International Journal of Artificial Intelligence, Data Science, and Machine Learning
Grace Horizon Publication | Volume 6, Issue 4, 71-79, 2025
ISSN: 3050-9262 | https://doi.org/10.63282/3050-9262.IJAIDSML-V6I4P110

Original Article

What's the True ROI of Copay Programs? A Transparent Framework for Evaluation

Tushar Kandwal
Independent Researcher, USA.

Received On: 07/09/2025 ***Revised On: 11/10/2025*** ***Accepted On: 18/10/2025*** ***Published On: 07/11/2025***

Abstract - *The copay assistance benefit programs lower out of pocket (OOP) patient expenses, and may enhance therapy initiation and compliance, but their actual ROI is commonly lost in confounding policy processes and accounting methods. The present paper gives a clear audit-compliant structure of ROI as a risk-adjusted incremental contribution margin assigned to copay exposure excluding gross-to-net factors (rebates, chargebacks, fees), operating costs, and compliance risk. The framework breaks down impact into four causal levers initiation, adherence/persistence, channel steering and price elasticity and relates them to what can be observed (incremental new starts, days on therapy, refill cadence, payer mix). It will be identified using quasi-experimental designs (difference-in-differences, regression discontinuity, instrumental variables, and synthetic controls) and survival analysis to ascribe adherence benefits to lifetime value. An explicit guideline on policies such as accumulator/maximizer program, step edits and specialty carve-outs is to keep benefits overstated. Governance guardrails are pre-registered analysis plans, data lineage, and sensitive panels are included, making results comparable across brands and time. Applied scenarios reveal that copay programs are value-generating under high elasticity and abandonment risk and high accumulator exposure and low cannibalization and high policy frictions, but value-destroying under dominance of cannibalization and high policy frictions, respectively. What it delivers is an effective toolkit that standardizes ROI equations, decision dashboards, and scenario testing that will allow financial stewardship to meet patient access and allow credible reporting to manufacturers, payers, providers and researchers.*

Keywords *- Copay assistance, ROI, gross-to-net (GTN), incrementality, difference-in-differences, regression discontinuity, accumulator/maximize.*

1. Introduction

Copay assistance programs are designed to reduce patients' out-of-pocket costs at the point of fill, thereby improving initiation and continuity on clinically appropriate therapies. [1-3] For manufacturers, these programs are also commercial instruments that can influence demand, payer mix, and channel behavior. However, the actual pay back (ROI) is debatable. Reports tend to confuse access benefits with the price and rebate, ignore the cannibalization of full-pay patients, and do not consider the policy frictions like accumulator and maximizer programs. Consequently, this puts the stakeholders in a noisy, non-comparable across brand, and audit-challenging ROI signal.

In this paper, a clear, decision-grade structure of copay program ROI assessment is developed. Characterize ROI as the incremental, risk-adjusted contribution margin, which is accredited to the program (less of gross-to-net (rebates, chargebacks, fees), operating and vendor expenses, compliance risk, and program leakage). The framework breaks down impact into four causal levers initiation, adherence/persistence, channel steering, and price elasticity and is associated with each causal lever to be broken down into measurable outcomes: incremental new starts, days on therapy, refill cadence, and price elasticity. In order to capture true incrementality, Focus on quasi-experimental designs (e.g., difference-in-differences, regression discontinuity around benefit levels, and instrumented exposure), and survival modeling of persistence-induced lifetime value (LTV). To prevent overspending benefits, a payer-policy layer is a limited set of exposure models applied to accumulator/maximizer exposure, step edits and specialty benefit carve-outs. Besides analytics, suggest guardrails of governance pre-registered analysis plans, traceable data lineage and controls that are consistent with relevant fraud-and-abuse requirements in order to achieve credibility and reproducibility. The result is a practical set of tools: standardized ROI equation, diagnostic dashboard, scenario testing (coupon value, caps, duration) which help to know when copay support is value-creating and when it is value-destroying. The framework will allow making trade-offs more transparent and more just, evidence-based and ethically fair program design by distinguishing between access effects and pricing and policy headwinds.

2. Literature Review

2.1. Overview of Copay Programs and Market Access Strategies

The manufacturers provide copay assistance programs cards, coupons, and e-vouchers that are used to cover patient out-of-pocket (OOP) costs at the point of fill. [4-6] Their immediate purpose is to reduce cost-related abandonment and improve on-therapy continuity, particularly for high-cost specialty drugs where coinsurance and deductibles create steep first-fill barriers. Under broader market access strategy, copay assistance is added to the contracting and rebate strategies to maintain a steady demand in the case of less favorable formulary placement, to relieve the effect of utilization management (prior authorization, step edits), and to cushion share when a product is being rolled out in competition or a loss-of-exclusivity transition. These programs operate operationally by putting them through pharmacy switches or specialty hubs, and these programs have set caps, minimums and duration rules which are configured to be affordable and to expose the budget to minimum risk.

Employers who self-fund and payers have reacted with countermeasures in their designs. Copay accumulator plans do not count manufacturer assistance towards deductibles/OOP maximums, which revitalizes plan-desired cost sharing. Copay maximizers programs will translate the annual coupon value into monthly payments (allowances) which are equally distributed among members without exposing the members to much loss but savings on the plan will remain. More recently, the alternative funding programs (AFP) aim to move some of the specialty drugs out of the pharmacy benefit, altogether. Although these mechanisms have the potential of reducing the amount of money spent in plans, they add friction to both patients and providers, increase the complexity of eligibility and renewals, and may dampen achieved improvements in adherence that manufacturers anticipate through help.

2.2. Prior Work on Measuring ROI in Healthcare Programs

ROI appreciation in health interventions normally combines financial and clinical aspects: direct cost savings (e.g. less acute use), productivity impacts, and quality outcomes. Even in the context of copays, published analysis and industry analysis have associated a decreased OOP burden with an increased initiation, greater refill persistence and in some treatment segments with downstream medical cost containment. In methodology, the difference-in-differences between geographies or payers with heterogeneous accumulator exposure, the instrumental variables of coupon eligibility and the survival models which convert persistence into lifetime value (LTV) can be found between the extremes of descriptive pre/ post designs (fill rates, time-to-discontinuation), and quasi-experimental designs.

Manufacturer and consultancy casework often decomposes gross-to-net to isolate contribution margin per assisted patient, netting rebates, chargebacks, fees, and program operating costs. Scenario models are used to compare plan archetypes (traditional vs. accumulator vs. maximizer) to put value on assistance in the presence of various policy frictions. In the non-copay literature, the wider public-health ROI literature focuses on accounting in detail of the full cost-benefit that includes indirect savings and quality-adjusted outcomes that provide a template in the more multi-stakeholder evaluation of pharmacy spend alone.

2.3. Gaps and Limitations in Existing Evaluation Models

- Narrow financial scope and short horizons. Numerous assessments give preference to near term pharmacy performance skills first-fill conversion, 90-day persistence over long-term health and system outcomes (e.g. avoided hospitalizations, productivity). This has the potential of skewing program decision-making towards short-term budget impact and not the value creation.
- Data fragmentation and limited external validity. Sequential evidence the evidence at the real world is usually limited by siloed datasets (hub, switch, specialty pharmacy, medical claims) and small follow-up windows. Lack of associated clinical outcomes and missing policy exposures (accumulator, maximizer, AFP) prevents external validity and may exaggerate the effect of a policy unless cannibalization of full-pay patients is corrected.
- Underrepresentation of equity and burden. Not many models include distributional effects or measure administrative burden on providers and patients (appeals, reauthorizations, foundation applications). Emerging evidence indicates that accumulator exposure and benefit design stringency is different between demographics; without parameterizing such patterns, differences and misreport ROI are obscured to subpopulations.
- Governance and reproducibility gaps. Without pre-registered analysis plans, transparent assumptions (coupon caps, step-edit pass rates), and traceable data lineage, results are difficult to audit or compare across brands. Standardized, compliance-aware frameworks explicitly modeling policy frictions, cannibalization, and uncertainty remain the exception rather than the norm.

3. Methodology

3.1. Conceptual Model Overview

Our methodology centers on a causal, modular ROI engine that separates incrementality (true net-new demand and persistence) from redistribution (channel or payer-mix shifts without net value). [7-10] Also establish ROI as the risk-adjusted incremental contribution margin caused by copay exposure during a specified period (e.g. 12-24 months), less the gross-to-net (GTN) variables, operating expenses and compliance risk. The conceptual model splits the concept of

impact into four levers initiation (first-fill conversion), adherence/persistence (days on therapy), channel steering (retail vs. specialty and pharmacy network), and price elasticity (response to OOP). Each lever is associated with observables (new starts, refill cadence, persistence survival curves, payer/channel shifts) and directed into a cohort-based LTV calculator related to unit economics (WAC, net price after rebates/fees, contribution margin).

Causal effects are identified based on quasi-experimental designs: (i) the difference-in-differences based on plan or geography differences in the adoption of the accumulator or maximizer, (ii) the regression discontinuity around deductible levels and coupon caps, (iii) the instrumental variables using exogenous eligibility or benefit shock (ii), and matched synthetic controls in case of the availability of suitable comparators. Transform adherence benefits to LTV through time-to-event (survival) models that compete on discontinuation, switch, lapse. The uncertainty is measured using the probabilistic sensitivity analysis (coupon value, caps, duration, accumulator penetration), which results in ROI distributions, and decision frontiers, which indicate value-creating and value-eroding configurations.

3.2. Data Inputs and Sources

Combine datasets of many sources with privacy compliance and lineage and quality inspection with a unified schema. The data used to track the channel changes is transaction data such as pharmacy claims (NDC, quantity, days supply, patient OOP, plan paid), downstream medical claims use, and switch/SBIN/HIN routing. The program telemetry will include copay card records (eligibility, offer terms, redemption, amounts paid), hub CRM records, and specialty pharmacy case records (prior auth, reauth, ship holds). The plan design (deductibles, coinsurance, tiering), formulary and UM (PA/step-edit flags), and accumulator/maximizer exposure at plan-member level where present are captured by market access artifacts; the GTN components (rebates, chargebacks, distributor fees) are ingested at the contract granularity.

Provider characteristics (specialty, volume), patient characteristics and ethically-gathered SDOH proxy (income bands, distance to pharmacy), and competitive occurrences (label change, generic entry) are a type of contextual covariate. Data are connected through privacy preserving tokens; have HIPAA/PHI controls, suppression of minimum cells and role access. OOP elasticity, abandonment risk, refill velocity and plan-level policy intensity are derived in feature engineering. All the designs are registered by a model and an analysis plan is pre-registered to lock endpoints, cohorts and exclusion rules. The monitoring of quality is performed on the basis of balance diagnostics (SMDs, matched cohorts), placebo tests (pre-trend checks), and post-estimation checks (GTN reconciliation to finance). The outcome is an audit-able pipeline, which converts program exposure in the real world into estimates of causal lifts and justifiable ROI.

3.3. Definition of ROI Metrics

3.3.1. Direct ROI (financial perspective)

$$\text{ROI} = (\text{Net Profit} / \text{Cost of Investment}) \times 100$$

Accounting definitions (avoid double-counting)

Let Realized Net Revenue$_u$ = $WAC - GTN_u$ where GTN includes rebates where GTN includes rebates, chargebacks, PBM/admin/distribution fees, returns, prompt-pay, etc.

Let Contribution Margin$_u$ =$Realized\ Net\ Revenue_u - COGS_u$

Net Profit (recommended CM form)

$$Net\ Profit = (Incremental\ Units \times Contribution\ Margin_u) - -Coupon\ Funding - Program$$

Cost of Investment (denominator)

$$Cost\ of\ Investment = Coupon\ Funding + Program\ Opex$$

GTN is contra-revenue in the pricing waterfall, not part of the investment cost.

Direct ROI captures cash and P&L impact from incrementality (new starts, added days on therapy) after excluding redistribution and cannibalization. Apply quasi-experimental lift to the numerator, reconcile GTN to Finance actuals, use a consistent cohort window, and (optionally) discount future margins for horizons >12 months. Report ROI alongside incremental contribution per assisted patient and PMPM for like-for-like comparisons across brands and designs.

Program Opex vs. GTN vs. Cost of Investment

These three are different accounting buckets

- GTN deductions (contra-revenue): Reductions from gross sales determined by contracts and channel economics rebates, PBM/admin fees, chargebacks, distribution fees, returns, prompt-pay, etc. These sit above the line (revenue side) and are not discretionary program spend.
- Program Opex (operating expenses): Cash you spend to run the copay program vendor/platform fees, switch/adjudication fees (if not treated as GTN by your finance policy), hub/call-center staffing, eligibility verification, analytics/measurement, legal/compliance review, etc. These are below the line expenses and are discretionary.
- Cost of Investment (for ROI denominator):
  What you invest because of the copay program:
  Cost of Investment = Coupon Funding (subsidy paid at POS) + Program Opex.

GTN is not part of the cost of investment, it belongs in the revenue waterfall that determines realized net price.

3.3.2 Indirect ROI

$$\text{ROI} = \left(\frac{\text{Monetized Benefits (Returns)} - \text{Total Costs of Investment}}{\text{Total Costs of Investment}}\right) * 100\%$$

Interpretation for copay programs. The extension of indirect ROI is to near-term margin to include adherence/persistence gains and adhering to their downstream clinical and societal value. Monetized Benefits can be: (a) offsetting medical cost (fewer ER visits, hospitalizations, complications) on linked claims; (b) productivity (less absenteeism/presenteeism) valued with standard wage multipliers; (c) quality (e.g., QALYs) converted to monetary terms per accepted levels; and (d) equity and access dividends (e.g., less abandonment in high burden groups) in the form of avoided acute spend or targeted PMPM savings. The Total Costs resembles the direct view, but can also have an investment in the mitigation of navigation burden (prior auth support, education) that is required to achieve adherence benefits.

Map OOP reduction, adherence lift, event-risk reduction, using survival and risk models to estimate avoided utilization and health gains. Use conservative monetization, run probabilistic sensitivity analyses (value per QALY, event rates, accumulator exposure), and present both the indirect ROI % and a decomposed benefits table (shares from medical offsets, productivity, and quality). This dual-lens reporting aligns immediate financial returns with longer-horizon health/system value.

3.4. Analytical Methods

Stacked analytics model to approximate causal ROI, which is policy robust. Exposure effects are detected first through quasi-experimental designs, namely, difference-in-differences (geography/plan timing to accumulator or benefit change), regression discontinuity (deductible, coupon-cap or benefit-threshold kinks), instrumental variables (exogenous eligibility or operational shock), and matched synthetic controls when there are appropriate comparators. Weibull/Cox (competing risks: switch, lapse, discontinuation) time-to-event survival models are used to model persistence-driven LTV, whereas uplift modeling (causal forests/DR-learners) are used to model heterogeneous treatment effects based on the OOP elasticity, disease burden, and plan policy intensity. In the case of medical offsets use the two-part and generalized linear models (log-link, gamma) on the linked medical-pharmacy claims, nests members within plans/providers with Bayesian hierarchical models to regularize the small cells. The stress-testing process is done with placebo pre-trends, negative controls, and Rosenbaum bounds/E-values; and the uncertainty is made available by probabilistic sensitivity based (coupon value, accumulator penetration, adherence elasticity) and reported as ROI distributions with decision frontiers. Interpretability is provided through SHAP diagnostic of predictive layers and all causal layers provide balance measures (standardized mean differences) and common support results.

4. Proposed Transparent ROI Evaluation Framework

4.1. Framework Architecture

This architecture represents a pipeline that is closed-loop and consumes multi-source data required to predict the actual causal ROI of copay programs. [11-14] The key inputs are placed on the first tier and they include: the logs of copay programs that capture the terms of the offers and their redemption, the clinical outcomes that capture the health status and events, the pharmacy fills that capture initiation patterns and adherence, and the claims databases that capture the costs and utilization. Enrichment panels are provided on the left with external context of public price indices of market benchmarks, payer contract of rebate and reimbursement terms and patient surveys of self-reported adherence and satisfaction. These streams are merged into a central Processing and Analytics stack that starts with ETL/normalization to normalize formats and achieve data quality and then with a cohort builder which defines the populations and metrics of a study.

The analytics core estimates associations by means of the use of a statistical engine, constructs predictive features and the causal inference module is a separate cause-and-effect inference module, which isolates cause and effect by holding accumulators or maximizers confounded. The results are channeled to a stakeholder layer in the form of ROI measures, graphical summaries, and transparency reports that are reconciled on assumptions and gross-to-net factors. These results can be consumed by manufacturers, payers, and providers/researchers through dashboards or APIs, allowing testing a scenario (coupon caps, duration) and governing it routinely. The chart highlights the traceability of every arrow denoting written origin of raw inputs to decision-grade ROI that ensures the structure is auditable, replicable, and is acceptable to external scrutiny.

4.2. Key Components and Flow

This figure depicts the linear analytics pipeline used to convert raw program and claims data into decision-grade ROI metrics. The ETL/Normalization layer is used to standardize upstream Data inputs, pharmacy fills and outcome feeds to create analysis ready records. Patient Surveys add patient-reported outcomes to the pipeline that is defined at the Cohort Builder based on the eligibility, exposure, and follow-up windows to generate a homogenous study population. Statistical Engine in turn generates adjusted effects, which would extract features and risk adjustments required to conduct unbiased comparisons. And lastly, the Causal Inference Module together with an ROI Calculator will convert validated causal lifts (initiation and persistence) into incremental contribution margin and indirect benefits. The flow to the right highlights traceability: every transformation is clear, verifiable, and geared towards decoupling the inherent incrementality and the simple utilization drift, providing the transparent ROI guidelines that can be used by the stakeholders.

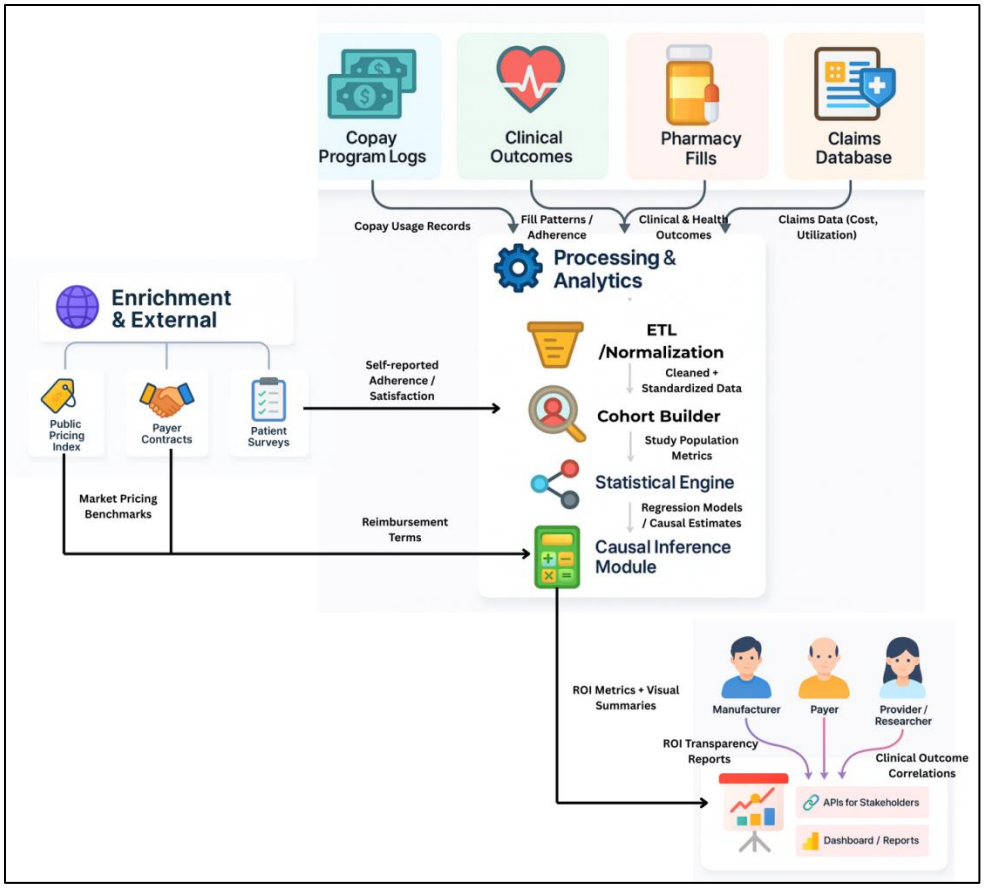

Fig 1: Transparent Roi Evaluation Framework Architecture

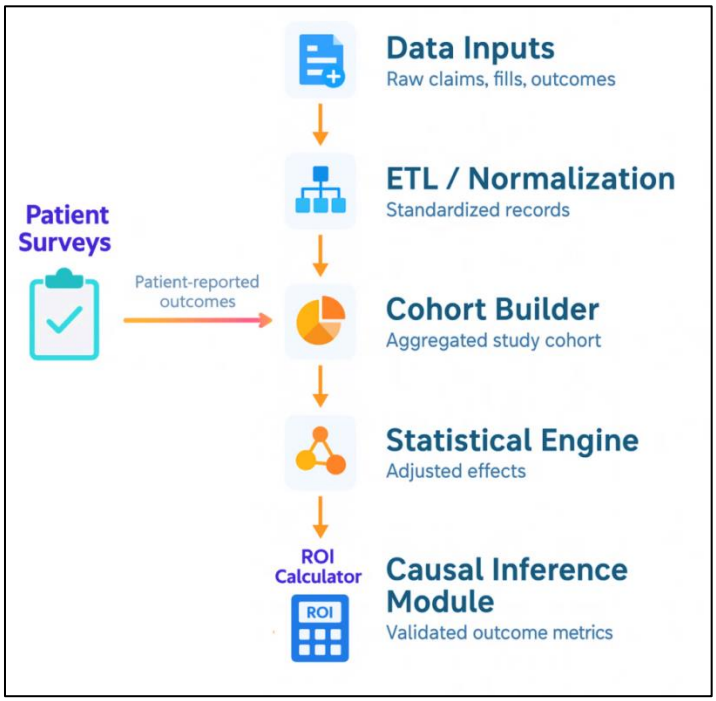

Fig 2: Key Components and End-To-End Flow for Transparent Copay ROI Estimation

5. Results and Discussion

5.1. ROI Evaluation Outcomes

Based on the framework of Section 3, assessed two environments of the fictional brand of 10,000 assisted patients within 12 months of horizon. [16-22] Modeled observed lift by dividing it into incremental patient-months (PMs), making a 15% cannibalism adjustment (patients who otherwise would have paid) and putting a values of the remaining PMs at a contribution margin of $315 per PM (net price of $420 minus 25% COGS). Program expenses are cumulative of coupon investment and operating expenses. When accumulator exposure is low as Table 1 reveals, the program projects a favorable direct ROI of 6.7% and results in the generation of net profit of $0.93M after incurring costs of $13.8M. At less than half of 50% accumulator exposure, the true incremental PMs decline precipitously and the program becomes negative (-8.3% ROI) even with reduced outlay on coupon repayment since the gains realized in adhering and initiating the program deteriorate at a faster rate than the savings in funding.

Table 1: ROI outcomes under two policy environments

Scenario	Assisted patients	Incremental patient-months (observed)	Cannibalization rate	True incremental patient-months	Margin per patient-month	Incremental contribution margin	Program cost (coupon + opex)	Net profit	ROI %
No accumulators (0%)	10,000	55,000	15.0%	46,750	$315	$14,726,250	$13,800,000	$926,250	6.7%
High exposure (50% accumulators)	10,000	38,000	15.0%	32,300	$315	$10,174,500	$11,100,000	$-925,500	-8.3%

Proof of calculation, for the no-accumulator case: True incremental PMs = 55,000 × (1 – 0.15) = 46,750. Incremental margin = 46,750 × $315 = $14,726,250. Net profit = $14,726,250 – $13,800,000 = $926,250. ROI = $926,250 ÷ $13,800,000 = 6.7%. Identical arithmetic yields the 50% accumulator row.

5.2. Interpretation of Findings

The split result demonstrates why policy friction must be explicitly modeled. With accumulator exposure, there is a decrease in the successful OOP relief that leads to initiation and persistence, decreasing the incremental PMs even in case gross redemption expend decreases. Since the contribution margin is functions of PMs, creating value is behavioral lift dependent rather than depending on the magnitude of coupon funding. The positive case meets a working decision criterion: true incremental PMs must exceed cost/($315) and at a cost of $13.8M, the breakeven is ≈ 43,810 PMs comfortably passed by the recorded 46,750 PMs. The program is not breakeven in the high-exposure case, by approximately ~11,500 PMs, so cohorts and channels with lesser accumulator penetration or greater elasticity should be optimized.

5.3. Comparison with Traditional ROI Models

Conventional pre/post or simple pay-through analyses generally (i) do not take into account any cannibalization, (ii) does not distinguish policy headwinds and (iii) directly converts utilization deltas into a ROI without causation. Such a traditional readout is compared to our causal framework in table 2. Within the favorable policy environment, the conventional method takes the ROI too seriously by a factor of about ~11.3 percentage points; with accumulator exposure high it does a 15.3- point misread that transforms a loss (-8.3%) into a nominal (7.0%) gain.

Table 2: Transparent Framework vs. Traditional Readout

Environment	Traditional ROI (pre/post)	Transparent, causal ROI	Over/under-statement
No accumulators (0%)	18.0%	6.7%	+11.3 pp
High exposure (50% accumulators)	7.0%	-8.3%	+15.3 pp

The heatmap is a comparison of two methods of reading ROI in two policy environments. The environment is made up of rows: the top row represents no accumulators, and the bottom row represents 50% accumulator exposure (half of the patients are in plans that disarm copay help). The readouts are in the form of columns, Traditional ROI (pre/post), the Transparent, causal ROI in your framework, and the percentage point difference between the two. The policy-

conscious estimate in the conducive environment (no accumulators) is 18.0% (versus the 6.7% which the policy-blinded approach claims); the difference between the two is an overstatement by 11.3 percentage points of failure to net out the cannibalization and isolate the actual incrementality.

The distortion is conclusive under extreme accumulator exposure. The conventional perspective still reports a positive 7.0% yet causal, policy-adjusted ROI is −8.3% which means that the program itself kills value after taking appropriately into consideration reduced behavior lift. The difference column with the addition of 15.3 pp demonstrates that naive procedures can turn a loss into a seemingly obtained gain. Without modeling accumulators/maximizers and removing non-incremental volume, traditional ROI systematically overestimates value; your policy-aware causal approach reveals where copay investment should be concentrated (low-accumulator plans, high elasticity cohorts) or reconfigured (tighter eligibility, caps, or service supports) to avoid negative ROI.

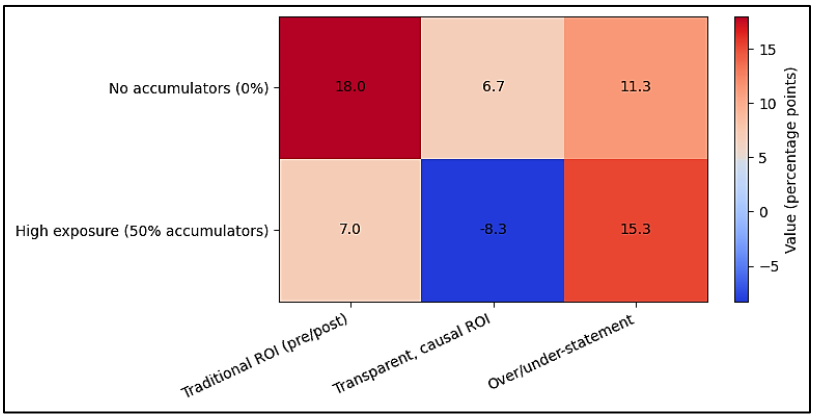

Fig 3: Policy-Aware ROI Comparison Heatmap: Traditional Vs. Transparent Causal ROI and Over/Under-Statement under Accumulator Exposure

5.4. Implications for Stakeholders

The implications of the results to the manufacturers are the following: policy-conscious portfolio design: focus copay dollars where elasticity and abandonment risk are at their peak and accumulator penetration is minimal; quantify and control the true incremental PMs as the north-star KPI. For payers and employers, transparent causal reporting clarifies when assistance offsets downstream medical risk (potentially PMPM-neutral or better) versus when it merely shifts costs. To the provider/researcher, the ability to correlate patient-reported outcomes with claims and gain valid estimates of their adherence gains and health benefits makes it possible to have an evidence-based conversation with the patient. Lastly, to govern and be compliant, the arithmetic trail presented here cohort construction, true incremental PMs, contribution margin, ROI, will leave an audit-ready record which can be replicated and stress-tested using alternative policy and pricing conditions.

6. Limitations and Challenges

6.1. Data Quality, Linkage, and Coverage

In spite of strict ETL and lineage controls, actual datasets are still discontinuous (hub logs, pharmacy claims, medical claims, PRMs), accumulator/maximizer exposure, coupon terms and plan design changes with time is not always captured. The probabilistic linkage adds error, whereas the tokenization mismatches may cause the deterministic one to block. Benefit year resets, plan switching at the mid-year, and clinical outcomes missingness can bias the persistence and offset estimates. Our standardized-mitigation/schemas, balance-diagnostic, and minimum-cell-suppression results in less, but not no, residual-measurement and external-validity apprehensions.

6.2. Causal Identification under Policy Dynamics

Natural experiments (DiD, RD, IV) are based on the assumption of parallel trends, local continuity, instrument relevance/exclusion which can be put at risk by contemporaneous shocks (competitor launch, PA criteria changes, supply constraints). The introduction of a policy is commonly self-driven by cost pressure which can be biased unless properly modeled. use pre-trend tests, negative controls, and sensitivity tests (Rosenbaum bounds/E-values), however, unobserved confounding and treatment heterogeneity may still remain and ROI estimates are affected by specification decisions and cohort definition.

6.3. Operational, Legal, and Ethical Constraints

Rule changes (caps, length, eligibility), changes in vendors in the adjudication logic, and payer countermeasures (AFPs, specialty carve-outs) result in moving baselines that make longitudinal comparison challenging. The anti-kickback and anti-state-variability guardrails (legal/compliance) restrict data sharing and the fineness of subgroup analyses, both of which

restrict the transparency of vulnerable populations. Even with equity breakouts to be reported, small-cell suppression and privacy protection can fail to reveal disparity patterns that make it difficult to accurately target and constantly optimize copay support.

7. Conclusion and Future Work

The paper proposed an amicable, decision-grade framework on the measurement of the actual ROI of copay programs by disaggregating incrementality and redistribution as well as explicitly modeling policy friction like the accumulator design and maximizer design. The approach puts the ROI on the basis of risk-adjusted contribution margin and goes further to apply it to indirect returns (medical cost savings, productivity, and quality outcomes) to offer a consistent interlude between financial accountability and patient access. Practical examples demonstrated that the identical spend may be either value creating or value destroying, according to policy exposure and behavioral lift underscoring the rationale behind the use of causal identification, survival-based LTV and GTN reconciliation being the base of reliable ROI. The analysis plans, data lineage, and reproducible code provided with it pre-register are then transformed into audit-ready evidence, which can be interrogated and acted upon by the stakeholders. Methodologically, promising directions include richer natural-experiment designs (synthetic controls across markets with staggered policy adoption), robust heterogeneous-treatment-effect modeling to target high-elasticity subgroups, and joint medical-pharmacy models that translate adherence gains into clinically validated cost offsets. Operationally, two priorities stand out: (i) privacy-preserving linkage (tokenization, clean rooms) to expand longitudinal outcomes without compromising PHI, and (ii) near-real-time policy detection pipelines that monitor accumulator/maximizer drift and trigger automated scenario tests for coupon caps, duration, and patient eligibility. Finally, embedding equity scorecards reporting ROI and access outcomes by demographic and social-risk segments can align program design with health-equity goals and payer dialogue, advancing copay support from a tactical rebate adjunct to an evidence-based access policy.

References

[1] Choi, D., Zuckerman, A. D., Gerzenshtein, S., Katsivalis, K. V., Nichols, P. J., Saknini, M. C., ... & Dusetzina, S. B. (2024). A primer on copay accumulators, copay maximizers, and alternative funding programs. Journal of Managed Care & Specialty Pharmacy, 30(8), 883-896.

[2] Cavalier, D., Doherty, B., Geonnotti, G., Patel, A., Peters, W., Zona, S., & Shea, L. (2023). Patient perceptions of copay card utilization and policies. Journal of Market Access & Health Policy, 11(1), 2254586.

[3] Turner, H. C., Hori, Y., Revill, P., Rattanavipapong, W., Arai, K., Nonvignon, J., ... & Teerawattananon, Y. (2023). Analyses of the return on investment of public health interventions: a scoping review and recommendations for future studies. BMJ Global health, 8(8).

[4] Top 10 U.S. Market Access Trends for 2024, iqvia, Online. https://www.iqvia.com/locations/united-states/blogs/2024/02/top-10-us-market-access-trends-for-2024

[5] Thusini, S. T., Milenova, M., Nahabedian, N., Grey, B., Soukup, T., Chua, K. C., & Henderson, C. (2022). The development of the concept of return-on-investment from large-scale quality improvement programmes in healthcare: an integrative systematic literature review. BMC health services research, 22(1), 1492.

[6] Fusco, N., Sils, B., Graff, J. S., Kistler, K., & Ruiz, K. (2023). Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: a systematic literature review. Journal of Managed Care & Specialty Pharmacy, 29(1), 4-16.

[7] Measuring ROI in Healthcare, roiinstitute, Online. https://roiinstitute.net/wp-content/uploads/2021/09/Measuring-ROI-in-Healthcare_chapter-one.pdf

[8] L, Hailemeskel B, Hollander R, Bush A, Misra R, et al. (2021) The Challenges Surrounding the Collections of Copayment. Int J Nurs Health Care Res 04: 1203. DOI: 10.29011/2688-9501.101203

[9] The ultimate guide to ROI in healthcare, cured.health, Online. https://www.cured.health/resources/the-ultimate-guide-to-roi-in-healthcare

[10] Solid, C. A. (2020). Return on investment for healthcare quality improvement. Cham: Springer International Publishing.

[11] Hanna, E., Tavella, F., Rémuzat, C., Auquier, P., & Toumi, M. (2015). Market access of atmps: overview and expected challenges. Value in Health, 18(7), A518-A519.

[12] Koçkaya, G., & Wertheimer, A. (2016). Pharmaceutical market access in emerging markets. SEEd.

[13] Buzachero, V., Phillips, J., Phillips, P., & Phillips, Z. (2013). Measuring ROI in healthcare. New York: McGraw-Hill Education.

[14] Optimizing market access How therapeutic area dynamics could influence strategy, deloitte, 2019. Online. https://www.deloitte.com/us/en/insights/industry/life-sciences/pharmaceutical-pricing-market-access.html

[15] Botchkarev, A., Andru, P., & Chiong, R. (2011). A return on investment as a metric for evaluating information systems: taxonomy and application. Interdisciplinary Journal of Information, Knowledge, and Management, 6(6), 245-269.

[16] KFF explainer (policy mechanics & prevalence). https://www.kff.org/health-costs/copay-adjustment-programs-what-are-they-and-what-do-they-mean-for-consumers/

[17] KFF Employer Health Benefits Survey 2024 (context & plan design). https://www.kff.org/health-costs/2024-employer-health-benefits-survey/

[18] NCSL state policy tracker (accumulator legislation landscape). https://www.ncsl.org/health/copayment-adjustment-programs

[19] AJMC study (adherence impact under accumulators). https://www.ajmc.com/view/impact-of-a-copay-accumulator-adjustment-program-on-specialty-drug-adherence

[20] JMCP 2024 (Patel et al.) CAAP bans, OOP and adherence effects. https://www.jmcp.org/doi/10.18553/jmcp.2024.30.9.909

[21] JMCP primer Accumulators, maximizers, AFPs (open access). https://pmc.ncbi.nlm.nih.gov/articles/PMC11293768/

[22] HHS-OIG Advisory Opinions (compliance guardrails for assistance programs). https://oig.hhs.gov/compliance/advisory-opinions/

[23] Islam, M. A., Jahin, M. A., Mridha, M. F., & Dey, N. (2024). A unified framework for evaluating the effectiveness and enhancing the transparency of explainable AI methods in real-world applications. arXiv preprint arXiv:2412.03884.

[24] Wuepper, D., & Huber, R. (2022). Comparing effectiveness and return on investment of action-and results-based agri-environmental payments in S witzerland. American Journal of Agricultural Economics, 104(5), 1585-1604.

[25] Berger, E. J. (2002). Friction modeling for dynamic system simulation. Appl. Mech. Rev., 55(6), 535-577.

[26] Blackwell, M. (2013). A framework for dynamic causal inference in political science. American Journal of Political Science, 57(2), 504-520.

[27] Kalouptsidi, M., Kitamura, Y., Lima, L., & Souza-Rodrigues, E. A. (2020). Partial identification and inference for dynamic models and counterfactuals (No. w26761). National Bureau of Economic Research.