AAM REPORT

Middlemen Increasingly Block Patient Access to New Generics

JANUARY 2023

Executive Summary

New generic drugs offer significantly lower prices for patients. Nonetheless, drug supply chain middlemen like health plans and pharmacy benefit managers (PBMs) increasingly block patient access, delaying coverage of new generics in favor of higher-priced brand drugs with high rebates. This report analyzes six years of data showing the extent to which plans and PBMs delay patient access to lower-cost generic drugs.

Policymakers should ensure patient access to new, lower-cost generic medicines by addressing the perverse incentives of brand drug rebates to increase savings for patients, employers and taxpayers.

First Generics Offer Savings for Patients

Competition from lower-cost generics is the cornerstone for affordability and accessibility of medicines for patients. Polling consistently ranks prescription drug prices as one of the most important issues to the American public.[1] Fortunately, generic drugs offer a proven track record of savings — over $373 billion in 2021 and more than $2.6 trillion over the last ten years.[2]

The Food and Drug Administration (FDA) considers first generics — "the first approval which permits a manufacturer to market a generic drug in the United States"[3] — to be a public health initiative worthy of prioritized review.[4] In 2021, the FDA approved ninety-three first generic drugs, introducing more affordable therapeutic options for a variety of conditions. And the use of first generics approved over the past ten years generated $86 billion in savings in 2021 alone. This is due to the well-documented trend whereby generic prices can rapidly fall by more than 95 percent when compared to brand prices.[5]

For example, the brand drug Northera (droxidopa) is indicated for the treatment of orthostatic dizziness in adult patients with neurogenic postural hypotension and has a list price of $6,407 for a thirty-day supply. The first generic versions launched in February 2021 with list prices ranging from 87 to 98 percent less than the brand, and the average price of generic Northera continued to fall to roughly $390 today with ten generic competitors.[6]

1 Kaiser Family Foundation. (October 2022). "Public Opinion on Prescription Drugs and Their Prices". Accessible at: https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

2 Association for Accessible Medicines. (October 2022). "U.S. Generic and Biosimilar Medicines Savings Report". Accessible at: https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf

3 U.S. Food and Drug Administration. (July 2022). First Generic Drug Approvals. Accessible at: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

4 Association for Accessible Medicines. (May 2022). AAM Comment Letter on the FDA Safety and Landmark Advancements Act (FDASLA)

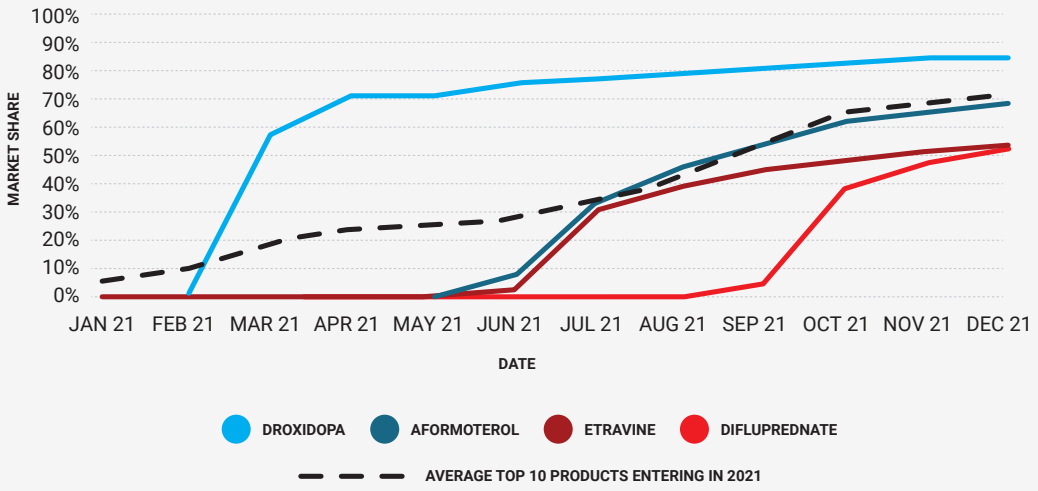
5 U.S. Food and Drug Administration. (December 2019). "Generic Competition and Drug Prices". Accessible at: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

6 IQVIA. (December 2022). National Sales Perspectives

PBMs and Plans are Delaying Patient Access to New Generics

Nonetheless, many generics are experiencing slower than expected adoption. Generics historically achieved rapid adoption of 80 percent or more within only a few months. But this is increasingly no longer the case.[7] In 2021, the top ten new generics averaged 70 percent market share of total prescriptions, reflecting a palpable shift in market dynamics. This slower adoption is a direct result of PBM and plan coverage decisions.

Many Generics Face Delays in Adoption



Source: IQVIA. (December 2022). National Sales Perspective

AAM previously documented delays in both commercial and Medicare drug formulary coverage of first generics.[8] These delays are driven by the perverse incentives of PBMs to prefer high-priced drugs with high rebates over drugs with lower list prices. As the U.S. Department of Health and Human Services notes, "large rebates offered by manufacturers for higher-cost [drugs] benefit plan sponsors but provide little relief to beneficiaries who received the drugs or the Medicare program."[9,10]

This updated analysis uses Medicare and commercial formulary data to assess the coverage and management of first generic drugs since 2016.[11]

7 Avalere. (January 2020). "Variation in Generic Substitution Rates Among Part D Plans". Accessible at: https://avalere.com/insights/avalere-analysis-finds-variation-in-generic-substitution-rates-among-part-d-plans

8 Association for Accessible Medicines. (July 2021). "New Generics Are Less Available in Medicare Than Commercial Plans". Accessible at: https://accessiblemeds.org/resources/reports/new-evidence-shows-medicare-part-d-plans-continue-fail-get-new-generics-seniors

9 U.S. Department of Health and Human Services Office of Inspector General. (August 2022). "Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending". Accessible at: https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf

10 Formulary coverage challenges for lower priced medicines are not unique to generics. Note formulary coverage of insulin products, specifically the limited coverage of the lower-priced unbranded version of the interchangeable insulin Semglee. IQVIA. (November 2022). "Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars." Accessible at: https://www.iqvia.com/locations/united-states/library/white-papers/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars

11 Description focuses on the cohorts of first generic drugs launched in 2016 and 2021. See appendix for full results.

MEDICARE PART D PLANS ARE SLOW TO COVER NEW GENERICS

In 2016, twenty-four first generics became commercially available. However, Medicare Advantage and Part D plans covered these lower-cost options only 22 percent of the time. It appears to take nearly three years before first generics are covered on more than half of Medicare drug formularies. Even today, six years later, these new generics are covered by fewer than two-thirds of all Medicare drug formularies.

This is not an outlier. As reflected in the appendix, subsequent years tell a consistent story. This includes the most recent group of twenty-five first generics approved and launched in 2021. Consistent with prior findings, these products were covered by only 23 percent of Medicare formularies in 2021 and only 46 percent in 2022.

COMMERCIAL PLANS ALSO DELAY COVERAGE

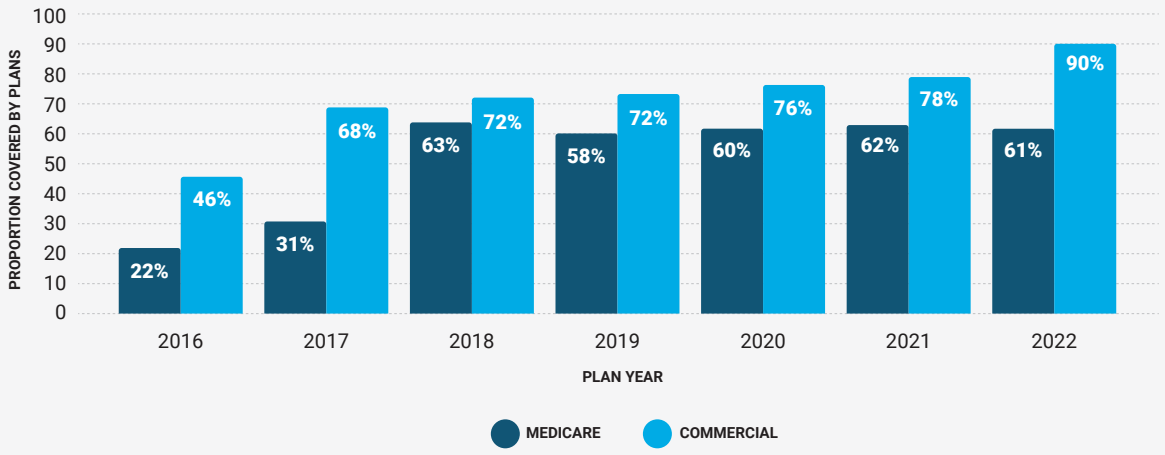
But these challenges are not limited to the Medicare prescription drug program. Although commercial plans demonstrate better coverage of new generics, they nonetheless fall short of ensuring patient access to lower-cost medicines.

For instance, first generics that launched in 2016 were covered only 46 percent of the time. Coverage of these generics eventually reached 90 percent in 2022, however this was six years after the generics first came to market.[12]

These coverage delays restrict patient access to lower-cost generics and expose patients to unnecessarily high cost-sharing even though lower-cost alternatives are available.

New Generics Face Slow Formulary Coverage

Coverage of New Generics Launched in 2016 by Plan Year



Source: IQVIA. (December 2022). National Sales Perspective

12 Although coverage rates improved from 2021 to 2022, a longitudinal assessment has not yet determined that this trend is enduring.

Plans and PBMs Use Consolidated Market Power to Block New Generics

Recent reporting has provided fresh insights into the lengths to which some PBMs go to reduce generic utilization. The document highlights a lawsuit alleging that a vertically integrated Part D plan sponsor, its PBM, and its pharmacy network coordinated to limit consumer access to first generics.

The practice began with a sophisticated "do not substitute" (DNS) strategy that allegedly prevented consumers from obtaining low-cost generics if the company profited through rebate agreements from the brand drug.[13]

Under the DNS strategy, the company informed its plan sponsors that the program could help protect their revenue generated by brand drug rebates from new lower-price generics. Although the company claimed the generics would be incorporated if they would result in an equal or lower cost to patients, the report alleges that these generics were blocked well past their initial launch phase. For example, the company continued to prefer the brand version of Renvela, in spite of eight lower-priced generic competitors.

Despite the availability of at least eight generic competitors, the company maintained Renvela tables under brand-only coverage.

Renvela 800mg
(sevelamer carbonate)

Generic	$135.65
Brand	$540.35

Source: IQVIA. (December 2022). National Sales Perspective

As part of their rebate agreements, the company agreed to not stock the generic equivalents of those drugs in any of its retail pharmacies

Advair Diskus
(fluticasone-salmerterol inhalation powder)

Generic	$135.74
Brand	$421.27

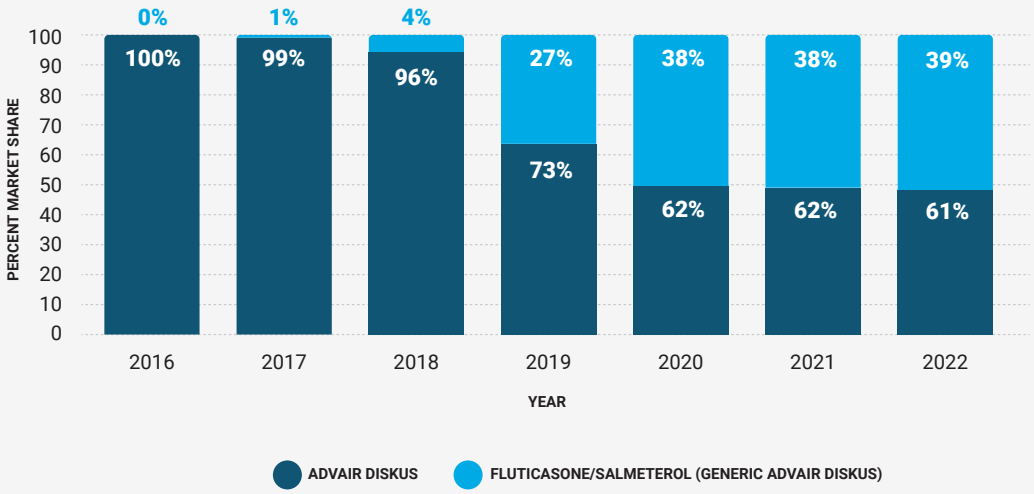
Source: IQVIA. (December 2022). National Sales Perspective

13 Silverman, Ed. (June 2022). "A 'Veritable Playground': CVS Whistleblower Details How Patients Were Charged Higher Drug Prices." STAT News. Accessible at: https://www.statnews.com/pharmalot/2022/06/16/cvs-whistleblower-silverscript-medicare-generics/

To compound matters, the company allegedly trained call center representatives to mislead patients on pricing for the generic options and to discourage beneficiaries from filing formulary exceptions. And the company executed the scheme by refusing to stock the generic versions in its pharmacy, even for patients willing to pay cash.

This practice increased costs for Medicare beneficiaries, taxpayers, and its retail pharmacy customers. Generics for widely used drugs such as Renvela and Advair Diskus were not only denied for Medicare patients but also for any customers filling a prescription at this national retail pharmacy chain.[14, 15]

Generic Advair Faced Slow Adoption



Source: IQVIA. (December 2022). National Sales Perspective

14 Used to treat chronic kidney disease and Chronic Obstructive Pulmonary Disease respectively.

15 Silverman, Ed. (June 2022). "A 'Veritable Playground': CVS whistleblower details how patients were charged higher drug prices". STAT News. Accessible at: https://www.statnews.com/wp-content/uploads/2022/06/CVS-Miller-whistleblower-lawsuit.pdf

Policymakers Can Ensure Patient Access to New Generics

Policymakers at the Centers for Medicare and Medicaid Services (CMS) and in Congress have a range of tools at their disposal to lower patient drug spending through generic medicines. In its role overseeing the Medicare drug program, CMS establishes the rules governing formulary construction, including coverage of generic drugs. For instance, the agency permits plan sponsors to replace brands with new generic drugs on their formularies as "opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year." [16] But this analysis suggests that many plans are not using CMS' flexibility to pass generic savings on to patients.

Likewise, Congress has the legislative authority to ensure patient access to new generics. And while recent legislation eliminated the Medicare Coverage Gap Discount Program and shifted greater financial liability to drug manufacturers, it has not fully removed the perverse incentives of high rebates on expensive brand drugs that prevent patients from receiving lower-cost generics.

Accordingly, policymakers should act to increase patient access to new, lower-price generics. This includes ensuring that Medicare Advantage and Part D plans cover all generic products at launch, particularly first generics, or requiring Part D plans to review first generics and biosimilars within a specified time frame and provide written justifications to CMS if they are not placed on formulary after that review.

16 Centers for Medicare and Medicaid Services (January 2016) Medicare Prescription Drug Benefit Manual Chapter 6 — Part D Drugs and Formulary Requirements. Accessible at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

Conclusion

America's patients and health care system rely on generic medicines. Generics reduce costs, expand access to care, and result in greater patient adherence — ultimately keeping patients healthy and productive. This track record of success is jeopardized by market abuses that delay patient access to new generics. To realize the full value of new generic competition, as well as savings from new biosimilar medicines, policymakers at CMS and in Congress must ensure rapid plan coverage of new generics and biosimilars.

Methodology

On behalf of AAM, Avalere analyzed plan benefit and formulary data for 2022 from the Medicare Part D Public Use Files released in October 2021. Avalere included in the analyses the corresponding brand products matched using drug name from first-to-market generic drugs approved between and marketed from 2016 to 2021. Avalere excludes products that have not launched at the time of the analysis, as well as products that were approved from October-December of each year. This assessment includes generic drugs under 180-day exclusivity periods and those for which there are no prohibitive patents or exclusivities.

Consistent with previous analyses, results are not weighted by enrollment.

Appendix

Percent of New Generics Covered by Medicare Part D and Commercial Plans by Formulary Year

Launch Year	2016		2017		2018		2019		2020		2021		2022	
	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%
2017			12%	58%	25%	73%	58%	73%	65%	76%	65%	76%	64%	89%
2018					17%	39%	27%	49%	51%	59%	54%	60%	54%	84%
2019							31%	44%	59%	60%	72%	61%	72%	88%
2020									21%	55%	41%	66%	60%	90%
2021											23%	86%	46%	89%

MEDICARE PART D (M) COMMERCIAL (C)

Source: Analysis of Medicare Part D formulary data from CMS and commercial market formulary data from Managed Markets Insight & Technology, LLC.

accessiblemeds.org

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