

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

May 2022

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Introduction

Pharmacy benefit managers (PBMs) typically negotiate discounts and rebates with pharmaceutical manufacturers on behalf of their clients (insurers, employers, and other payers) to create and manage prescription medicine formularies. The PBM market is highly consolidated, with just 3 PBMs—CVS Caremark, Express Scripts, and OptumRx—handling 80% of all prescriptions in the United States (US).¹

In addition to their concentrated negotiating power, PBMs have a variety of tools they can leverage to achieve deep discounts and rebates on medicines, including placing medicines on preferred or nonpreferred cost-sharing tiers, restricting access with utilization management requirements like prior authorization and step therapy, and excluding medicines from formularies altogether.²

Formulary exclusions can limit patient and provider choice and may prevent a patient from accessing a particular medicine unless they pay completely out of pocket or undertake a burdensome appeals or exceptions process.^{3,4} 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 began in 2016.⁷

In 2020, Xcenda evaluated the formulary exclusion lists of CVS Caremark, Express Scripts, and OptumRx and found that the PBMs' standard formularies excluded almost 850 unique prescription drugs that year.⁸ Since then, the pace of formulary exclusions has continued at an astonishing rate. In 2022, the 3 largest PBMs placed a total of 1,156 unique medicines on their standard formulary-exclusion lists.

Historically, PBM exclusions have focused on medicines with generic equivalents or classes where multiple products have been shown to achieve similar clinical outcomes. **Now, PBMs are often excluding medicines for conditions where it is particularly important for patients and physicians to have multiple treatment options, such as oncology and autoimmune disorders.** This white paper provides general observations about PBM formulary exclusions and these emerging trends.

Methodology

In 2020, Xcenda created a database of the 2014 to 2020 standard commercial formulary exclusion lists for Express Scripts, CVS Caremark, and OptumRx.⁹⁻¹¹ We recently updated the 2020 paper by adding drugs excluded from formularies in 2021 and 2022 to the original database created for the 2020 white paper. This database 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, therapeutic areas, and for single- vs multi-source medicines. The database was compared to the National Cancer Institute's comprehensive list of approved drugs to identify medicines used in cancer treatment across multiple therapeutic classes.¹² Xcenda also identified biosimilar products and drugs approved under the Food and Drug Administration's (FDA) expedited pathways.

To calculate cumulative totals over the study period, we classified medicines as "excluded" if they were placed on 1 or more of the 3 PBM formulary exclusion lists for at least 1 plan year between 2014 and 2022. Duplicate exclusions were removed when analyzing market-wide and therapeutic area 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).

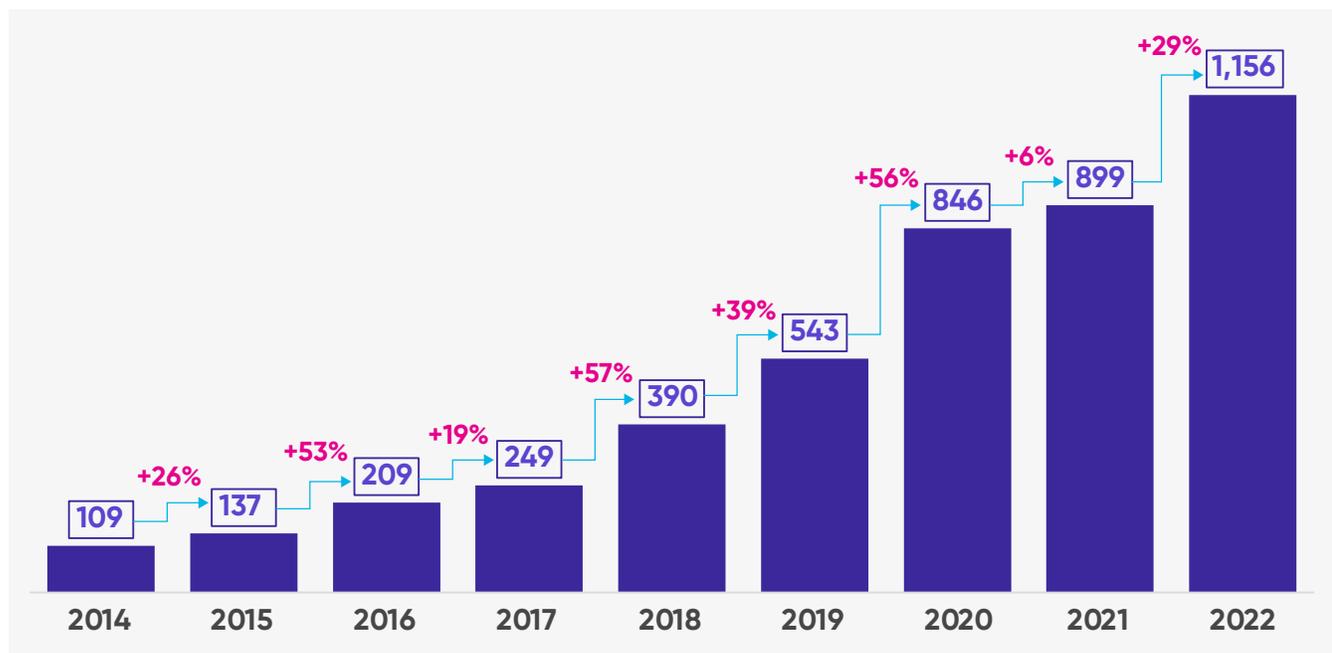
Data shown in the figures throughout are based on a compilation of CVS Caremark, Express Scripts, and OptumRx's formulary exclusion listings from 2014 to 2022.

Findings

Market-wide trends

In 2022, 1,156 unique prescription medicines were excluded from the standard formularies of at least 1 of the 3 PBMs, a 961% increase from 2014, when 109 medicines were excluded (**Figure 1**).^a From 2014 to 2022, the number of medicines excluded by 1 or more PBM increased by an average of 34% per year.

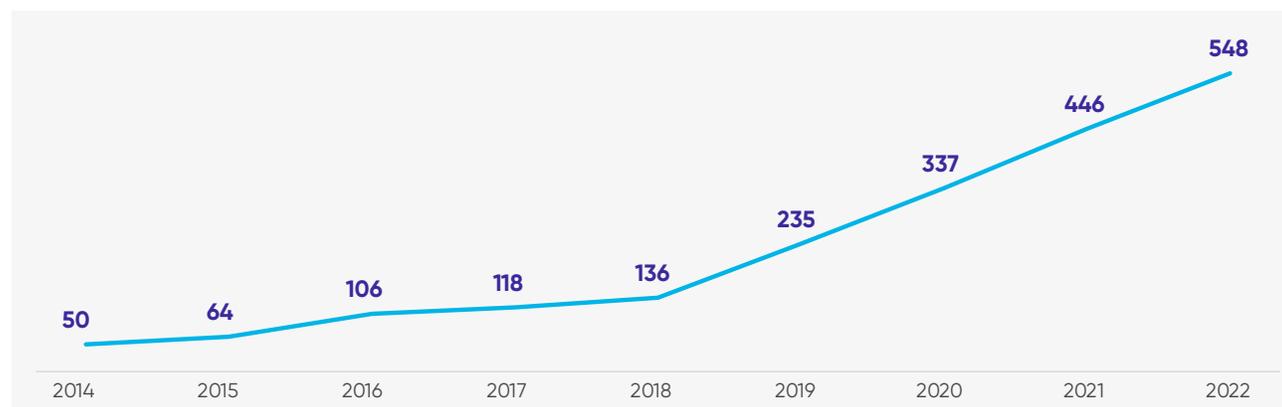
Figure 1. Number of prescription medications excluded from 1 or more PBM formulary, by year



^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.

Of the 1,357 unique prescription medicines that were excluded by 1 or more PBM for at least 1 year over the study period, 654 (48%) were single-source brand medicines at the time of exclusion (**Figure 2**). (This number—1,357—is higher than the 1,156 total for 2022 because some drugs were excluded and then added back to the formulary.) The number of single-source medicines excluded from at least 1 PBM formulary increased from 50 in 2014 to 548 in 2022—a 996% increase.

Figure 2. Number of single-source medicines excluded from 1 or more PBM formulary, by year



Therapeutic area trends

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 (**Table 1**). 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 exacerbations and poorer health outcomes.^{13,14}

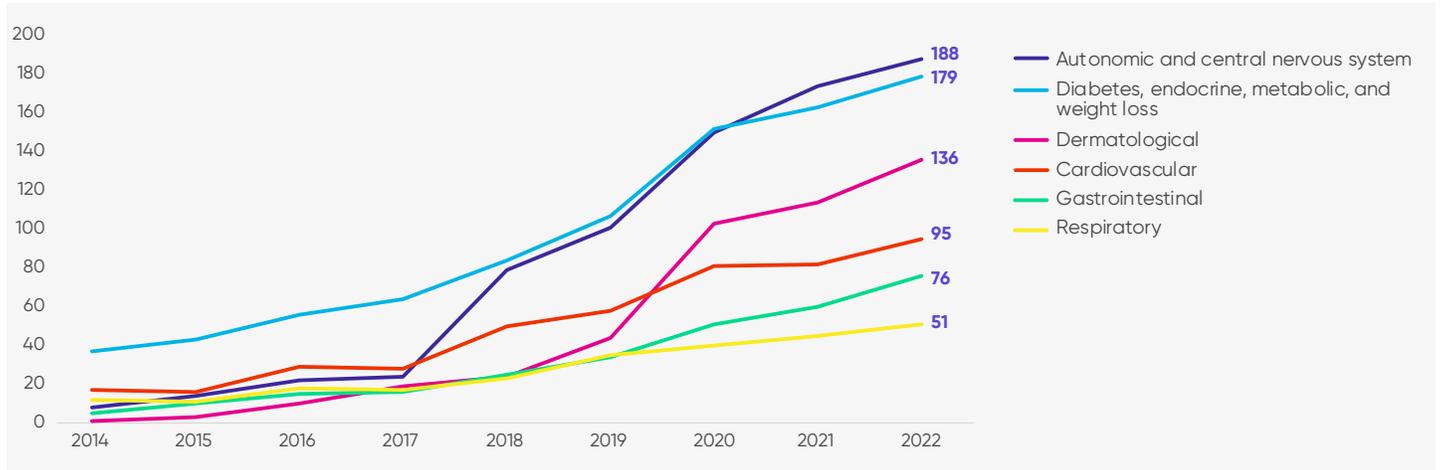
Table 1. Therapeutic areas for medicines excluded from 1 or more PBM formulary, 2014–2022

Rank	Therapeutic area	# of medicines excluded*	% of total exclusions
1	Autonomic and central nervous system	225	16.6%
2	Diabetes, endocrine, metabolic, and weight loss	209	15.4%
3	Dermatological	151	11.1%
4	Oncology, hematological, and antineoplastic/immunosuppressant	117	8.6%
5	Cardiovascular	109	8.0%
6	Gastrointestinal	82	6.0%
7	Musculoskeletal, rheumatology, and osteoarthritis	80	5.9%
8	Respiratory	78	5.7%
9	Obstetrical and gynecological	65	4.8%
10	Ophthalmic	64	4.7%
11	Antivirals and anti-infectives	61	4.5%
12	Ear/nose/throat/mouth and allergies	32	2.4%
13	Urological	28	2.1%
14	Inflammatory conditions	20	1.5%
15	Hepatitis	17	1.3%
16	Immunomodulators and transplant	9	0.7%
17	Nephrology and renal disease	8	0.6%
18	Hepatology	2	0.1%
Total		1,357	100%

* Unique medicines excluded for at least 1 plan year by 1 or more PBM.

The number of medicines facing exclusion climbed steeply year over year for several therapeutic areas (**Figure 3**). Conditions disproportionately affected by formulary exclusions included diabetes, autonomic and central nervous system disorders, cardiovascular disease, and dermatological conditions. For example, compared to 2014, almost 6 times more cardiovascular treatments were excluded from 1 or more PBM formulary in 2022.

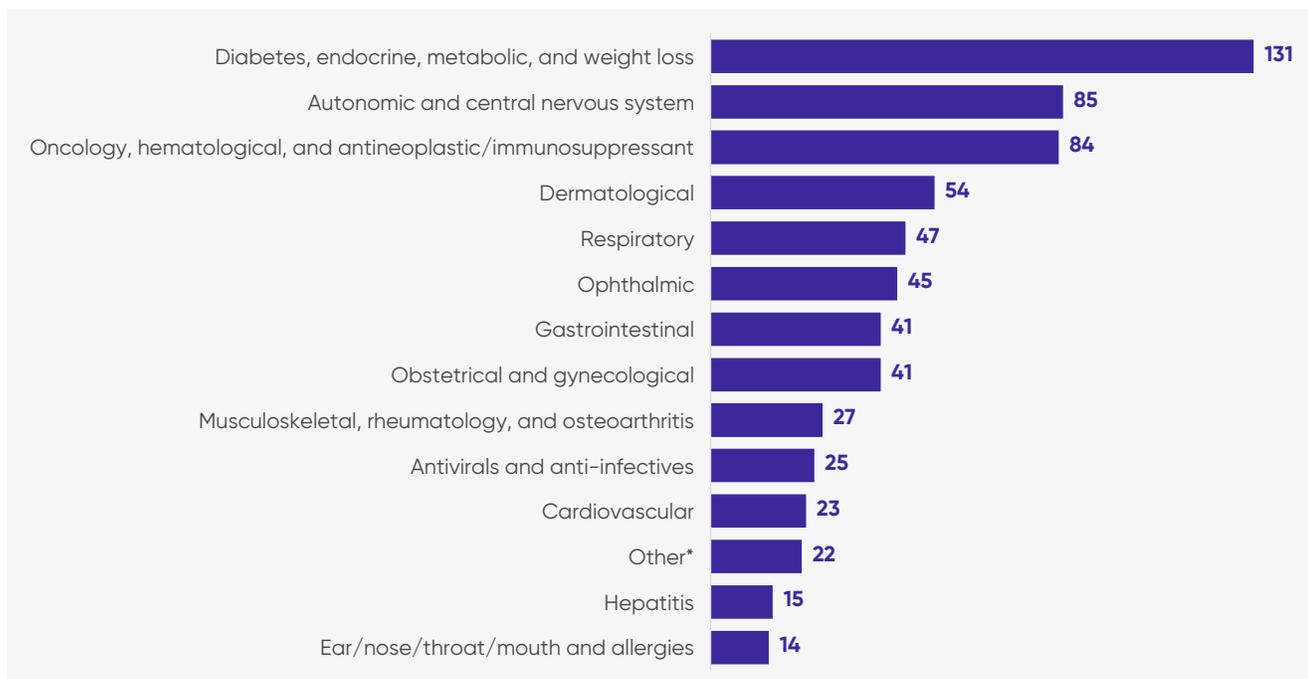
Figure 3. Number of unique medicines excluded from 1 or more PBM formulary in select therapeutic areas, by year



Autonomic and central nervous system medicines excluded by at least 1 PBM increased by 2,350% over the study period. This therapy area, which includes medicines to treat multiple sclerosis, mental health disorders, Parkinson’s disease, epilepsy, and other serious and complex conditions, experienced particularly dramatic growth in exclusions from 2017 to 2022, when the number of exclusions increased from 24 to 188—an annualized increase of 51% during the 6-year period.

In many instances, PBM formularies excluded single-source medicines used to treat common chronic conditions (**Figure 4**). Exclusions of single-source medicines can be particularly problematic for chronic conditions where the nature of the disease progression or a patient’s lifestyle require them to cycle through several treatments over the course of their lifetime as they develop resistance to or diminishing results from medicines over time.¹⁵

Figure 4. Number of single-source medicines excluded from 1 or more PBM formulary between 2014 and 2022, by therapy area (n=654)

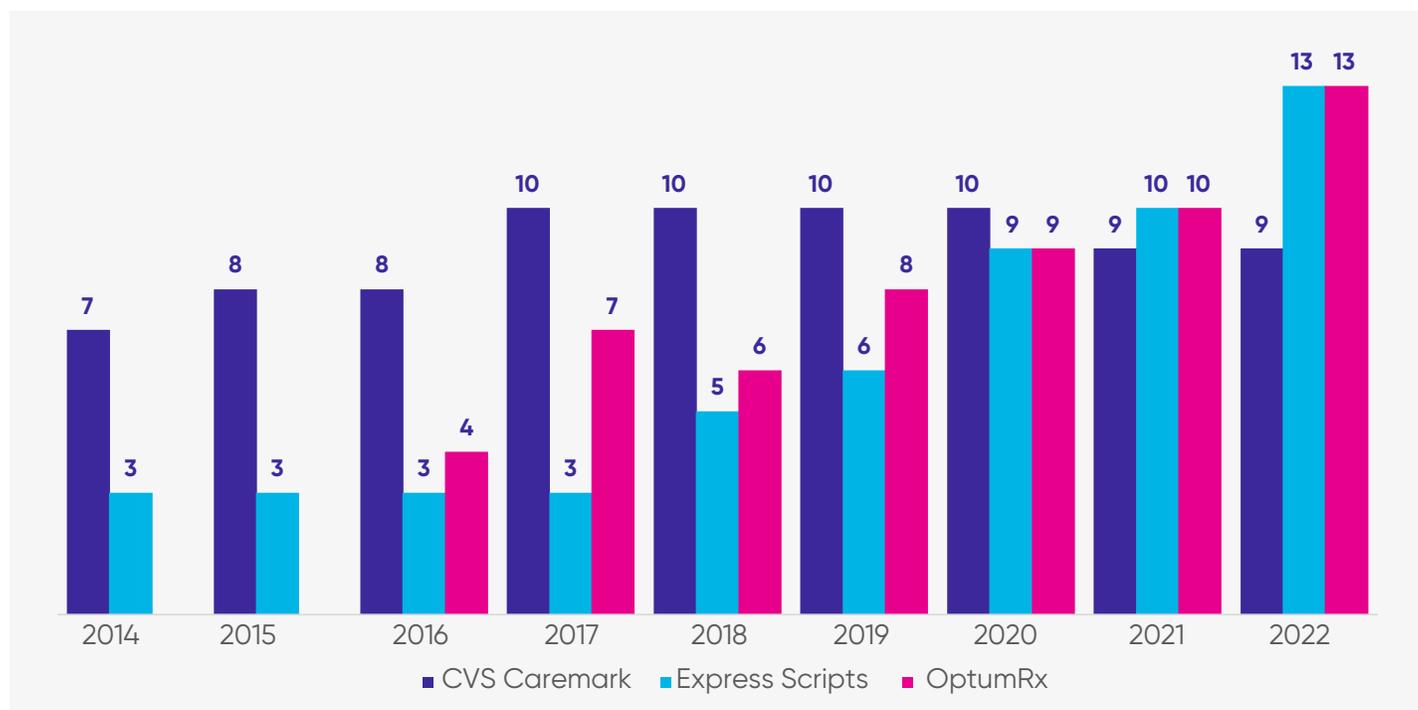


* Other includes immunomodulators, nephrology, renal disease, allergies, urological, and inflammatory conditions.



Single-source medicines to treat diabetes and related conditions faced the greatest number of formulary exclusions over the study period. Insulin was among the first classes of medicine to face formulary exclusions, and the number of insulins excluded has increased over time (Figure 5). In 2014, Express Scripts and CVS Caremark excluded 6 and 7 insulins, respectively. OptumRx excluded 4 insulins in 2016, its first year with an exclusion list. As of 2022, insulins have faced 193 total plan-years of exclusion across the 3 PBMs since 2014.

Figure 5. Number of insulins excluded from 1 or more formulary, by year and PBM



Exclusions, potentially driven in part by misaligned PBM incentives, have had an extensive impact on patients' access to insulin over the study period. Lower list-priced insulins have been available since 2016—including follow-on insulins, "authorized generic" insulins,^b and, more recently, biosimilar insulins. However, PBMs often exclude these insulins from their formularies in favor of products with higher list prices and larger rebates. For example, 2 of the 3 PBMs have excluded the 2 insulin authorized generics from their formulary exclusion lists since 2020, instead favoring the higher list-priced equivalents. Remarkably, this was true even though the list prices for these authorized generic insulins can be half the list price of the brand.^{16,17}

In addition to the exclusions of authorized generic insulins, lower list-priced biosimilar insulins have also faced formulary exclusions. The first biosimilar insulin was launched in 2021. Due to prevailing market dynamics, 2 identical versions of the product were simultaneously introduced—one with a higher list price and large rebates and one with a lower list price and limited rebates—giving payers the option of which to cover. All 3 PBMs excluded the lower-list priced version in 2022, instead choosing to include the identical product with a higher list price.¹⁸

A similar dynamic was observed for authorized generic versions of direct-acting antiviral (DAA) treatments for hepatitis C virus (HCV). Two of the 3 PBMs excluded the lower list-priced authorized generic versions of HCV DAAs, instead preferring the higher list-priced equivalent product. Excluding lower list-priced medicines from formularies can substantially increase out-of-pocket costs for patients in plans using deductibles or coinsurance, where cost-sharing is typically determined based on the medicine's full list price.¹⁹ This trend of favoring higher list-priced products raises serious concerns about patient affordability and access to insulins.

^b An authorized generic medicine is a "brand name drug that is marketed without the brand name on its label." Additionally, "even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug."²⁰

Emerging trends

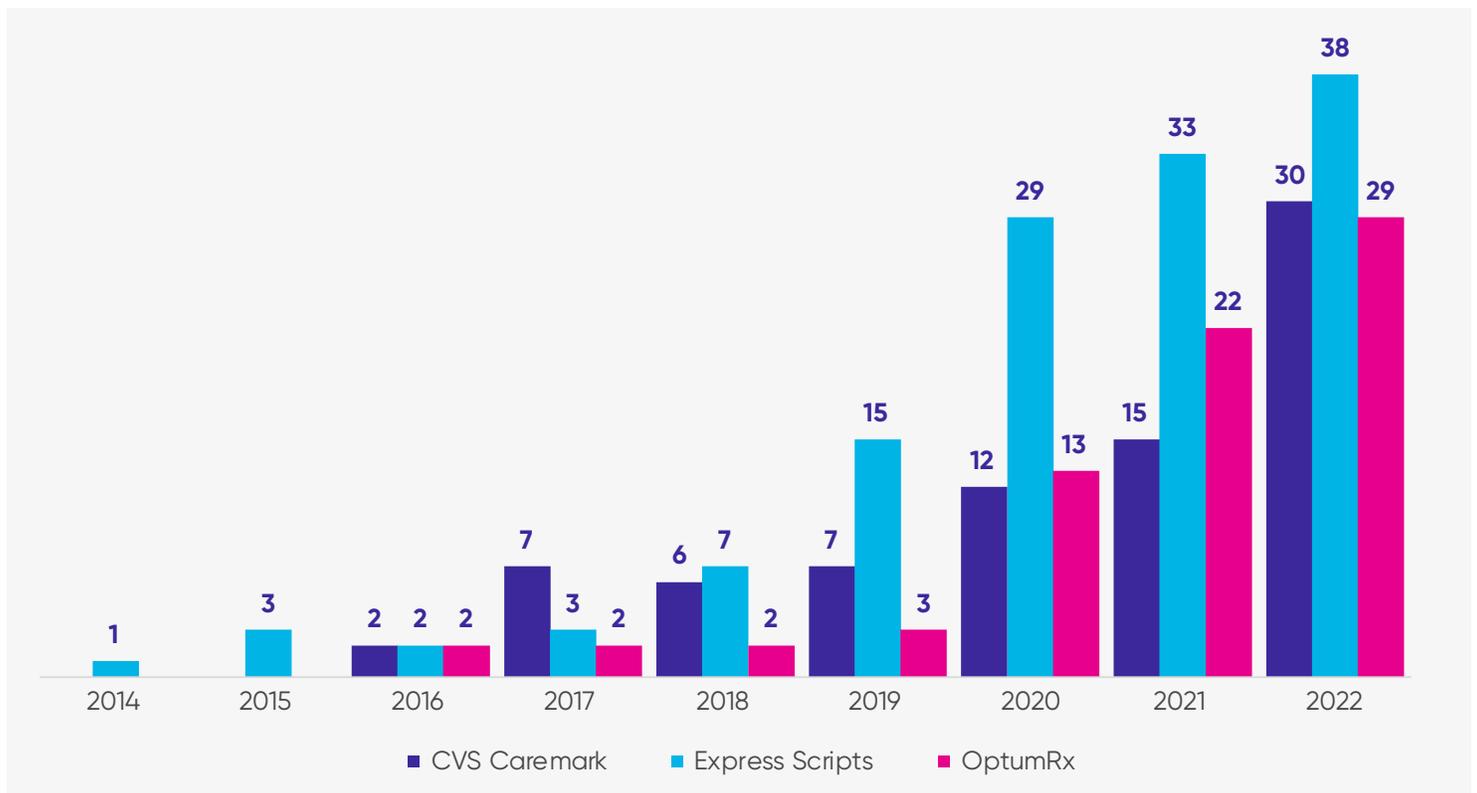
Cancer medicines and supportive therapies

Historically, cancer medicines and supportive therapies were not a major target for PBM formulary exclusions. For example, Express Scripts excluded just 1 of these medicines from its standard formulary during the first 2 years of the study period. However, in recent years, the rate of exclusions affecting patients with cancer has accelerated.

Between 2014 and 2022, Express Scripts excluded 46 unique cancer medicines and supportive therapies, representing 7% of its total exclusions during the study period.^c In comparison, CVS Caremark excluded 32 cancer and supportive-care medicines, accounting for 5% of its exclusions, and OptumRx excluded 30 medicines, accounting for 5% of its exclusions (**Figure 6**).

The highest number of oncology exclusions occurred in 2022 for each of the 3 largest PBMs. The trend in formulary exclusions for oncology medicines suggests some patients with cancer may face barriers to access for medications included in their treatment plan.

Figure 6. Number of cancer medicines and supportive therapies excluded from 1 or more formulary, by year and PBM



^c Medicines to treat cancer span several therapy areas, as defined by the National Cancer Institute.¹²

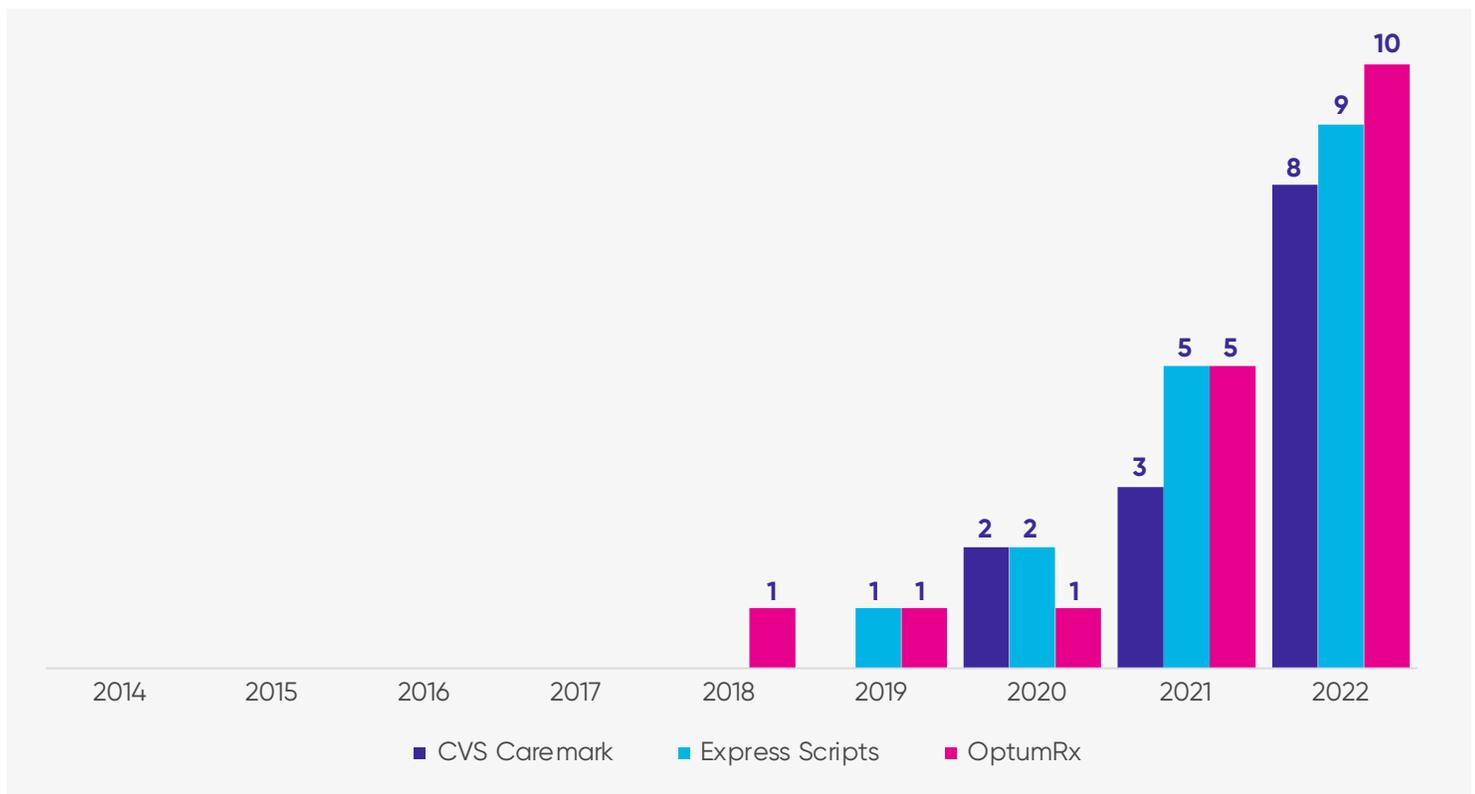
Biosimilars

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.²¹ The first biosimilar was launched in 2015 and, as of April 2022, there were 21 biosimilars on the market in the US.²²

Biosimilars directly compete with reference products, resulting in fierce competition for preferred formulary status. In general, biosimilars are lower priced than the reference product, offering savings to payers and the system as a whole. However, as previously discussed, misaligned PBM incentives have resulted in an increasing number of lower list-priced products, including biosimilars, being excluded from formularies. For patients with cost-sharing tied to the undiscounted list price of medicines, this can lead to higher out-of-pocket costs.

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. While the PBMs have taken different approaches to excluding reference products and biosimilars from their standard formularies, in total, 14 biosimilars have been excluded by at least 1 or more PBM for at least 1 year (**Figure 7**).

Figure 7. Number of biosimilars excluded from 1 or more formulary, by year and PBM



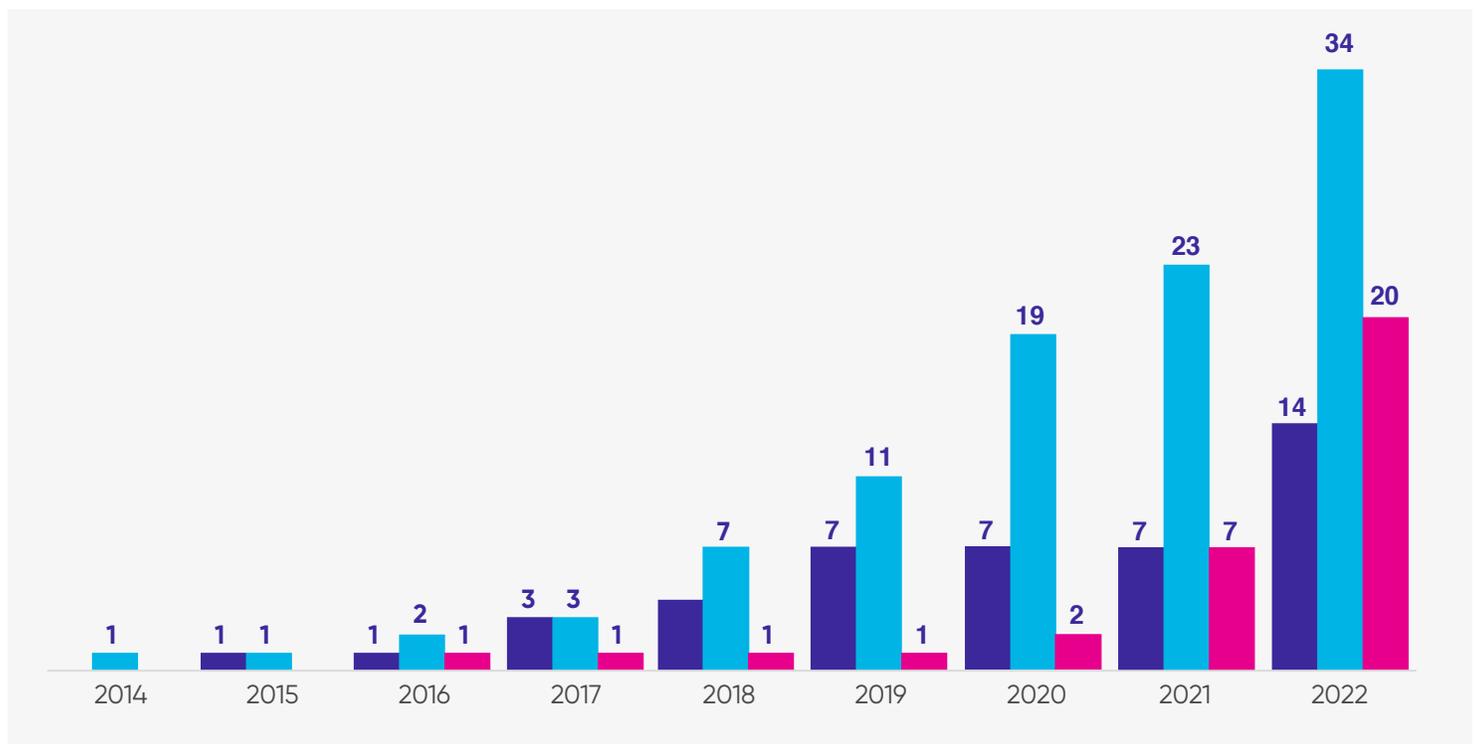
FDA expedited pathways

Congress has established multiple FDA programs to incentivize, facilitate, and expedite the development and review of new drugs, including Fast Track Designation, Breakthrough Therapy Designation, Accelerated Approval, and Priority Review.²³ These expedited pathways offer more efficient review of novel medicines that meet specific criteria and address unmet medical needs in the treatment of serious or life-threatening conditions. The programs have been successful in reducing the time it takes to get these new medicines to patients who currently have few treatment options. Prior research finds that medicines approved through an expedited review pathway provided patients with larger health gains, on average, compared to drugs approved through conventional review processes, demonstrating the immense value these products offer to patients.²⁴

In recent years, medicines approved under 1 of these 4 expedited pathways have increasingly faced exclusions from PBM formularies. In 2016, the PBMs each excluded just 1 or 2 products approved through an expedited pathway from their standard formularies (**Figure 8**). However, exclusions accelerated rapidly after 2018. In total, 178 unique products approved through an expedited pathway were excluded by 1 or more PBM for at least 1 year over the study period.

Because these medicines offer treatment options to patients with unmet medical needs, formulary exclusions undermine the intent of Congress to get safe and effective medicines to patients lacking other treatment options.

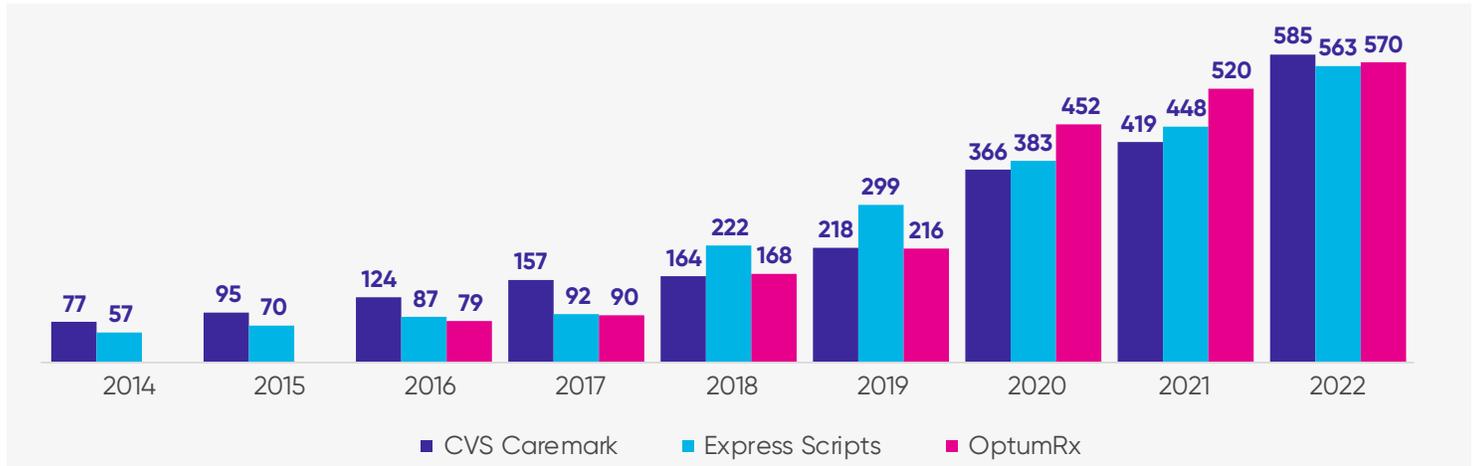
Figure 8. Number of drugs approved under expedited pathways excluded from 1 or more formulary, by year and PBM



PBM-specific trends

In 2014, CVS Caremark and Express Scripts exclusions affected 109 unique medicines. OptumRx did not begin excluding medicines from its formulary until 2016. By 2022, the 3 PBMs imposed formulary exclusions affecting 1,156 unique medicines (Figure 9). CVS Caremark, Express Scripts, and OptumRx collectively increased the number of formulary exclusions almost 13-fold in 9 years—a 130% annualized increase.

Figure 9. Number of medicines excluded from 1 or more formulary, by year and PBM



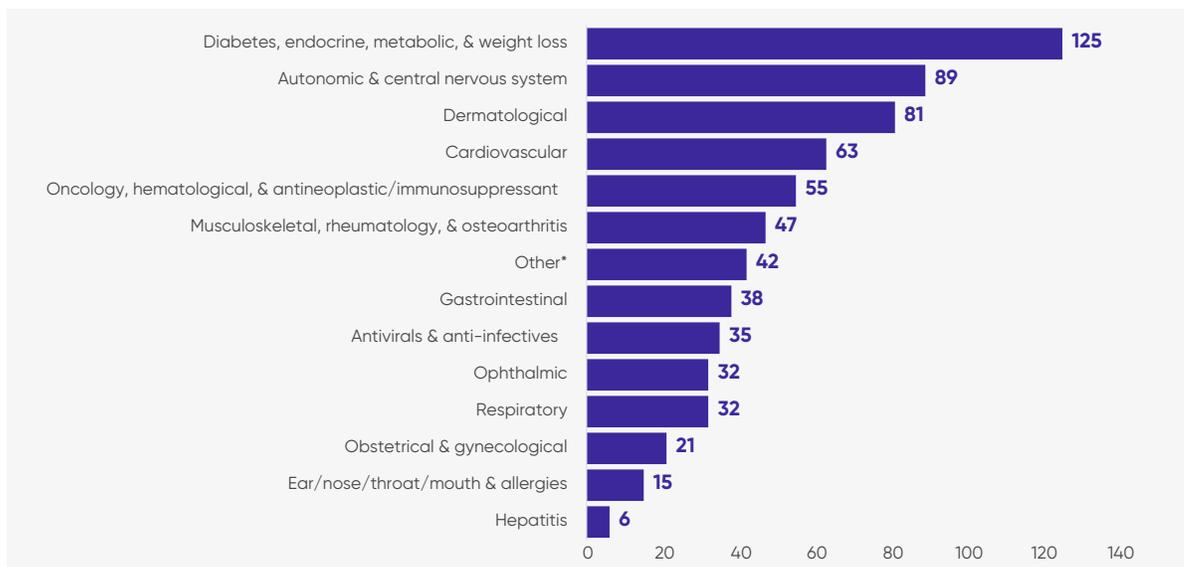
About one quarter (27%, 306 medicines) of the 1,156 medicines that faced exclusion in 2022 were excluded from the standard formularies of 2 PBMs, while 128 medicines (11%) were excluded from all 3. Of the medicines excluded from all 3 formularies in 2022, almost half were single-source brand medicines that did not have a generic equivalent or biosimilar alternative available on the market at the time of exclusion.

CVS Caremark

The number of medicines excluded from CVS Caremark’s standard formulary increased from 77 in 2014 to 585 in 2022, a 660% increase. Between 2021 and 2022 alone, CVS Caremark added 166 additional medicines to their formulary exclusions list, a 40% increase in a single year.

Diabetes and related medicines were the most affected by CVS Caremark’s formulary exclusions, representing nearly one quarter (23%) of all excluded products over the study period (Figure 10). In 2014, 26 diabetes and related products were excluded from CVS Caremark’s formulary. As of 2022, diabetes and related products faced 515 total plan-years of exclusion from CVS Caremark’s formulary since 2014.

Figure 10. Number of drugs excluded from CVS Caremark’s formulary between 2014 and 2022, by therapeutic area



* Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, urological, and inflammatory conditions.

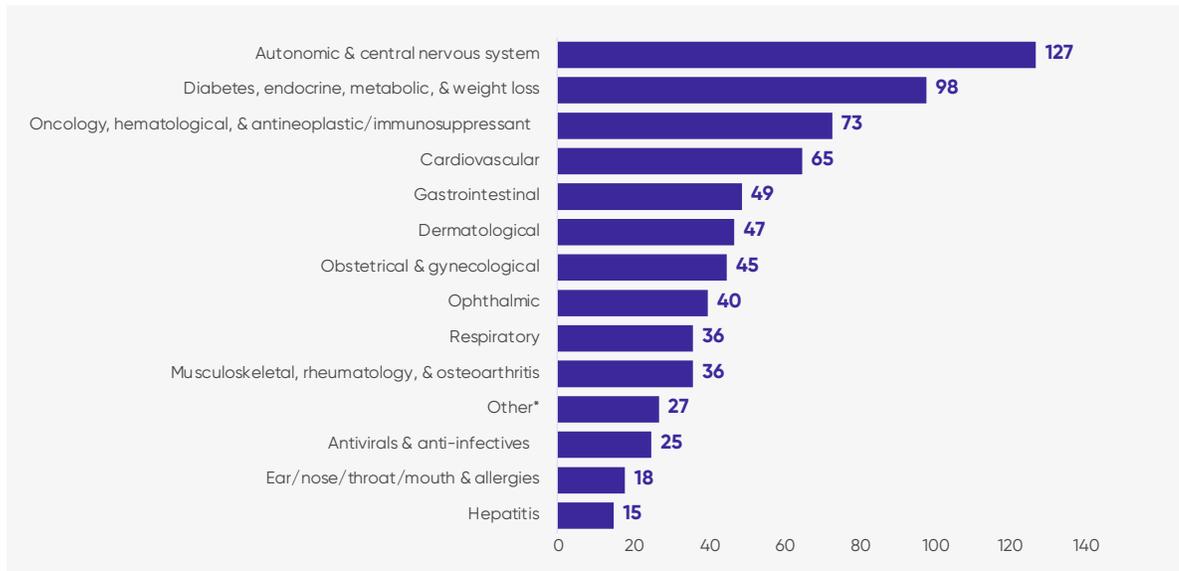


Express Scripts

The number of medicines excluded from Express Scripts' standard formulary increased from 57 in 2014 to 563 in 2022, an 888% increase.

Medicines to treat autonomic and central nervous system disorders were most heavily affected by Express Scripts' exclusions (**Figure 11**). During the study period, Express Scripts increased the number of autonomic and central nervous system medicines excluded from their standard formulary by more than 2,000%, from 4 products in 2014 to 127 in 2022.

Figure 11. Number of drugs excluded from Express Scripts' formulary between 2014 and 2022, by therapeutic area

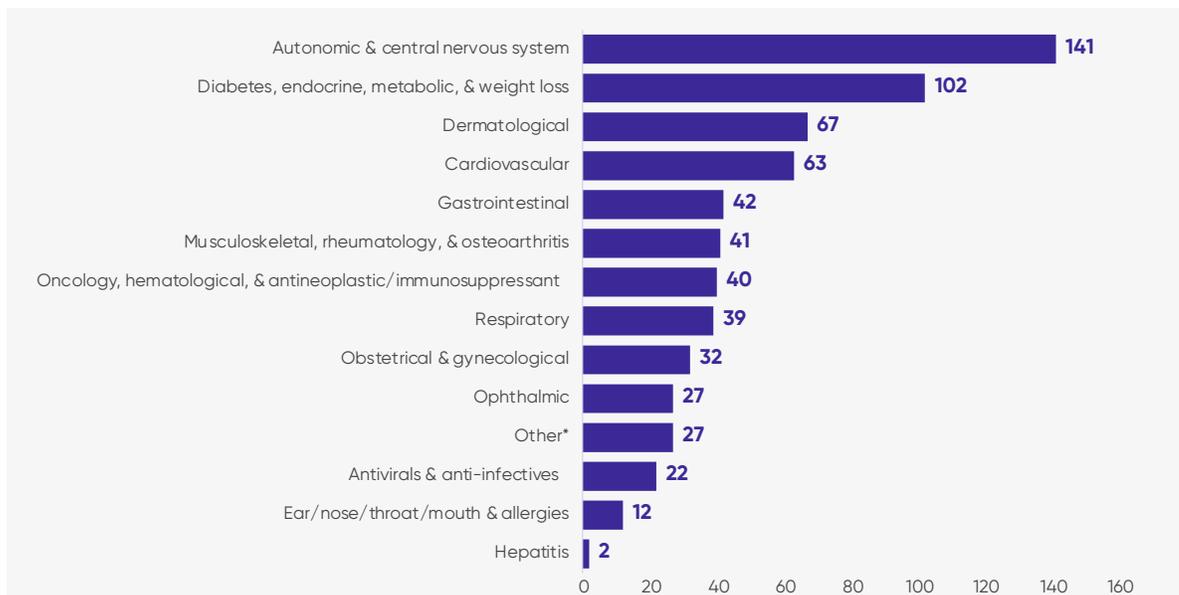


* Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, urological, and inflammatory conditions.

OptumRx

OptumRx did not begin excluding medicines from its standard formulary until 2016, 2 years after CVS Caremark and Express Scripts began the practice. Additionally, of the 3 PBMs included in the study, OptumRx excluded the fewest medicines from its 2022 formulary. However, in comparison to the other 2 PBMs, OptumRx has increased the number of exclusions most rapidly, growing their exclusions list by 623% in just 7 years. (**Figure 12**).

Figure 12. Number of drugs excluded from OptumRx's formulary between 2016 and 2022, by therapeutic area



* Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, urological, and inflammatory conditions.

Implications

The patient-physician decision-making process used to determine the best therapy for an individual's condition and circumstances may be undermined by formulary exclusions. The number of medicines excluded from the standard commercial formularies of the nation's 3 largest PBMs have skyrocketed in recent years, increasing by an astounding 1,183% since 2014. **Because each PBM excludes different medicines from their formularies, and different health plans contract with different PBMs, patients who change jobs or health plans may find they no longer have their current medicines covered.**

Patients who find their medicines suddenly excluded from their formularies may be required to pay completely out of pocket or begin a burdensome appeals process to access their treatment. When medicine choices are limited because of formulary exclusions, patients may experience delays in initiating treatment, medication nonadherence, or premature discontinuation of therapy.²⁵ Research has shown that medication nonadherence and discontinuation are associated with worsening health outcomes and increased utilization of costly emergency and hospital care.²⁶⁻²⁸ Additionally, patients could be compelled to switch to a different medicine that may result in less optimal outcomes.²⁹ This "nonmedical switching" is associated with higher healthcare costs and poorer clinical outcomes.³⁰⁻³²

Some PBMs have claimed that formulary exclusions only affect a small share of their enrollees.³³⁻³⁵ However, each of the 3 largest PBMs manage prescription drug coverage for tens of millions of commercially insured patients. This means that hundreds of thousands of individuals may be forced to switch from their current medication to their PBM's preferred alternative each year. Because medicines to treat chronic diseases are among the most frequently targeted by formulary exclusions, vulnerable patients with chronic illnesses are disproportionately affected.²⁵ For these patients, who often have treatment regimens involving multiple medications that need to work together, having access to choice of medicines can be critical, and frequent changes can be particularly problematic, as changes in 1 medicine can trigger the need for other changes and disrupt treatment. **Rising rates of PBM exclusions for medications to treat complex conditions such as cancer, HIV, and autoimmune disorders, for which variation in patient response to treatment is well documented,³⁶⁻³⁸ also raise potentially serious concerns about quality of care.**

These challenges can be particularly burdensome for certain populations that already struggle to navigate the healthcare system and get timely access to medicines, such as those with low health literacy, individuals with language barriers, and individuals who lack access to paid leave and/or transportation.³⁹⁻⁴¹ Many patients who face these challenges also tend to have greater disease burden and need for prescribed medicines. Consequently, formulary exclusions can disproportionately affect underserved populations and may exacerbate existing health disparities.^{42,43}

While PBMs do offer exceptions processes for patients to petition for coverage of an excluded medicine in specific cases, receiving coverage approval can be time-consuming and burdensome for both the patient and their physician. There may be delays or disruptions in continuity of care as the patient's physician undergoes administrative work to comply with prior authorization requirements or the payer requires the patient to fail on an alternative medication first (ie, step therapy).⁴⁴ The alarming growth in the number of medicines excluded from PBMs' formularies warrants additional research on the impacts such coverage restrictions have on patients, providers, and the healthcare system.

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