Copay Assistance Programs for Prescription Drugs

Policy Brief with Literature Review

So-Yeon Kang, Ph.D., M.B.A,
Assistant Professor of Health Management and Policy
with Erica Kim and Allison Kim
Georgetown University School of Health

GEORGETOWN UNIVERSITY

Copay Assistance Programs for Prescription Drugs

Overview

Copay assistance programs aim to reduce patients' out-of-pocket (OOP) costs for prescription drugs. These include manufacturer-sponsored coupons and patient assistance programs (PAPs). While they help individuals afford high-cost drugs, especially amid rising prices and high-deductible plans, they also raise concerns about healthcare spending and insurance benefit design distortion. In 2020 alone, manufacturer coupons accounted for $14 billion in discounts.

- Coupons are brand-specific strategic marketing tools that promote high-cost brand-name medications. They're prohibited for federal program enrollees due to anti-kickback laws and are linked to sustained high list prices.
- PAPs, often operated by independent charities, offer disease-specific aid and may support Medicare patients. However, most require insurance coverage, excluding the uninsured (Kang et al., 2019).

Policy Landscape

Federal regulation centers on the Anti-Kickback Statute (AKS), which bans financial inducements in Medicare/Medicaid. Despite this, many PAPs are indirectly influenced by manufacturers, leading to major DOJ settlements for unlawful steering of patients. State-level action is growing:

- Bans on coupons for brand-name drugs with generic alternatives (e.g., CA, MA).
- Copay accumulator and maximizer programs by insurers exclude coupon values from deductibles/OOP caps, shifting burden back to patients and manufacturers.
- In response, 21 states + D.C./PR now require insurers to count copay assistance toward OOP limits.

Research Gaps & Policy Considerations

Literature consistently finds these programs promote brand-name drug use and hinder generic substitution, raising total costs (Dafny et al., 2017; Daubresse et al., 2017; Rome et al., 2021).
Key findings:

- PAPs often lack transparency and may exclude the uninsured.
- Coupons are more common for late-market brand drugs and orphan drugs but are often "one-and-done", which refers to when a manufacturer copay coupon is offered only once, typically for the initial prescription fill (Kang et al., 2023).
- No strong evidence links coupon uses to socioeconomic status, and patients on multiple drugs are less likely to use them.
- Limited data on actual financial support disbursed or impact on long-term medication use.

Conclusion

Copay assistance programs alleviate short-term OOP burdens but may increase overall healthcare costs and limit insurance design effectiveness. Their continued use reflects complex commercial incentives, opaque eligibility criteria, and regulatory ambiguity. Stronger transparency, better data, and further research are needed to inform balanced policies that protect affordability without undermining systemic cost control.

Policy Brief: Copay Assistance Programs for Prescription Medications

So-Yeon Kang, PhD, MBA, Assistant Professor of Health Management and Policy at Georgetown University, with Erica Kim and Allison Kim

Overview

Copay assistance programs offer financial support to help patients reduce out-of-pocket (OOP) costs for prescription drugs and play a complex and often controversial role in the U.S. pharmaceutical market. These programs have become increasingly common with the rise of drug prices, high-deductible health plans and the growing use of high-cost specialty drugs (Congressional Research Service, 2022). According to a report by IQVIA (2021), manufacturer-sponsored coupons accounted for $12 billion in prescription drug discounts in 2019, increasing to an estimated $14 billion by 2020. The most common forms of copay assistance programs are **manufacturer-sponsored coupons**, which are aimed at particular brand name products and serve a profit-driven purpose, and **patient assistance programs (PAPs**), typically provided by non-profit charitable organizations for specific diseases. Although these programs may appear similar, they differ in designs, intended users, and related regulatory policies, all of which should be carefully considered in policymaking.

Manufacturer-sponsored Coupons

Manufacturer-sponsored coupons are product-specific (e.g., *Xarelto withMe Savings Card*) and are primarily used to promote brand-name drugs as a strategic marketing tool. These coupons are not available to federal health plan beneficiaries due to anti-kickback regulations. Manufacturers control patient eligibility, funding levels, and program availability. While these coupons reduce the immediate OOP cost for patients, they maintain high list prices to preserve manufacturer profit margins. Though helpful for individual patients, manufacturer coupons have been criticized for encouraging the use of high-cost drugs over lower-cost alternatives, potentially raising overall healthcare spending for insurers and payers.

Patient Assistance Programs (PAPs)

While some PAPs are operated by manufacturer-owned foundations or state governments, especially for essential or generic drugs, **most are provided by independent charitable organizations.** These programs typically offer financial aid or, rarely, free medications based on criteria such as income, insurance status, prescription details, and proof of U.S. citizenship or legal residence. Physician endorsement is often required, and support is usually time-limited (Kang et al., 2019). A key distinction from coupons is that PAPs are disease-specific (e.g., leukemia funds) and may be accessed by beneficiaries of federal health programs like Medicare Part D, provided they meet the clinical and financial eligibility criteria. Despite the assumption that PAPs support uninsured patients, research by Kang et al. (2019) found that nearly all PAPs require that patients have insurance coverage for the drug, effectively excluding the uninsured. Many PAPs rely heavily on funding from pharmaceutical manufacturers.

Federal and State-Level Policy Landscape and Regulatory Tensions Around Copay Assistance Programs

Copay assistance programs are primarily governed by the federal Anti-Kickback Statute (AKS), which prohibits pharmaceutical manufacturers from offering direct financial incentives to beneficiaries of federal health programs such as Medicare and Medicaid. The goal is to prevent unlawful inducements that could steer patients toward specific drugs. As a result, Medicare and

Medicaid beneficiaries are barred from using manufacturer-sponsored coupons, although they may still access support through independent charitable PAPs.

However, the line between charitable assistance and manufacturer influence has grown increasingly blurred. Despite their independent status, many PAPs rely heavily on pharmaceutical company funding. Allegations have emerged suggesting that some manufacturers indirectly shape PAP designs to steer patients toward their own high-cost brand-name drugs—raising questions about compliance with the AKS. The Department of Justice (DOJ) has ramped up enforcement efforts in this area, resulting in a series of high-profile settlements. Several large pharmaceutical manufacturers, such as Gilead Sciences and Astellas, agreed to pay multimillion-dollar settlements to resolve allegations that they unlawfully used a charitable foundation to cover Medicare copays for their drugs. Similarly, multiple foundations also agreed to pay multimillion dollars to resolve allegations that they enabled manufacturers to pay kickbacks to Medicare patients.

At the state level, some policymakers have taken proactive steps to limit copay assistance programs that may undercut cost-containment strategies. California and Massachusetts have enacted laws banning copay coupons for brand-name drugs when lower-cost generics are available. These policies stem from concerns that while coupons can improve drug adherence in the short term, they also discourage generic substitution and lead to higher overall drug spending (Massachusetts Health Policy Commission, 2020).

More recently, a growing tug-of-war has emerged between payers and state policymakers over manufacturer-sponsored coupons. In response to the increasing use of coupons, health insurers and pharmacy benefit managers (PBMs) have implemented copay accumulator and maximizer programs. These tools aim to preserve the intended effects of tiered cost-sharing by excluding copay assistance from counting toward a patient's deductible or out-of-pocket (OOP) maximum. Copay accumulators prevent coupon values from counting toward patient deductibles or OOP maximums. While these programs shift financial burden from insurers to patients and manufacturers, they have also drawn criticism for undermining affordability and patient access (Westrich et al., 2023).

In September 2023, federal courts reinstated rules requiring insurers to count copay assistance funds toward OOP costs, though enforcement remains delayed (Westrich et al., 2023). Twenty-one states, including Colorado, plus the District of Columbia and Puerto Rico, have passed laws requiring insurers and PBMs to apply copay assistance toward annual OOP cost-sharing limits (Westrich et al., 2023). These policies primarily target accumulator programs. Early evidence suggests that states with accumulator bans have seen reduced patient financial liability and improved adherence (Westrich et al., 2023).

Overall, federal and state policies regulating copay assistance and coupon programs remain complex and contentious. While both levels aim to reduce prescription drug spending, the involvement of third parties – PBMs, non-profits, and payers – and ongoing legal challenges create loopholes and enforcement challenges. These dynamics complicate efforts to strike balance between cost containment and access to prescription drugs.

Literature Review on Areas for Further Investigation and Policy Interventions

The literature generally agrees that **copay assistance programs undermine the effect of insurance benefit designs and may drive up the spending on prescription drugs**. They can benefit drug manufacturers by stimulating demand for newly launched therapies, preserving market share in competitive therapeutic areas, sustaining higher list prices, and improving adherence to brand-name medications (Dafny et al. 2017; Kang et al., 2021; Daubresse et al., 2017;

Rome et al., 2021). These programs also incentivize the use of expensive brand-name drugs over lower-cost generics.

While both coupons and PAPs provide copay support, eligibility criteria often hinge on insurance status—yet these criteria are not always clearly communicated. Nunley et al. (2022) highlight inconsistencies in PAP requirements, including restrictions based on insurance status, income thresholds, and delays between prescription and program initiation. Despite these barriers, the exact eligibility standards remain opaque, signaling a need for greater transparency and pharmacy-based interventions to assist prescribing physicians. Similarly, Kang et al. (2019) found that most of the six largest independent charity PAPs serving Medicare beneficiaries required insurance coverage and set income ceilings around 500% of the federal poverty level. **Lack of clarity around coupon availability, program continuity, and consistent of the coverage criteria** also presents challenges for both patients and providers.

The broader **impact of PAPs and manufacturer coupons on drug utilization and patient demand** remains contested. In a study on multiple sclerosis patients, Brouwer et al. (2021) found that PAPs in Washington reduced OOP costs but had no discernible effect on prescription utilization or demand. Kang et al. (2019) likewise emphasized the limited availability of data on actual assistance amounts disbursed or the degree to which these programs influence prescription drug use and spending. This highlights a persistent evidence gap in understanding the relationship between copay assistance and broader healthcare system outcomes. Regulatory concerns also persist. While the Anti-Kickback Statute (AKS) aims to prevent pharmaceutical manufacturers from using assistance programs to drive demand, questions remain about its effectiveness. Dafny et al. (2017) argue that manufacturers strategically fund condition-specific PAPs to increase profit margins. Similarly, Kang et al. (2019) raise ethical concerns regarding the high costs of drugs supported by independent charity PAPs, **questioning whether these programs prioritize affordability for patients or commercial returns for manufacturers**.

The literature highlights these programs as a critical tool in improving drug affordability for certain drug types (e.g., cancer drugs). Yet, their long-term effects on drug utilization, pricing, and system-wide expenditures remain unclear. There are also concerns about their sustainability, especially given their reliance on manufacturer funding. Several studies have explored the prevalence and targeting of coupons at both the drug and therapeutic class levels (Kang et al., 2021; Kang et al., 2023). Single-source brand-name drugs, especially those entering the market later in their class, and orphan drugs with high per-patient costs, are more likely to offer coupons (Daubresse et al., 2017; Kang et al., 2021). In a 2023 study, Kang et al. found **many coupons were "one-and-done" and there were no significant associations between coupon use and socioeconomic and demographic characteristics** such as neighborhood income, race, age, or sex. Interestingly, higher OOP costs did not correlate with increased coupon use. **These findings suggest that coupon targeting may be influenced more by market competition and manufacturer incentives to drive brand adoption than by patients' affordability needs.** Transparency regarding program design and long-term impact remains limited, underscoring the need for further policy evaluation and reform (Kang et al., 2019; Dafny et al., 2017).

In summary, copay assistance programs reduce patients' OOP costs but may drive up overall healthcare spending by promoting more expensive alternatives. While they can improve initial medication uptake, their long-term effects on access and total costs remain unclear because funders, particularly manufacturers, control the availability, eligibility, and intended users of these programs to serve commercial interests. Although these copay adjustment programs have been the subject of ongoing discussion, empirical evidence on their impact remains relatively limited. Continued empirical research is critical to shaping a regulatory framework that promotes drug affordability while minimizing unintended economic and ethical consequences.

Annotated Bibliography

Kang S, Sen A, Bai G, Anderson GF. (2019). Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs. JAMA, 322(5):422–429.

This study analyzed 274 programs from six major independent charity PAPs, revealing that nearly all required insurance coverage, effectively excluding uninsured patients. Support disproportionately targeted high-cost brand-name drugs. The study's comprehensive scope highlights systemic inequities in PAP access.

Dafny L, Ody C, Rokos T. Giving A Buck or Making a Buck? Donations By Pharmaceutical Manufacturers to Independent Patient Assistance Charities. Health Aff (Millwood). 2022 Sep;41(9):1263-1272. doi: 10.1377/hlthaff.2022.00177. PMID: 36067442.

Analyzing Medicare Advantage claims, this study shows that manufacturer donations to condition-specific PAPs are linked to increased sales of high-cost drugs. It provides evidence that current donation practices may circumvent AKS intent, supporting critiques of PAPs as manufacturer-funded marketing tools rather than pure aid mechanisms.

Dafny, L., Ody, C. and Schmitt, M., 2017. When discounts raise costs: the effect of copay coupons on generic utilization. American Economic Journal: Economic Policy, 9(2), pp.91-123.

This study examines the impact of copay coupons on branded drugs facing generic entry between 2007 and 2010, using variation in coupon legality across states and consumers to address endogeneity. They find that coupons boost branded sales by over 60%, entirely by reducing generic use, which leads to $30–$120 million in additional spending per drug, totaling up to $2.7 billion across the sample.

Kang S, Sen AP, Levy JF, Long J, Alexander GC, Anderson GF. Factors Associated With Manufacturer Drug Coupon Use at US Pharmacies. JAMA Health Forum. 2021

Using retail pharmacy claims and drug-level data, the authors show that coupon use is driven more by market positioning—particularly for late-to-market, high-cost drugs—than by patient OOP costs. The study offers supply-side insights, though limited by its cross-sectional nature. It informs policy discussions on how coupons are strategically deployed to protect market share rather than improve affordability.

Kang S, Liu A, Anderson G, Alexander GC. Patterns of Manufacturer Coupon Use for Prescription Drugs in the US, 2017-2019. JAMA Netw Open. 2023 May 1;6(5): e2313578.

This study of 35,000 patients with chronic conditions found that manufacturer coupons are most used at treatment initiation and suggest that the frequency of coupon use was associated with market competition but not patients' out-of-pocket costs.

Rome, B. N., Gagne, J. J., & Kesselheim, A. S. (2021). Association of California's prescription drug coupon ban with generic drug use. JAMA, 325(23), 2399–2402.

Using claims data, this study found no significant increase in generic drug use following California's coupon ban. While limited by short-term follow-up and population scope, it adds valuable real-world evidence suggesting that coupon bans alone may be insufficient and need to be paired with broader cost-containment policies.

Brouwer E, Yeung K, Barthold D, Hansen R. Characterizing patient assistance program use and patient responsiveness to specialty drug price for multiple sclerosis in a mid-size integrated health system. J Manag Care Spec Pharm. 2021 Jun;27(6):732-742.

This analysis in a single health system found that PAPs significantly reduced OOP costs but did not impact demand elasticity. Although generalizability is limited, the study shows how PAPs can reduce immediate financial burden without encouraging overutilization—adding nuance to debates about their effects on patient behavior.

Nunley E, Martinez A, Dains JE. Eligibility and Accessibility Barriers of Patient Assistance Programs for Oral Oncolytics in Patients With Cancer. Clin J Oncol Nurs. 2025 Jan 17;29(1):79-85. doi: 10.1188/25.CJON.79-85. PMID: 39933085.

This integrative review highlights how structural barriers – such as insurance requirements, income thresholds, and processing delays– impede timely access to PAPs for cancer patients. While based on a small sample, the study offers practical insights into care coordination challenges and the need for greater transparency in program eligibility.

Daubresse M, Andersen M, Riggs KR, Alexander GC. Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study. Pharmacotherapy. 2017

This study found that coupons for brand-name statins improved adherence but also led to sustained use of more expensive products. While enhanced by longitudinal data, its lack of a generic comparator limits conclusions on overall value. It contributes to broader debates on whether coupons undermine cost-control mechanisms in formulary design.

Wang Y, Kang S, Socal MP, Dusetzina SB. Manufacturer-sponsored drug coupon use and drug-switching behavior among patients with type 2 diabetes. J Manag Care Spec Pharm. 2024

This study reveals that coupons for brand-name diabetes drugs are associated with lower switching rates, reinforcing initial prescribing decisions. Though condition-specific, it offers important insight into how coupons can influence treatment stability and constrain formulary flexibility in chronic disease management.

Westrich, K., Buelt, L., Narain, A., & O'Brien, J. M. (2023). Copay accumulator and maximizer programs: The stakes rise for patients as federal rulemaking lags. Health Affairs.

This policy commentary outlines how accumulator and maximizer programs undermine copay assistance by excluding it from cost-sharing calculations, thereby raising patient financial burden. Though not empirical, the piece provides a policy overview and contextualizes insurer strategies amid regulatory debates.