Breaking Barriers: Harnessing the Potential of Generics in Medicare and Commercial Market Drug Spending

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Introduction

Generic and biosimilar medicines continue to provide critical savings throughout the U.S. healthcare system. Over the past decade, generic and biosimilar products have generated more than $3.1 trillion in savings, including $445 billion in 2023 alone. This includes over $137 billion in savings to Medicare and $206 billion across the commercial market in 2023.[1]

One way to monitor whether patients have access to lower-cost generic medicines is to examine plan coverage of first generics –medicines approved by the FDA as the first generic competitor to the brand. The quicker the coverage of first generics, the quicker patients have access to these lower cost options.

In 2022, as part of the Inflation Reduction Act (IRA), Congress shifted more financial responsibility to Medicare plans under the assumption that doing so would create a financial incentive and encourage greater use of lower-cost generic medicines. Unfortunately, systemic barriers imposed by pharmacy benefit manager (PBM) practices continue to undermine their adoption. A new analysis from the Association for Accessible Medicines (AAM) and Avalere Health examining coverage of first generics in both commercial and Medicare Part D confirms how these entrenched coverage practices, especially in Medicare, continue to limit generic drug utilization, exposing both patients and taxpayers to higher costs for longer.

Key Findings

- New analysis validates previous AAM findings, demonstrating that first generics still face coverage challenges in Medicare Part D. In 2025, Medicare Part D coverage of first generics remained similar to previous years, with an average of only 24% of plans covering generics first launched in 2024. Part D plans continue to have a multi-year "phase-in" period before first generics are covered. This delay restricts patient access to lower-cost generics, whereas an average of 50% or more of commercial plans typically cover first generics the year after launch.[2]
- While commercial coverage rates were higher, with an average of 78% of plans providing coverage in 2025 for first generics launched in 2024, the brand to generic coverage gap across commercial payers remains a challenge for new generic formulary placement.[3]
- The result is a continuing slowdown in the rate of generic adoption, which in turn costs money for America's patients and taxpayers.

Summary: Across All First Generics Launched in 2024, an Average of 24% of Medicare and 78% of Commercial Plans Provide Coverage in FY 2025

Percent of First Generics Covered by medicare Part D and Commercial Plans by Formulary Year

Launch year	2016		2017		2018		2019		2020		2021		2022		2023		2024		2025	
	M	C	M	C	M	C	M	C	M	C	M	C	M	C	M	C*	M	C*	M	C*
2016	22%	46%	31%	68%	63%	72%	58%	72%	60%	76%	62%	78%	61%	90%	55%	87%	56%	88%	54%	86%
2017			12%	58%	25%	73%	58%	73%	65%	76%	65%	76%	64%	89%	61%	95%	65%	95%	62%	93%
2018					17%	39%	27%	49%	51%	59%	54%	60%	54%	84%	53%	91%	54%	89%	54%	86%
2019							31%	44%	59%	60%	72%	61%	72%	88%	70%	90%	71%	90%	70%	88%
2020									21%	55%	41%	66%	60%	90%	58%	91%	58%	87%	59%	85%
2021											23%	86%	46%	89%	45%	84%	44%	81%	42%	81%
2022													39%	76%	44%	76%	45%	81%	58%	80%
2023															39%	72%	45%	88%	34%	86%
2024																	23%	84%	24%	78%

*New analysis

*Note: New commercial analyses were conducted using Clarivate data; previous analyses were conducted using MMIT data

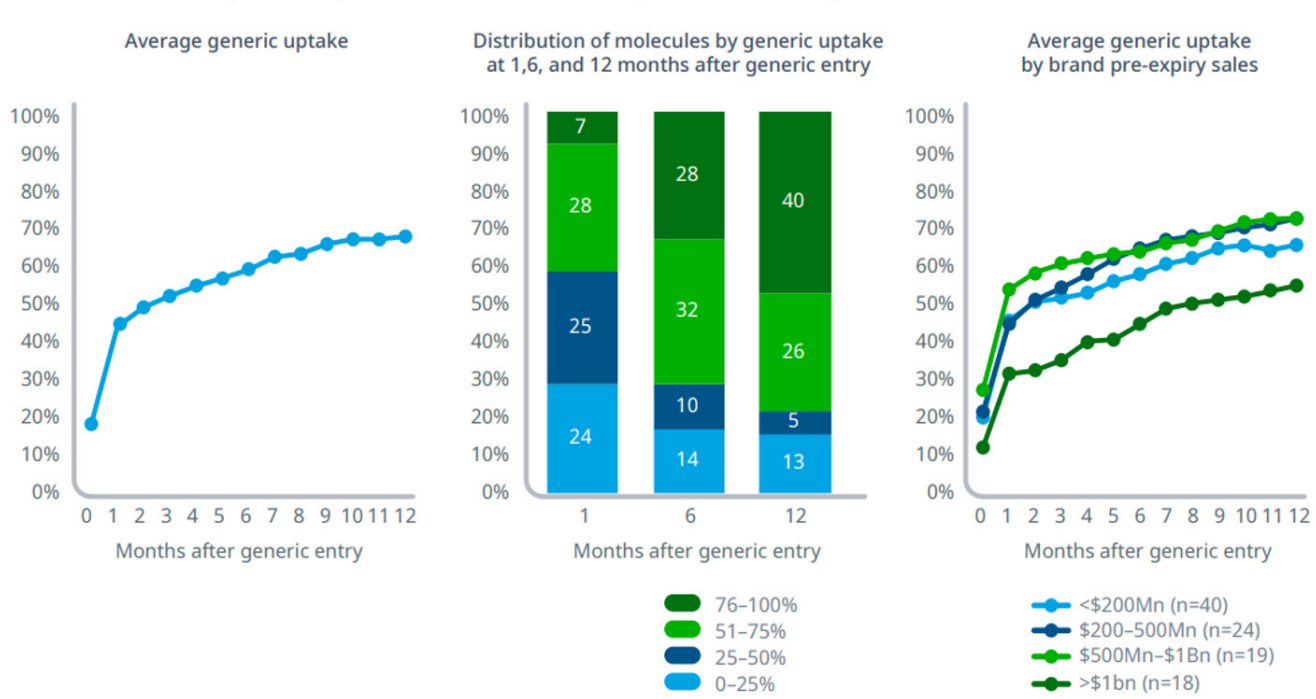
The ongoing coverage challenges for first generics among Medicare Part D and commercial plans highlight the need to reexamine program redesign and to implement policy changes to improve patient access to lower-cost medicines. Addressing these challenges will ensure that patients can benefit from the cost savings and therapeutic advantages offered by generic medications.

Misaligned Incentives Limit First Generic Coverage

Even though generic medicines offer demonstrably lower net prices to the Medicare Part D program, the rate of coverage of first generic drugs by Medicare prescription drug plans (PDP) and Medicare Advantage Prescription Drug (MA-PD) plans has slowed over the past several years. This reduces patient access to lower-cost generics, resulting in higher healthcare spending and lower patient medication adherence.[4]

IQVIA analyses demonstrate how eroding coverage trends have undermined first generic adoption rates. Over a five-year period between 2018-2022, average generic drug uptake within 1-year after launch was limited to 67 percent.[5] This trend contrasts sharply with more historic models, which saw generics capturing 80-90 percent of script share within months.

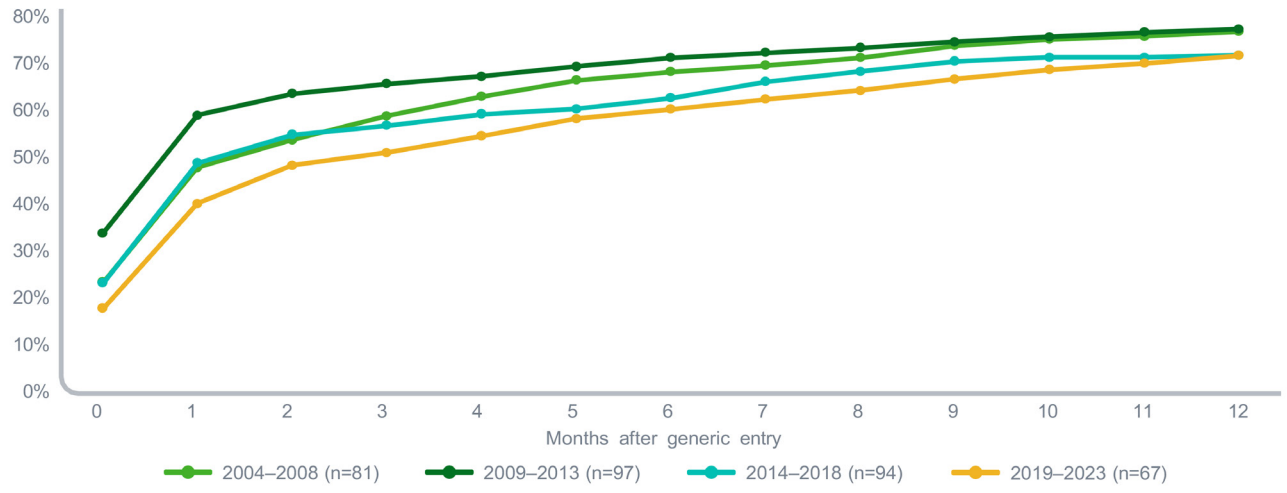
Overall Generic Uptake for Small Molecule Generics Entering 2018–2022



Source: IQVIA National Sales Perspective, Aug 2023; IQVIA Institute, Nov 203

More recent analysis makes it clear these coverage challenges remain a stringent obstacle to generic adoption. For new generic drugs launched from 2019-2023, IQVIA observed that while many generics were generally preferred by payers, PBMs continued to use formulary design and prior authorization restrictions to block over 25% of new generic prescriptions two years after they launched. IQVIA notes the current trend toward slower generic uptake may threaten the historic pattern of deep generic savings, suggesting "expected cost savings for payers and patients may not be realized."[6]

Average Generic Uptake for Small Molecule Generics by Generic Entry Year



Source: IQVIA National Sales Perspective, Dec 2024; IQVIA Institute, Mar 2025

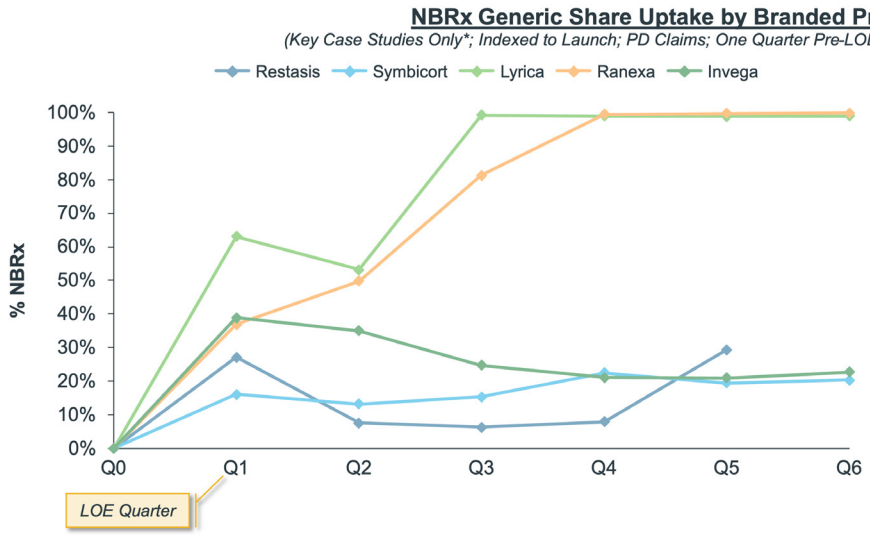
Medicare and Commercial Plan Policies Continue to Reward PBMs for Use of Reference Products instead of First Generic Drugs

Why are PDPs and MA-PDs preferring brand products? There are two reasons: (1) plan/PBM reliance on income earned from rebates and fees from brand manufacturers; and (2) market consolidation and vertical integration, resulting in three PBMs controlling formulary choices for almost all Americans, while owning their own specialty and mail-order pharmacies.

PBMs extract sizable rebates from reference manufacturers in exchange for limiting generic manufacturers' ability to gain market share when a generic launch occurs.[7] PBMs often exclude low-priced generic drugs from their formularies if the PBMs can collect more in rebates by using the reference product. Further, using "bundled rebates," the manufacturer of a reference product may withdraw or threaten to withdraw some or all of the rebates on a basket of products if the contracted entity—typically the health plan—utilizes a generic drug in place of the reference product.[8] These perverse rebate practices lead to PBMs blocking or delaying coverage and formulary status for lower cost generic drugs.[9]

The proliferation of rebates paid by manufacturers of reference products to PBMs has complicated market incentives and dynamics and created PBM schemes, including "brand for generic" contracting, that ultimately limit first generic coverage. To better understand these practices, AAM engaged IQVIA to help identify case studies in which payers preferred reference products rather than a generic alternative.[10] As part of its analysis, IQVIA examined select script share rates under four large Part D plans for first generic substitutes for brand Restasis®, Lyrica®, Ranexa®, and Invega®. IQVIA found Part D plans blocked coverage of generic substitutes through PBM point-of-service rejections at rate of 62 percent - even six months after loss of exclusivity (LOE). These plan and PBM coverage and utilization management practices limited generic product script share to 53 percent for the full period examined.[11]

"Though All Products of Interest Likely Benefitted From B4G Contracting, Varying Payer Control Over Time Drove Different Rates of Generic Uptake"



Product (Molecule)	Payer of Interest (Payer Channel)	Generic Share Six Quarters Post-LOE
Restasis (Cyclosporine)	Medicare - MPD	29%
Symbicort (Budesonide/ Formoterol)	Commercial	20%
Lyrica (Pregabalin)	Medicare - MPD	99%
Ranexa (Ranolazine)	Medicare - MPD	100%
Invega (Paliperidone)	Medicare - MPD	23%

Note:Key case studies only include 1 case study per molecule which limits to one payer channel/payer combination
Source: IQVIA LAAD; IQVIA Market Access Strategy Consulting Analysis

Medicare Part D Redesign Failed to Address Coverage

Policymakers sought to partially address these challenges through structural changes to the Medicare Part D benefit with the goal of reducing patient and government spending and modifying plan incentives. Among other changes, the IRA eliminated the Part D coverage gap and increased plan liability. Unfortunately, it also left PBM use of rebates untouched. It is abundantly clear that incentives for PBMs to continue prioritizing higher-priced brand drugs remains strong.

Although the Part D redesign intended to encourage faster Medicare adoption of first generics, data shows no improvement in the rate of generic formulary coverage in 2025, the first year of redesign implementation. In fact, the rate of first generic drug coverage actually declined in some cases. Across all first generics launched in 2024, an average of 24 percent of Medicare plans provided coverage in 2025.[12] Even for first generic drugs launched in 2021, the coverage rate among Part D plans was limited to 42 percent. The data is clear: Part D enrollees are being denied access to new, lower price generic medicines.

Solutions – Bringing Light to Medicare Formulary and Coverage Practices

Congress should pass legislation ensuring Medicare plan and PBM formulary design and medication utilization management practices are transparent to the government and to beneficiaries and to ensure these practices align with the goal of lowering healthcare costs for taxpayers and patients. Several provisions to improve plan and PBM transparency, reporting and accountability were included in the 2024 year-end omnibus bill. While this measure failed to advance despite strong bi-partisan support, these provisions should be included in any legislative package on PBM reform Congress takes up later this year.

However, legislation is only a first step towards fully addressing the challenges facing new generic adoption. It is vital that Congress continue work to reform the Medicare drug program and ensure that plans drive rapid first generic adoption through preferred formulary coverage whenever the generic costs less at a unit level.

In the meantime, CMS should take immediate steps to better measure drug product net cost to ensure rebates and fees that drive formulary design and product placement result in a lower net cost at *the unit level*.

- ***Net Cost Justification*** – Requiring sponsors to provide an explanation and justification when a formulary does not cover a generic drug, including whether the formulary is instead covering or preferring the reference product or an alternative product; what rebates, fees or other contractual arrangements apply; and attest that the covered or preferred reference drug or biological product is lower net cost at the unit level.
- ***Address Medicare Coverage Disparity*** – CMS could modify its formulary review and approval criteria to examine Part D plan sponsor coverage of generic drugs compared to coverage rates for those products in the commercial market. It is important to recognize that, although the commercial market also suffers from the perverse incentives favoring use of higher-priced reference products, it nonetheless demonstrates higher coverage rates for many first generic drugs and biosimilar products on commercial formularies.

Conclusion

Generic medicines and the savings they deliver are essential to the sustainability of the U.S. healthcare system. Nevertheless, the promise of ongoing savings through generic drug utilization is threatened by systemic barriers established by PBM formulary design and utilization management practices, which prioritize brand product rebate schemes over common sense reductions in list price. Despite previous efforts to address these practices in the Inflation Reduction Act and a patchwork of federal and state PBM reform initiatives, poor rates of first generic adoption persist in Medicare Part D and the commercial market, limiting the potential savings, prioritizing branded drugs and burdening patients with higher costs. By taking decisive action to reform coverage policies and increase transparency, Congress and CMS have the opportunity to deliver lasting benefits for patients, taxpayers, and the healthcare system as a whole.

Methodology

Avalere Health compiled a list of all first-to-market generics approved from 2016-July 2024 using the FDA First Generic Drug Approvals database (accessed October 2024). IQVIA provided launch dates (up to August 2024) for all products included in its SMART US database. Over-the-counter drugs and drugs that had not launched, as of August 2024, were excluded from further analyses.

Avalere Health analyzed formulary and benefit design data to assess first-generic drug coverage and tier placement in the Medicare Part D market. Avalere Health used plan benefit and formulary data for 2023, 2024, and 2025 from the Medicare Part D Public Use Files (PUFs). Avalere Health included in the analyses the corresponding brand products, matched using drug name from first-to-market generic drugs approved and marketed between 2016 and August 2024.

Avalere Health analyzed 2023, 2024, and 2025 plan formularies to assess drug coverage and tier placement in the Commercial market for first generics approved by FDA and marketed from 2016- August 2024. Avalere Health partnered with Clarivate to obtain formulary data for coverage analyses. Results were not weighted by enrollment.

References

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