Persistent growth in PBM formulary exclusions continues to raise concerns about patient access

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Introduction

Pharmacy benefit managers (PBMs) act as intermediaries between pharmaceutical manufacturers and their clients (insurers, employers, and other payers) to negotiate coverage and reimbursement arrangements for prescription medicines. In total, PBMs administer prescription drug benefits for more than 266 million publicly and privately insured Americans.[1] By creating and managing prescription medicine formularies that determine which medicines are covered, the cost-share patients pay, and any utilization management or restrictions on medicine use, PBMs exert enormous control over patients' access to medicines and whether or not they are affordable to patients.[2] The PBM market has become increasingly consolidated, with the 3 largest PBMs — CVS Caremark (owned by CVS Health), OptumRx (owned by UnitedHealth Group), and Express Scripts (owned by Cigna), collectively known as the "Big 3 PBMs" — controlling 80% of the market today.[3]

In recent years, the Big 3 PBMs have also combined with health insurers, specialty and mail-order pharmacies, and provider groups to form large vertically integrated organizations. This increasing horizontal and vertical concentration provides PBMs with significant negotiating power, which they leverage to negotiate deep discounts on medicines from manufacturers — often in exchange for inclusion on formularies. Beyond formulary placement, PBMs also employ a variety of tools to manage the use of medicines, such as utilization management (eg, prior authorization and step therapy), cost-sharing tiers, and restrictive pharmacy networks.[4]

This analysis focuses on formulary exclusions and is the third in a series examining trends over the past decade. The practice of formulary exclusions began in 2011, when CVS Caremark became the first PBM to exclude a subset of medicines from its standard formulary for the 2012 plan year.[5] Express Scripts adopted the practice for the 2014 plan year[6] and OptumRx followed suit in 2016.[7]

In 2020, Xcenda (now known as Cencora Global Consulting Services) evaluated the formulary exclusion lists of CVS Caremark, Express Scripts, and OptumRx, and found that the PBMs' standard formularies excluded nearly 850 unique prescription drugs that year.[8] Two years later, a follow-up analysis revealed the pace of formulary exclusions had accelerated at an astonishing rate, with a total of 1,156 unique medicines on their standard formulary exclusion lists, representing a 36% increase. Among these formulary exclusions were a growing number of biosimilars, despite the fact that these options can offer lower out-of-pocket costs for patients.[9]

In 2025, the 3 largest PBMs placed a total of

1,453 unique medicines

on their standard formulary exclusion lists.

Since Xcenda's analysis in 2022, PBM management of patient access to lower-cost treatment options has come under scrutiny in Congress and by the Federal Trade Commission (FTC). These investigations have noted that the Big 3 PBMs are often compensated based on list price-based rebates and fees, and as a result, they have incentives to prefer medicines with higher list prices and large rebates over lower-cost alternatives.[10]

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PBMs' preference for medicines with high list prices and large rebates is supported by increasing evidence that PBMs exclude coverage of generic and biosimilar medicines, even if they may offer lower costs to employers and patients.[11,12]

PBMs have a vested interest in having drug prices remain high and extracting rebates from these higher prices.

In particular, this trend was evident with the launch of adalimumab biosimilars in 2023. For more than a year, these biosimilars struggled to gain market share. By the first quarter of 2024, adalimumab biosimilars had captured just 1% of the market, with the Big 3 PBMs continuing to favor the brand name version of the medicine on formularies. This was true despite estimates showing that substituting biosimilars could lower employer costs by 58% and patient costs by 68%.[11]

Increasingly, slower inclusion of generics on formularies also signals that PBMs' preferences for products with higher list prices may be impeding access to generic medicines as well. Trends toward the slower adoption of generics and FTC scrutiny warrant an exploration of how formulary exclusions may play a role.

The purpose of this current analysis is to assess the degree of continued growth in formulary exclusions among the Big 3 PBMs in recent years, and to evaluate the extent of formulary exclusions among biosimilars and generics specifically. Further, the goal is to provide relevant observations about formulary exclusions and emerging trends influenced by vertical integration among PBMs in the pharmaceutical market.

Methodology

For this updated report, Cencora updated its database of the standard commercial formulary exclusion lists for Express Scripts, CVS Caremark, and OptumRx to encompass 2014 to 2025.[13] The drugs excluded from formularies in 2023, 2024, and 2025 were added to the database that was updated for the 2022 white paper. Our database of formulary exclusions was developed by a team of PharmDs who standardized the therapeutic categories and classes to facilitate comparison across the 3 PBMs. The resulting database allowed for the analysis of formulary exclusion trends across PBMs, years, and therapeutic areas. Cencora also identified biosimilars and unbranded biologics.

To calculate cumulative totals over the study period, we classified medicines as "excluded" if they were placed on 1 or more of the Big 3 PBMs' formulary exclusion lists for at least 1 plan year between 2014 and 2025. Duplicate exclusions were removed when analyzing market-wide and therapeutic trends (ie, unique medicines were not counted more than once if they appeared on more than 1 list or for more than 1 year during the period).

Generic medicines were defined as multisource drugs using the Micromedex RED BOOK. Multisource drugs are available through more than 1 manufacturer but have the same active ingredients and dosage form.

Biosimilars and biologics were identified using the Food and Drug Administration's (FDA's) Purple Book as products licensed under the Section 351(k) pathway and Section 351(a) pathway, respectively. Biologics that had unbranded versions made by the same manufacturer as the reference product were classified as branded products for the sake of calculating single- vs. multisource exclusions.

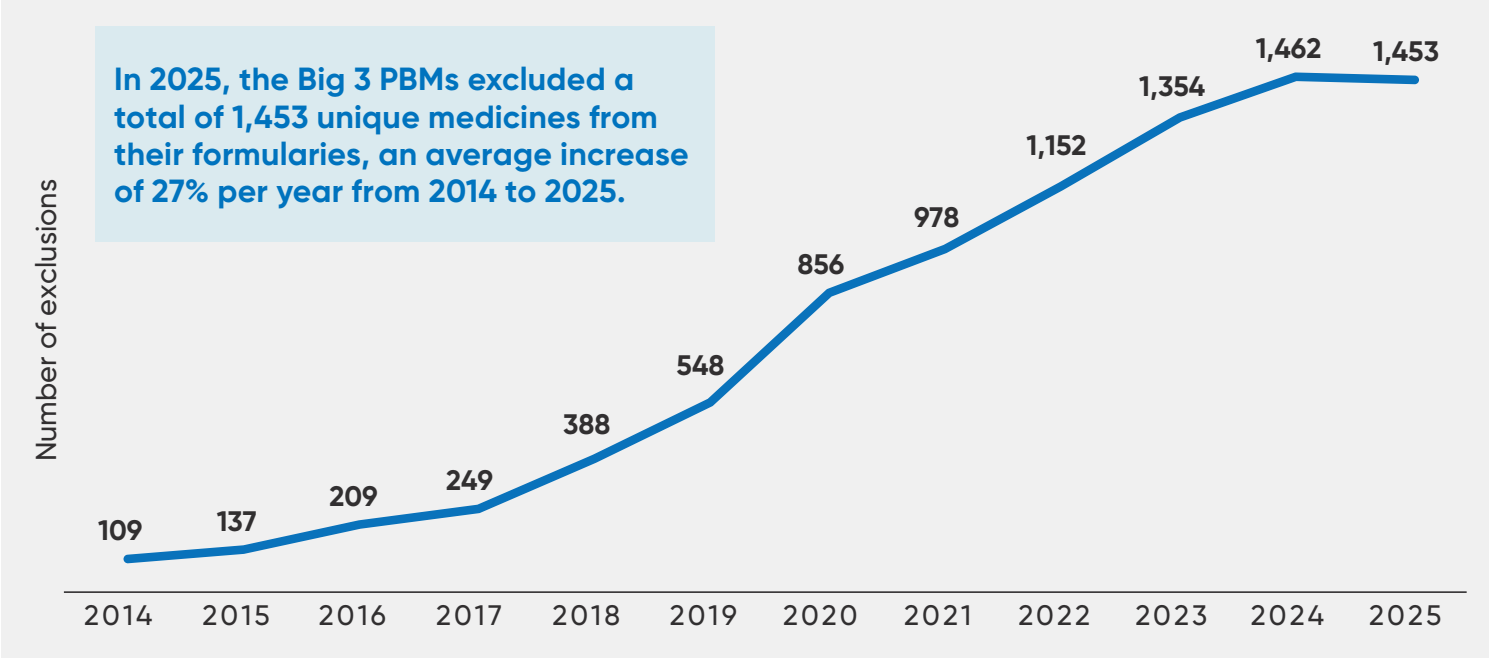
Data shown in the figures throughout are based on a compilation of CVS Caremark, Express Scripts, and OptumRx's formulary exclusion listings from 2014 to 2025.

Findings

Market-wide trends

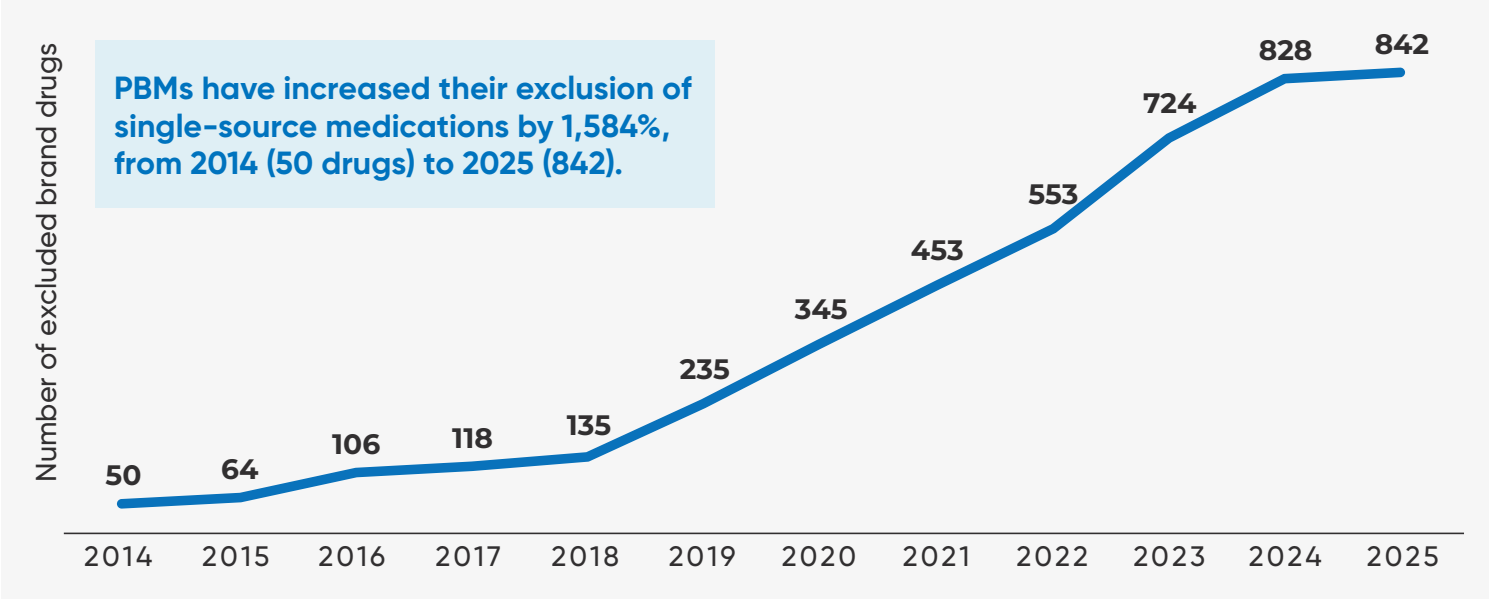
In 2025, 1,453 unique prescription medicines were excluded from the standard formularies of at least 1 of the Big 3 PBMs, a 1,233% increase from 2014, when 109 medicines were excluded.[a] For the 12-year period from 2014 to 2025, the number of medicines excluded by 1 or more of the Big 3 PBMs increased by an average of 27% per year, as shown in **Figure 1**.

Figure 1. Number of prescription medications excluded from 1 or more of the Big 3 PBMs' formularies by year (2014-2025)



As **Figure 2** shows, PBMs are also increasingly excluding single-source (ie, brand) medicines in many cases where there may be few therapeutic alternatives and options may be limited. Of the 1,453 unique prescription medicines that were excluded by 1 or more of the Big 3 PBMs in 2025, 842 (58%) were single-source brand medicines at the time of exclusion. The number of single-source medicines excluded from at least 1 Big 3 PBM formulary increased from 50 in 2014 to 842 in 2025 — a 1,584% increase.

Figure 2. Number of single-source (brand) medicines excluded from 1 or more of the Big 3 PBMs' formularies by year (2014-2025)



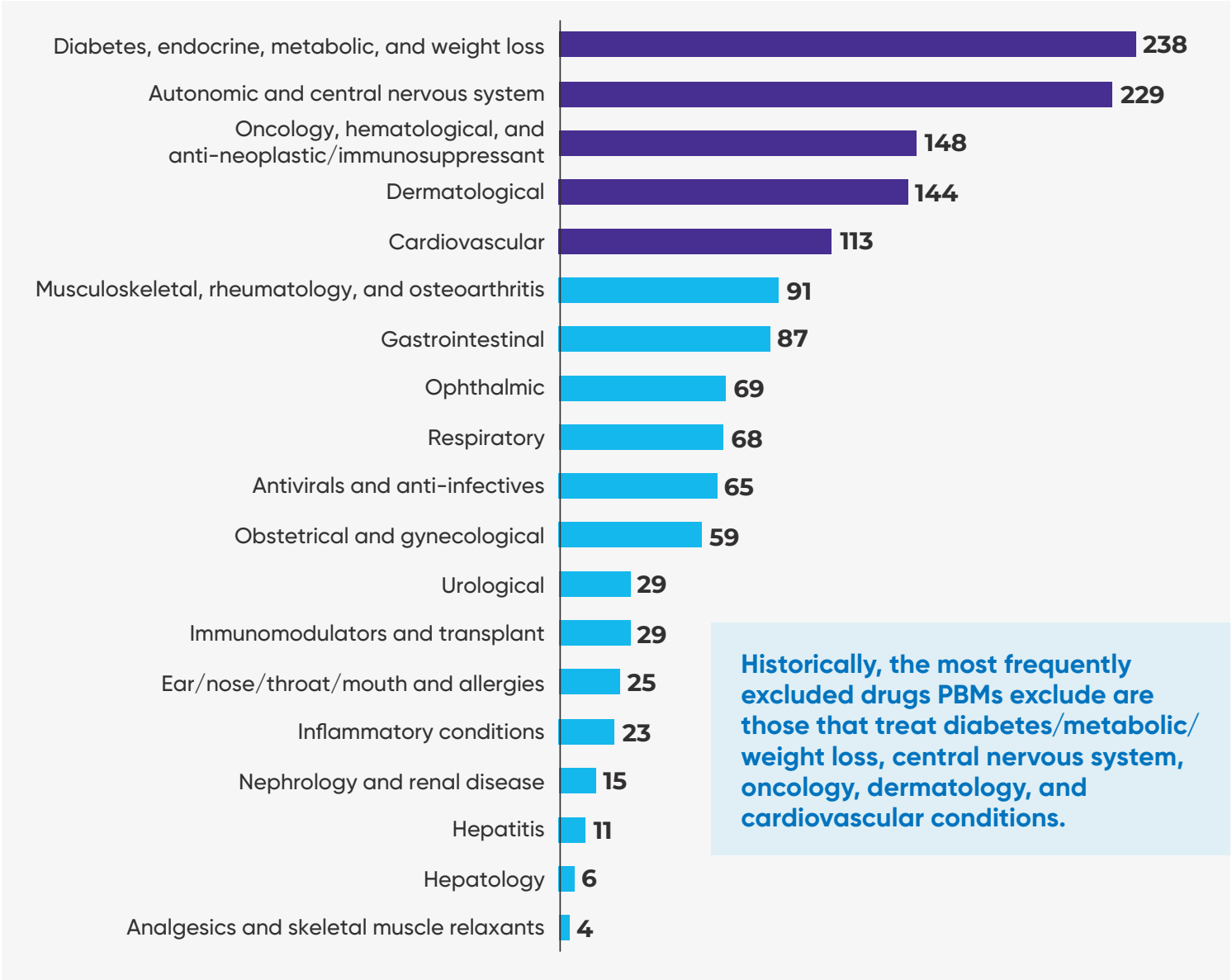
[a] In 2014, medicines were either excluded from CVS Caremark, Express Scripts, or both. OptumRx did not begin excluding medicines from its formulary until 2016.

Therapeutic area trend

Although patients with chronic conditions typically require long-term, continuous treatment to slow or prevent the progression of disease, medicines to treat these conditions — including insulin, antidepressants, antipsychotics, and antiarrhythmics — are most frequently targeted by PBM formulary exclusions. In cases where formulary exclusions may interrupt, delay, or prevent timely access to treatment, patients may be unable to adhere to their prescription medication regimens, leading to disease exacerbation and poorer health outcomes.[14,15]

Figure 3 shows the exclusions by therapeutic area. As in past years, in 2025, the medicines most often excluded by PBMs are treatments for diabetes/metabolic/weight loss, neurology, oncology, dermatology, and cardiovascular conditions.

Figure 3. Number of unique medicines excluded (n=1,453) for at least 1 plan year by 1 or more of the Big 3 PBMs, by therapy area (2014-2025)



Historically, the most frequently excluded drugs PBMs exclude are those that treat diabetes/metabolic/weight loss, central nervous system, oncology, dermatology, and cardiovascular conditions.

Generics

Research shows many generics are experiencing slower-than-expected adoption. Historically, generics typically gained 80% or more of the market share within months.[16] However, in 2021, the top 10 new generics averaged a 70% market share of total prescriptions, suggesting a potential degradation in generics' uptake. Additionally, evidence suggests that formulary access may be playing a role. One analysis found that new generics launched in 2016 were covered by commercial plans just 46% of the time that year. It was not until 6 years after these products launched that coverage reached 90% in 2022.[16]

The findings presented here demonstrate that generic exclusions are increasing, with 611 generic medicines excluded by at least 1 PBM in 2025, as shown in **Figure 4**. These exclusions represent 42% of the 1,453 unique prescription medicines that were excluded by 1 or more of the Big 3 PBMs for 2025. While year-over-year exclusions have grown more slowly than for brand medicines, generic drug exclusions have increased 936% over the last 12 years (from 59 in 2014 to 611 in 2025).

There may be clinically appropriate reasons for PBMs to exclude generic drugs from formularies that may not disadvantage patients (eg, drugs with better efficacy and/or safety are available, etc). However, the growth in exclusions of generics raises concerns that there are significant financial incentives slowing the adoption of generics.[18-20]

The greatest source of revenue that PBMs secure is rebates and fees from pharmaceutical manufacturers.[21] As a result, PBMs may favor drugs that have high list prices with higher rebates over similar drugs with lower net costs and lower rebates. The logical extension is that PBMs have a vested interest in having drug prices remain high and extracting rebates from these higher prices.[18] This practice negatively impacts beneficiaries with deductibles or coinsurance, whose out-of-pocket costs are typically based on the list price.

Because of these financial dynamics, generic drugs and, by extension, patients are clearly disadvantaged.

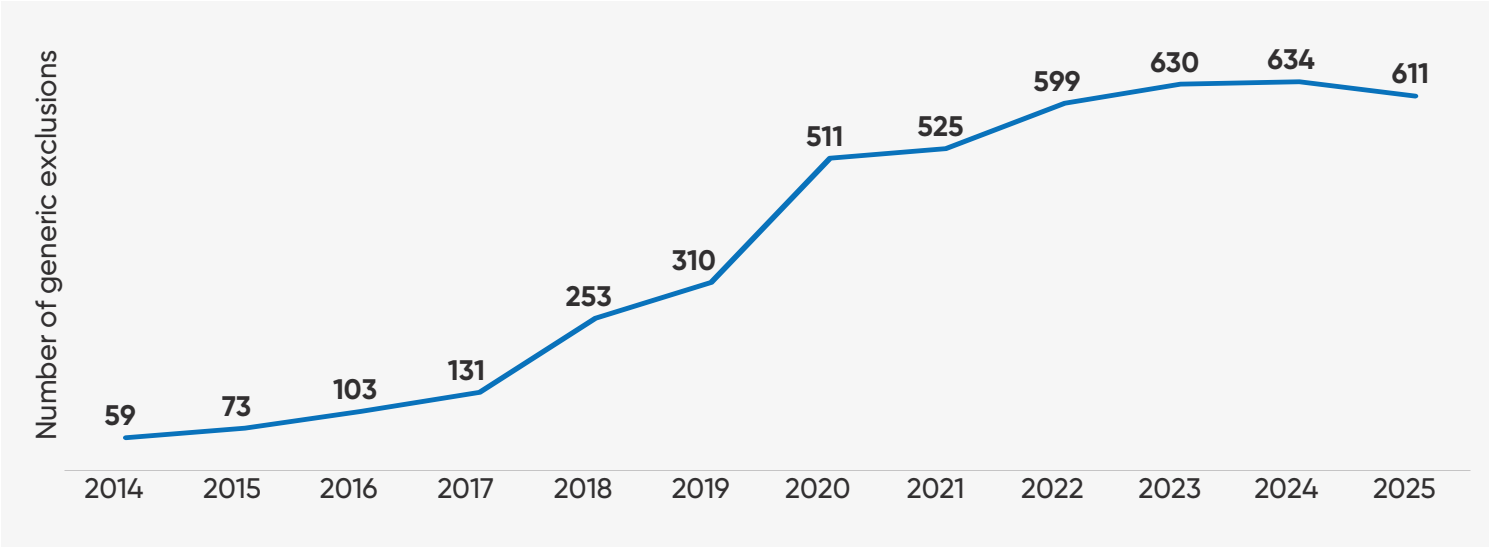
Case Study: Vertical Integration and Mark-Ups on Specialty Generics

While PBMs have been slowing the adoption of generics on formularies, they have also found ways to make dispensing generic medicines from PBM-owned pharmacies exceedingly profitable. As noted previously, the Big 3 PBMs have, over the years, combined with health insurers, specialty and mail-order pharmacies, and provider groups to form large vertically integrated organizations.

This increasing vertical integration provides PBMs with enormous control over patient access to medicines, including by steering patients to their own PBM-affiliated pharmacies and away from unaffiliated pharmacies. In these settings, PBMs mark up the cost of low-cost generic drugs and reimburse affiliated pharmacies significantly more than their pharmacies' acquisition costs.

In fact, a recent FTC investigation concluded that specialty generic drugs represented a growing profit center for the Big 3 PBMs and their affiliated pharmacies.[17] The commission found that the Big 3 PBMs marked up numerous specialty generic drugs by hundreds and thousands of percent, with the majority of the most highly marked-up drugs dispensed by the PBMs' own affiliated pharmacies.

Figure 4. Number of multisource (generic) medicines excluded from 1 or more of the Big 3 PBMs' formularies by year (2014-2025)



Biosimilars

Previous editions of the formulary exclusion report have highlighted how the Big 3 PBMs started excluding lower-cost biosimilars in favor of their reference products. Below, we describe the growing trend among these PBMs of excluding biosimilars from their formularies.

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing biologic medicine (known as a reference product) and is approved by the FDA after rigorous evaluation and testing by the manufacturer.[22] The first biosimilar was launched in 2015; as of February 2025, there were 44 biosimilars on the market in the US.[23,24]

Biosimilars directly compete with reference products, resulting in fierce competition for formulary placement among both biologics and biosimilars. In general, biosimilars are lower priced than the reference product, offering savings to payers, patients, employers, and taxpayers. However, PBMs' financial incentives have resulted in an increasing number of lower list-priced biosimilars being excluded from formularies.

OptumRx was the first of the 3 largest PBMs to begin excluding biosimilars, starting in 2018. CVS Caremark and Express Scripts followed shortly after in 2019. Since 2022, when a growing number of biosimilars were entering the market, the Big 3 PBMs began increasingly excluding these products from their formularies. Since then, the practice has skyrocketed.

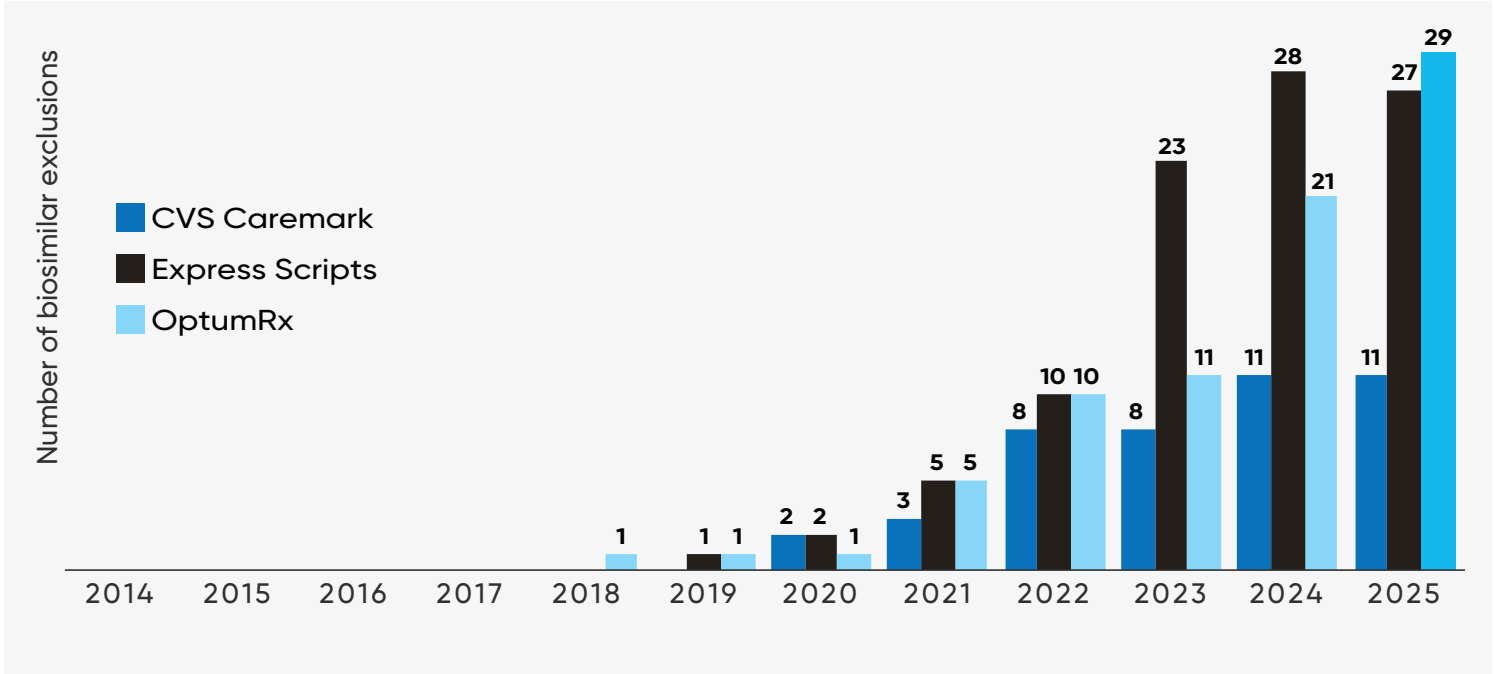
Vertical integration and the emergence of PBM-affiliated biosimilars

While the Big 3 PBMs have been excluding Humira biosimilars since the launch of these products, each of the Big 3 last year launched biosimilars produced through their own affiliates. Reports indicate PBMs are providing preferential coverage for these products while excluding reference products and non-PBM-affiliated biosimilars from formularies. In fact, as reported by Forbes, nearly all adalimumab biosimilars are excluded from formularies of the Big 3 PBMs, except for their own affiliated products.[27] And although these products have a lower list price than the brand, they do not have the lowest price relative to other available biosimilars.

Moving forward, vertical integration among PBMs may continue to play a role in driving utilization toward products in which PBMs have a financial stake, regardless of whether the PBMs' biosimilars are the lowest-cost option for patients.

As **Figure 5** shows, Express Scripts increased the number of biosimilars excluded from its formulary by 170% between 2022 and 2025 (from 10 biosimilars to 27). OptumRx has ramped up its biosimilar exclusions by 190% since 2022 (from 10 biosimilars to 29). CVS Caremark's biosimilar exclusions, by comparison, have increased relatively moderately: from 8 in 2022 to 11 by 2025 (a 38% increase). In total, 37 biosimilars have been excluded in 2025 from the formulary of at least 1 of the 3 largest PBMs for at least a year — representing a 164% increase since 2022 alone.

Figure 5. Number of biosimilars excluded from 1 or more of the Big 3 PBMs' formularies by year and PBM (2014-2025)



In 2020, the Department of Health and Human Services, Office of Inspector General indicated that PBMs may have incentives to penalize manufacturers for reducing list prices, including by removing medicines from formulary or placing them on less favorable cost-sharing tiers.[25] Sensitivity to these preferences is reflected in the decision by many biosimilar manufacturers to offer both high list price biosimilar products with large rebates in addition to low list price versions of their products. This trend has been particularly apparent with the launch of Humira biosimilars, where the majority of biosimilar manufacturers pursued this strategy.[26]

Conclusions

After more than 2 decades of horizontal and vertical consolidation, the Big 3 PBMs have come to wield enormous control over which medications patients can access and the degree to which they are affordable. The findings presented here show that the number of medicines excluded from the standard commercial formularies of the nation's 3 largest PBMs has grown dramatically since this practice began, increasing by 1,584% since 2014. These trends are particularly troubling for patients who may require treatment with a formulary-excluded medicine and may be forced to pay the full price out of pocket or undertake a burdensome appeals process, which may ultimately delay treatment.

Increasing vertical integration between PBMs, insurers, and pharmacies also appears to be intensifying misaligned incentives that have been shown to encourage these large healthcare conglomerates to prefer medicines with higher list prices over lower-cost alternatives. The findings presented here indicate these incentives may have contributed to the more than 900% increase in generic formulary exclusions since 2014 and could be playing a role in the slower adoption of generics in the market today. Similar trends are apparent among emerging biosimilars. While the availability of biosimilars competing for coverage under the pharmacy benefit has increased dramatically over the past few years, the number of biosimilars excluded from at least 1 of the 3 largest PBM formularies for at least a year has increased by 164% since 2022 alone, significantly limiting patient access to these lower-cost treatment options.

The accelerating trend of PBMs excluding generics and biosimilars from formularies is particularly troublesome for patients. PBMs and health plans have increasingly shifted healthcare costs onto patients through high deductibles and coinsurance, where they are typically required to pay a cost-share based on the list price of a medicine. These patients face higher out-of-pocket costs when lower-cost alternatives, such as generics or biosimilars, are excluded from coverage in preference for products with higher list prices and rebates.

Increasing consolidation of PBMs, insurers, and pharmacies to form vertically integrated healthcare behemoths is additionally alarming, as it has also enabled these entities to engage in anticompetitive business practices that may increase costs for patients, employers, and the healthcare system. PBMs and their vertically integrated entities have been shown to steer patients toward their own pharmacy, toward their own private-label biosimilars, and toward highly rebated medicines instead of toward generic alternatives, regardless of whether these are the lowest cost or most convenient options for patients. Through these actions, PBMs and their parent companies inflate their own profits, while premiums and out-of-pocket costs increase for patients.

Unfortunately, in the absence of changes to underlying financial incentives that drive PBMs' preferences for high list prices and rebates, much of this anticompetitive behavior will continue, often to the detriment of patients and competition in the pharmaceutical marketplace.

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