts, we added back the per-unit historical CGDP amount, a byproduct of the net price estimation, then subtracted the newly calculated CGDP discount per unit. Per-unit discounts were calculated as:

$$Historical\ CGDP\ discount\ per\ unit = \frac{Total\ Historical\ CGDP\ Discounts_{2026}}{Volume_{2026}}$$

$$Updated\ CGDP\ discount\ per\ unit = \frac{Total\ Updated\ CGDP\ Discounts_{2026}}{Adjusted\ Volume_{2026}}$$

(2) Manufacturer Discount Program (Scenario 3)

Beginning in 2025, the IRA eliminates both the coverage gap phase and patient cost-sharing in the catastrophic phase, replacing them with a \$2,000 annual OOP cap which is updated annually

thereafter. In this new structure, the CGDP is replaced by a Manufacturer Discount Program (MDP), which introduces manufacturer liabilities of 10% in the initial coverage phase and 20% in the catastrophic phase. These manufacturer discounts are excluded from TrOOP, and TrOOP exclusively determine phase progression. Unlike the previous model, this revised structure applies uniformly to all Part D beneficiaries, including those receiving LIS.

Benefit Design

We applied the CMS published 2026 benefit parameters, \$610 to enter the initial coverage phase and \$2,100 to enter the catastrophic phase, and partitioned each claim's adjusted spending into deductible, initial coverage, and catastrophic phases.

Phase Progression

Under the MDP, TrOOP exclusively determines a beneficiary's progression through the benefit phases. For each beneficiary, claims were chronologically ordered, and cumulative TrOOP was computed as the running sum of TrOOP-eligible costs, which include patient payments, low-income subsidy, and other third-party.

We defined the TrOOP range, $[S_i^{TrOOP}, E_i^{TrOOP}]$, for each claim and computed its overlaps of with each benefit phase interval:

$$S_i^{TrOOP} = CumTrOOP_i - TrOOP_i$$

$$E_i^{TrOOP} = CumTrOOP_i$$

For phase ϕ and claim i , allocation fraction (f_i^ϕ) were obtained by dividing the overlap in that phase by total TrOOP.

Total amount of CGDP discounts

We compared the adjusted volume (V_{2026}^{adj}) , which incorporates expected uptake of biosimilars or generics, against the unadjusted forecast (V_{2026}^{unadj}) . The entry substitution ratio measures the proportional reduction in brand-name volume attributable to market entry of biosimilar or generic drugs.

$$V_{entry} = \frac{V_{2026}^{adj}}{V_{2026}^{unadj}}$$

Total amount of manufacturer discounts was calculated as the sum of:

10% of TGCD at ingredient costs ($TGCD_i^{ing}$) in the initial coverage phase; and

20% of TGCD at ingredient costs ($TGCD_i^{ing}$) in the catastrophic phase

$$\text{For claim } i, MDP_i^{with} = (0.10 \times f_i^{int} \times TGCD_i^{ing}) + (0.20 \times f_i^{cat} \times TGCD_i^{ing})$$

$$MDP^{with\ Negotiation} = \left(\sum_i MDP_i^{with} \right) \times V_{entry} \times Multiplier$$

Per-Unit MDP discounts

Spending in the scenario (3) was calculated as projected 2026 spending at the net price. Since the 2021 net price already reflected CGDP discounts, we added back the per-unit historical CGDP amount, a byproduct of the net price estimation, then subtracted the newly calculated MDP discount per unit. Per-unit discounts were calculated as:

$$Historical\ CGDP\ discount\ per\ unit = \frac{Total\ Historical\ CGDP\ Discounts_{2026}}{Volume_{2026}}$$

$$MDP\ discount\ per\ unit = \frac{Total\ Updated\ MDP\ Discounts_{2026}}{Adjusted\ Volume_{2026}}$$

Data and Cohort Definition

We analyzed a 5% random sample of 2022 PDE records to measure the accumulation of TrOOP and TGCD, which are necessary to determine phase progression.⁶⁸ The cohort of our interest consisted of beneficiaries who were continuously enrolled in a standalone Prescription Drug Plan for the entire calendar year and who had at least one claim for a selected drug. For each of these beneficiaries, we retained all prescription drug claims to reconstruct their individual trajectories of TGCD and TrOOP accumulation and benefit phase transitions. (Figure 1A - 1)

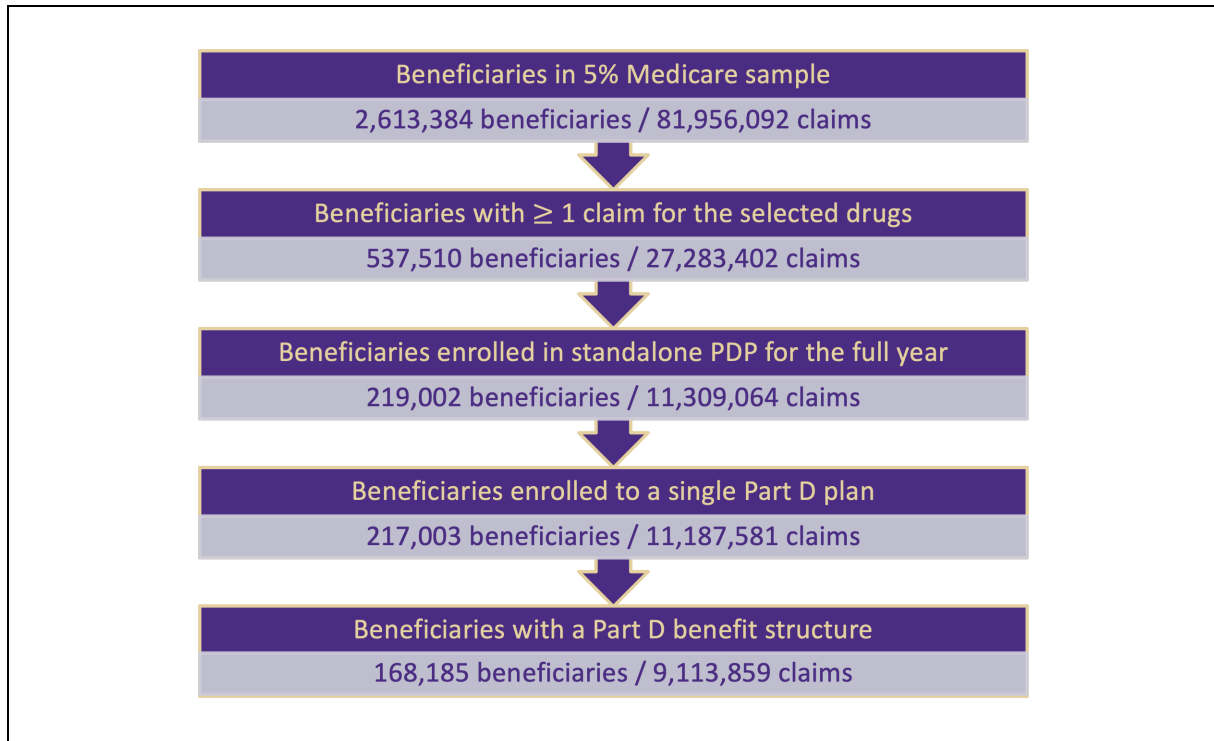


Figure 1A - 1: Analyzed Sample for Manufacturer and Coverage Gap Discounts Estimation

The final analytic sample included approximately 168,185 out of 537,510 total beneficiaries in the 5% sample who used at least one selected drug. To estimate total discounts at the full Part D population level, we applied a scaling factor, which reflects the proportion of selected-drug users in the sample and adjusts for the 5% sampling frame. (Figure 1A - 1)

$$Multiplier = \frac{168,185}{537,510} \times 20 \approx 6.256$$

Cost Inflation and Secular Volume Trend

Prior to estimating CGDP and MDP discounts, each claim's cost components in the PDE data were adjusted to the 2026 scenario by inflating 2022-dollar values to 2026, using the API, which reflects average per-capita growth in Part D drug spending. Specifically, each cost field in 2022 was multiplied by

$$API_{22 \rightarrow 26} = \prod_{y=2023}^{2026} (1 + r_y)$$

where r_y is the year-over-year growth rate for aggregate Part D drug expenditures in year y .

We scaled up the volume to reflect secular demand growth between 2022 and 2026.

(3) Phase-In Policy

The IRA includes a phase-in policy that temporarily reduces manufacturer discount obligations for certain applicable drugs. Specifically, this applies through 2031 to drugs that account for less than 1.0% of total Part D spending and are dispensed to LIS beneficiaries, as well as to certain drugs produced by small manufacturers. We do not incorporate this provision into our analysis, as IPAY 2026 selected drugs are not applicable.

(4) Biosimilar and Generic Entry Adjustment

Small Molecule Drugs (Entresto, Januvia, and Xarelto)

Proprietary net prices were not available and thus, we used a publicly available price benchmark to avoid overestimating drug costs. Specifically, we defined each drug's adjusted net price as the lower of its projected brand-name net price; or an acquisition costs paid by pharmacies for the generic formulations.

To construct a drug-specific generic benchmark, we applied the published generic-to-brand price ratios from Jamjoom et al. (2024) to National Average Drug Acquisition Cost (NADAC). At generic launch, the median NADAC for generics as 73.1% of the brand's unit price; at 12 months this ratio falls to 44.2%, at 24 months to 34.8%, and at 36 months to 16.8%.⁷⁰ We interpolated these four anchor points into a continuous monthly decay curve using linear interpolation.

When a generic drug was expected to enter the market mid-month, we calculated a prorated adjustment factor using the number of days before and after the entry date, weighting the two adjacent monthly factors accordingly. We then multiplied the corresponding factor by each drug's projected volume to produce the forecast adjusted for generic entry.

Biologic Drugs (Novolog and Stelara)

To adjust net prices for insulin aspart (Novolog) and ustekinumab (Stelara) after biosimilar entry, we used the observed post-entry price declines of two reference biologics, Remicade for ustekinumab (Stelara) and insulin glargine for insulin aspart (Novolog), obtained from San-Juan-

Rodriguez et al. (2019).⁷¹ While infliximab and insulin glargine differ from ustekinumab and insulin aspart in route of administration and onset of action, they served the closest available reference.

For each reference product, we collected the published net prices post-biosimilar entry. Given the fluctuation observed in the reference volume, we fit four candidate parametric distributions, exponential, gamma, Weibull, and lognormal, to those values, comparing goodness-of-fits via Akaike Information Criterion (AIC). The Weibull distribution provided the best fit. From each fitted Weibull model, we generated a continuous sequence of monthly price-share factors and applied them to the insulin aspart (Novolog) and ustekinumab (Stelara) net prices. We also prorated within each month by weighting the previous month's factor and the current month's factor according to the exact number of days before and after launch.

(5) MFP (Scenario 2)

For each selected drug, we aggregated NDC9-level Manufacturer Fair Prices (MFPs) to the brand level using a weighted average. We denote MFP_n as the MFP per unit for $NDC9_n$ and U_n as the number of dosage units dispensed in 2022 according to Medicare Part D PDE data. The brand-level MFP is given by

$$\overline{MFP} = \frac{\sum_n MFP_n \times U_n}{\sum_n U_n}$$

By law, MFP cannot exceed the lower of (1) the 2022 average net price paid by Part D plans, or (2) 40 to 75 percent of non-federal average manufacturer price (non-FAMP), with the rate determined by years since market entry.¹⁶

E. Spending

(1) Spending under the Scenario (1)

$$\begin{aligned} Net Price_{2026}^{adj} = & Net Price_{2026}^{unadj} + Historical\ CGDP\ discount\ per\ unit \\ & - Updated\ CGDP\ discount\ per\ unit \end{aligned}$$

$$Spending_{2026}^{without\ IRA} = \sum_d Net\ Price_{2026,d}^{adj} \times V_{2026,d}^{adj}$$

(2) Spending under the Scenario (2)

$$Spending_{2026}^{with\ Negotiation} = \sum_d \overline{MFP}_d \times V_{2026,d}^{adj}$$

(3) Spending under the Scenario (3)

$$Net\ Price_{2026}^{adj} = Net\ Price_{2026}^{unadj} + Historical\ CGDP\ discount\ per\ unit \\ - MDP\ discount\ per\ unit$$

$$Spending_{2026}^{without\ Nego} = \sum_d Net\ Price_{2026,d}^{adj} \times V_{2026,d}^{adj}$$