



SkYROCKETING Growth in PBM Formulary Exclusions Raises Concerns About Patient Access

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Contents

Introduction.....	3
Methodology.....	4
Findings.....	4
Market-Wide Trends.....	4
Therapeutic Area Trends.....	6
PBM-Specific Analysis.....	9
CVS Caremark.....	10
Express Scripts.....	11
OptumRx.....	12
Implications.....	13
References.....	15



Introduction

Pharmacy benefit managers (PBMs) typically negotiate discounts and rebates with pharmaceutical manufacturers on behalf of their clients—insurers, employer groups, 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—managing the pharmacy benefits for approximately 256 million Americans.¹ In 2019, these 3 PBMs handled 74% of all prescriptions processed in the U.S.²

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 non-preferred 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 without paying completely out of pocket or undertaking a burdensome appeals or exceptions process.³ 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.⁴ Express Scripts adopted the practice for the 2014 plan year,⁵ and OptumRx began in 2016.⁶

In less than 10 years, the practice of formulary exclusions has grown to exclude nearly a thousand prescription medicines across the 3 PBM formularies. To gain a better understanding of the potential implications of formulary exclusions, Xcenda analyzed how these trends have evolved since 2014 and which therapeutic classes have been most commonly subjected to formulary exclusion.

Methodology

Xcenda created a database of the 2014 to 2020 formulary exclusion lists for Express Scripts, CVS Caremark, and OptumRx.⁷ A team of PharmDs standardized the therapeutic categories and classes to facilitate comparison across the 3 PBMs. The database was also compared to the National Cancer Institute's comprehensive list of approved drugs to identify medicines used in cancer treatments across multiple therapeutic classes.⁸ The resulting database allowed for the analysis of formulary exclusion trends across PBMs, years, therapeutic areas, and for single- vs multi-source medicines.

To calculate cumulative totals over the study period, medicines were determined to be 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 2020. Duplicate exclusions were removed when analyzing market-wide and therapeutic area trends for the 3 PBMs combined (i.e., 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).

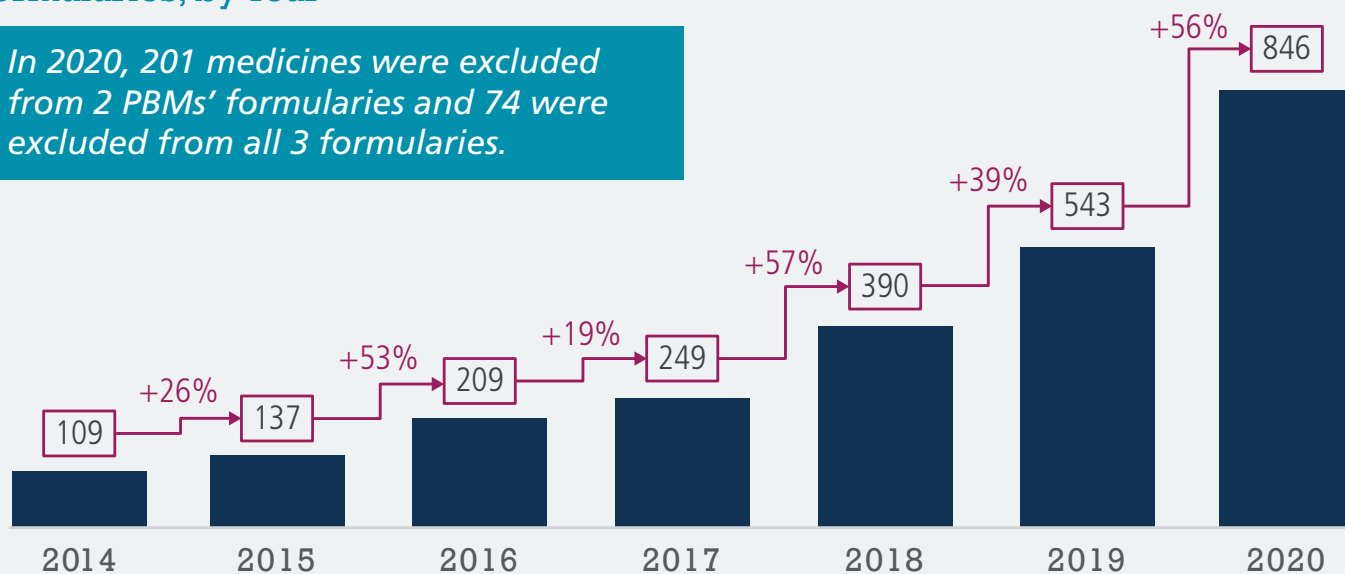
Findings

Market-Wide Trends

In 2020, 846 unique prescription medicines were excluded from the standard formularies of at least 1 of the 3 PBMs, a 676% increase from 2014, when 109 medicines were excluded.^a From 2014 to 2020, the number of medicines excluded by 1 or more PBM increased by an average of 34% per year.

Figure 1. Number of Prescription Medicines Excluded From 1 or More PBM Formularies, by Year

In 2020, 201 medicines were excluded from 2 PBMs' formularies and 74 were excluded from all 3 formularies.



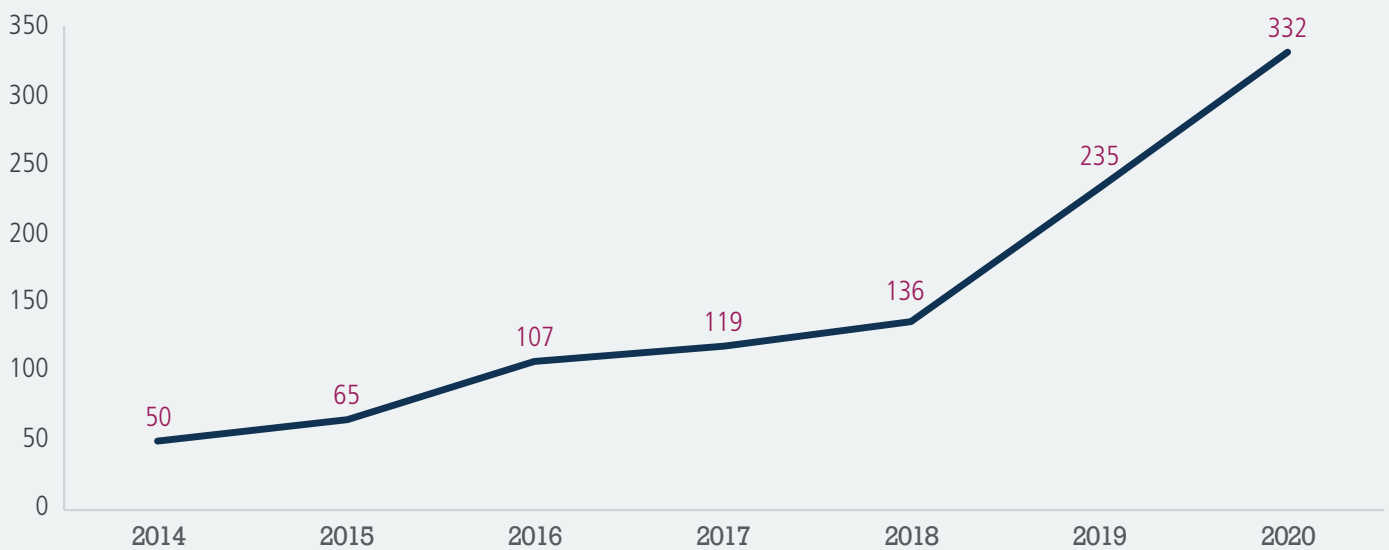
Source: Data shown in the figure above are based on a compilation of CVS Caremark's, Express Scripts', and OptumRx's formulary exclusion listings from 2014–2020.

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

One quarter (24%, 201 medicines) of the 846 medicines that faced exclusion in 2020 were excluded from the standard formularies of 2 PBMs, while 74 medicines (9%) were excluded from all 3. The number of medicines excluded from 2 or more formularies increased by 1,000% between 2014 and 2020, and the number of medicines excluded by all 3 formularies increased by 306% between 2016 and 2020.^b Of the medicines excluded from all 3 formularies in 2020, 1 in 5 were single-source brand medicines that did not have a generic equivalent or biosimilar alternative available on the market at the time of exclusion.

Over the study period, a total of 943 unique prescription medicines faced exclusion for at least 1 year. Of this total, 389 were single-source brand medicines. The number of single-source medicines excluded from at least 1 PBM formulary increased from 50 in 2014 to 332 in 2020—a 564% increase.

Figure 2. Number of Single-Source Medicines Excluded From 1 or More PBM Formularies, By Year



Source: Data shown in the figure above are based on a compilation of CVS Caremark's, Express Scripts', and OptumRx's formulary exclusion listings from 2014–2020.

^b OptumRx did not start excluding medicines from its formulary until 2016.

Therapeutic Area Trends

Medicines to treat chronic diseases, including insulin, antidepressants, antipsychotics, and antiarrhythmics, were most frequently targeted by formulary exclusions. Patients with chronic conditions typically require long-term, continuous treatment to slow or prevent the progression of disease. In cases where formulary exclusions 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.⁹

Table 1. Most Common Therapeutic Areas for Medicines Excluded From 1 or More PBM Formularies, 2014–2020

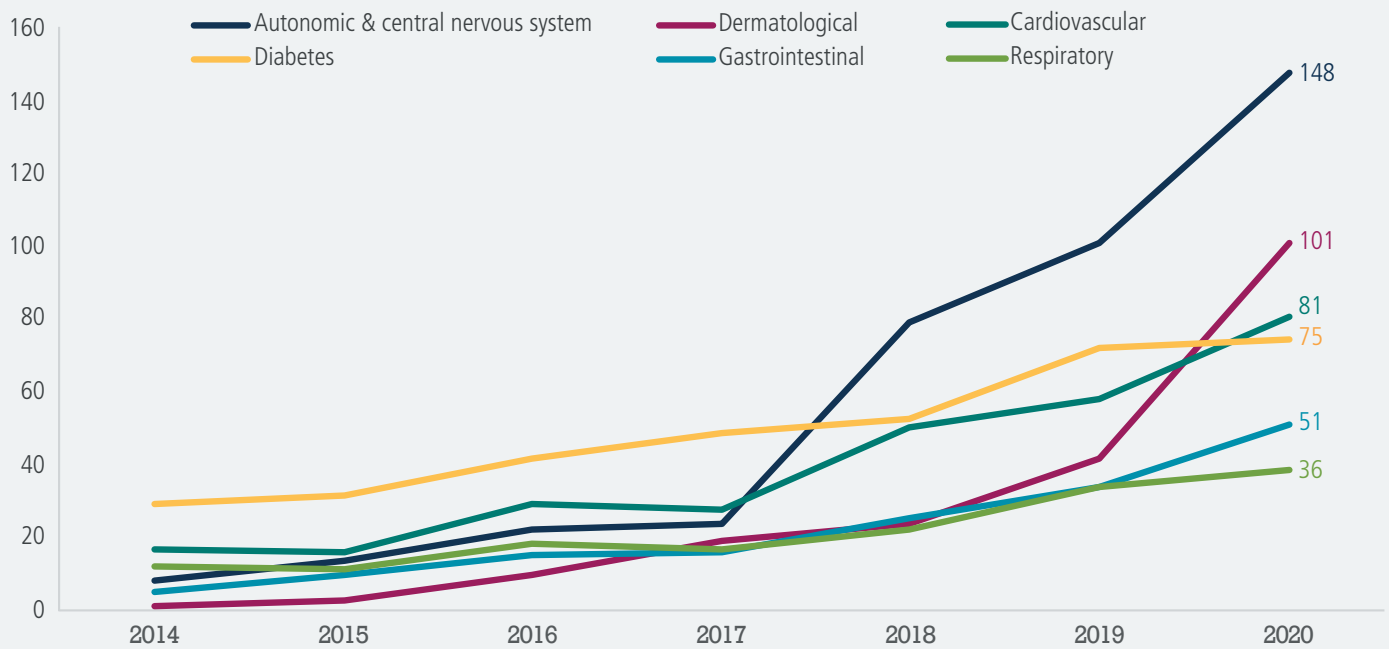
Rank	Therapeutic Area	# Medicines Excluded ^c	% of Total Exclusions
1	Diabetes, endocrine, metabolic, & weight loss	168	17.8%
2	Autonomic & central nervous system	160	17.0%
3	Dermatological	108	11.5%
4	Cardiovascular	89	9.4%
5	Oncology, hematological, & anti-neoplastic/immunosuppressant	63	6.7%
6	Gastrointestinal	55	5.8%
7	Respiratory	55	5.8%
8	Musculoskeletal, rheumatology, & osteoarthritis	51	5.4%
9	Anti-virals & anti-infectives	49	5.2%
10	Ophthalmic	41	4.3%
11	Obstetrical & gynecological	28	3.0%
12	Ear/nose/throat/mouth & allergies	25	2.7%
13	Urological	21	2.2%
14	Inflammatory conditions	15	1.6%
15	Nephrology & renal disease	9	1.0%
16	Immunomodulators & transplant	5	0.5%
17	Hepatology	1	0.1%
	Total	943	100%

Source: Data shown in the table above are based on a compilation of CVS Caremark's, Express Scripts', and OptumRx's formulary exclusion listings from 2014–2020.

The number of medicines facing exclusion climbed steadily year-over-year for several therapeutic areas. Conditions disproportionately impacted by formulary exclusions included autonomic and central nervous system disorders, cardiovascular disease, diabetes, and gastrointestinal conditions. For example, compared to 2014, there were 10 times more gastrointestinal treatments and nearly 5 times more cardiovascular treatments excluded from 1 or more PBM formularies in 2020.

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

Figure 3. Number of Unique Medicines Excluded From 1 or More PBM Formularies in Select Therapeutic Areas, by Year

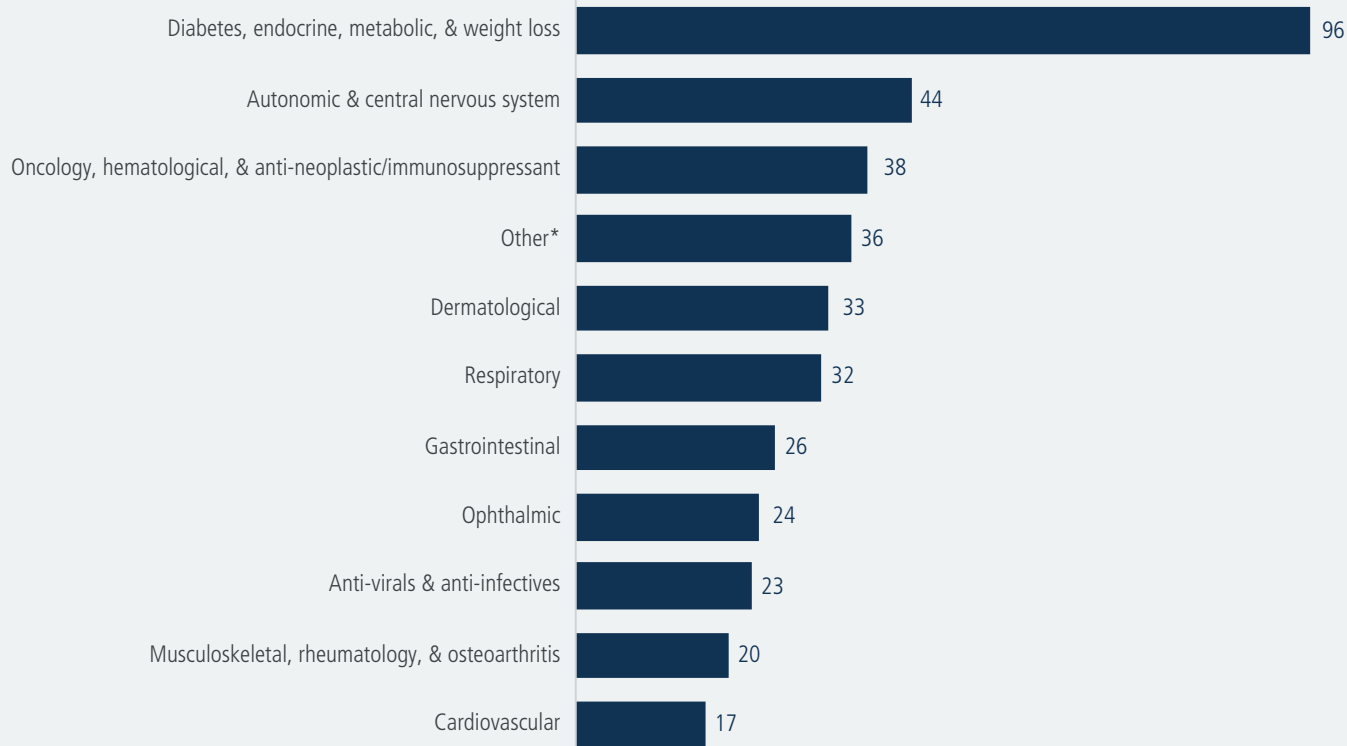


Source: Data shown in the figure above are based on a compilation of CVS Caremark's, Express Scripts', and OptumRx's formulary exclusion listings from 2014–2020.

Autonomic and central nervous system medicines excluded by at least 1 PBM increased by 1,850% over the study period. This therapy area, which includes medicines to treat multiple sclerosis, mental health disorders, Parkinson's disease, epilepsy, and other serious complex conditions, experienced particularly dramatic growth in exclusions from 2017 to 2020, when the number of exclusions increased from 24 to 148—an annualized increase of almost 400% during the 4-year period.

In many instances, PBM formularies excluded single-source medicines used to treat common chronic conditions. Exclusions of single-source medicines can be particularly problematic for chronic conditions where patients may need to cycle through several treatments over the course of their lifetime as they develop resistance to or diminishing results from medicines over time.¹⁰

Figure 4. Number of Single-Source Medicines Excluded From 1 or More PBM Formularies Between 2014–2020, by Therapy Area (n=389)



Note: Excluded for at least 1 year between 2014 and 2020.

*Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, ear/nose/throat/mouth, obstetrical and gynecological, urological, and inflammatory conditions.

Source: Data shown in the figure above are based on a compilation of CVS Caremark’s, Express Scripts’, and OptumRx’s formulary exclusion listings from 2014–2020.

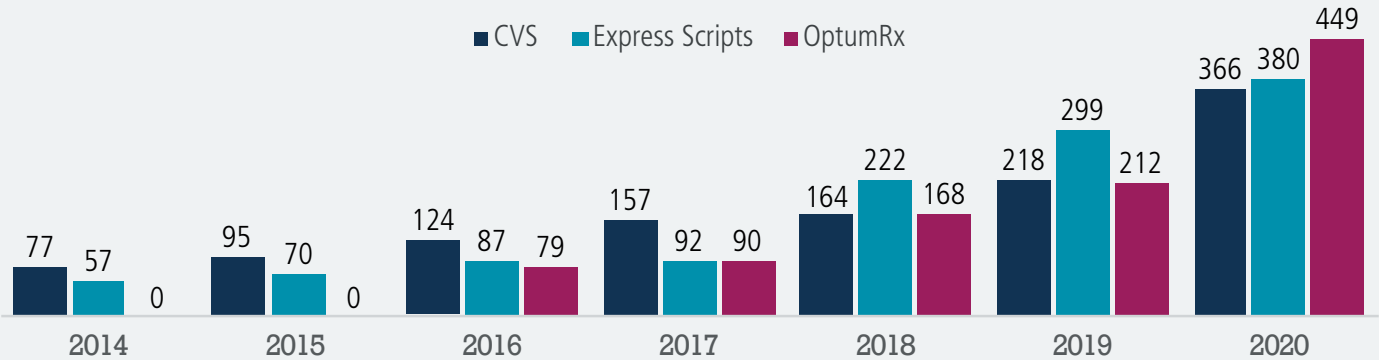
Despite the availability of lower price “authorized-generic”^d versions of certain insulin and hepatitis C medicines, 2 of the 3 PBMs excluded 1 or more of these lower price options in favor of the treatment with a higher list price. Remarkably, this was true even though the list prices for these authorized generics can be hundreds or even thousands of dollars lower per prescription.¹¹ Excluding these medicines from formularies could substantially increase out-of-pocket costs for patients in plans using deductibles or coinsurance, when cost-sharing is typically determined based on the medicine’s full list price, regardless of any discounts or rebates the PBM receives.¹²

^dAn 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.”¹³

PBM-Specific Analysis

In 2014, CVS Caremark and Express Scripts imposed a total of 134 formulary exclusions impacting 109 unique medicines (OptumRx did not begin excluding medicines from its formulary until 2016). By 2020, the 3 PBMs imposed 1,195 formulary exclusions impacting 846 unique medicines. CVS Caremark, Express Scripts, and OptumRx collectively increased the number of formulary exclusions almost 9-fold in 7 years—a 220% annualized increase.

Figure 5. Number of Medicines Excluded From 1 or More Formularies, by Year and PBM



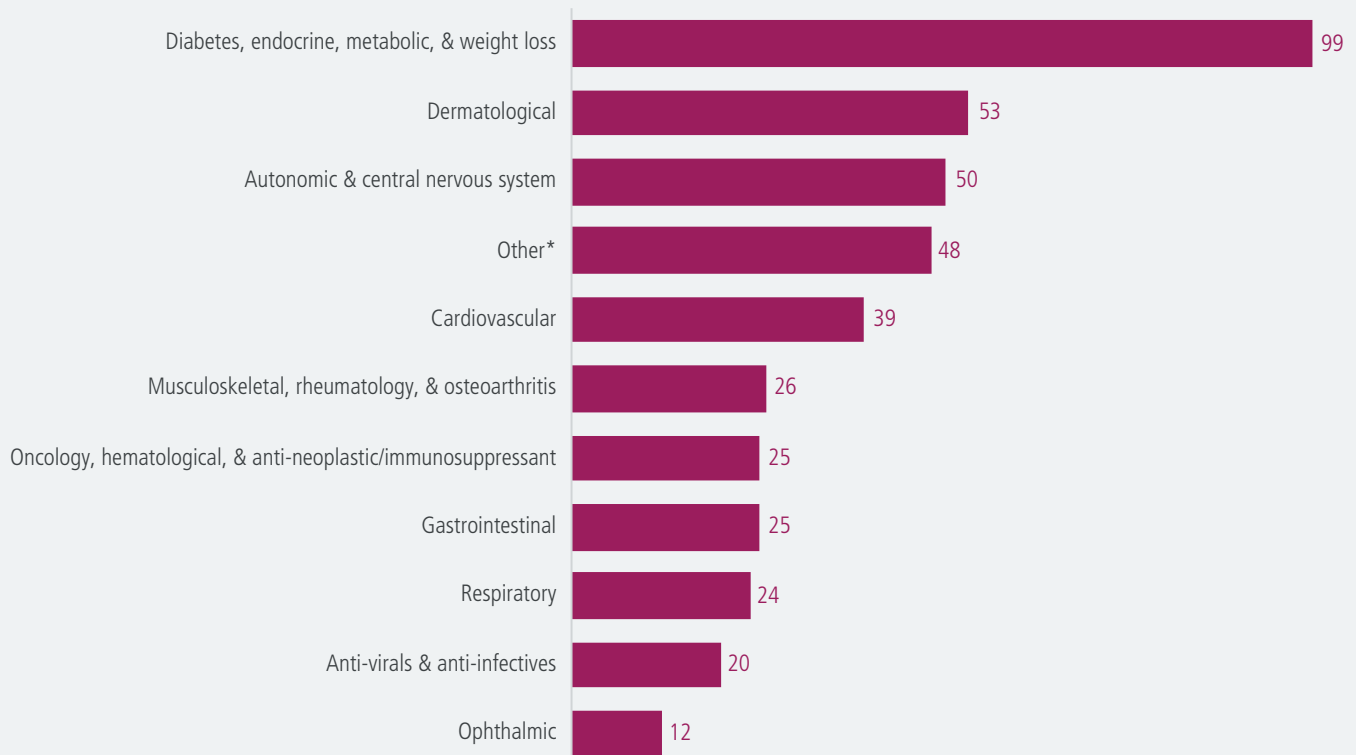
Source: Data shown in the figure above are based on a compilation of CVS Caremark's, Express Scripts', and OptumRx's formulary exclusion listings from 2014–2020.

CVS Caremark

The number of medicines excluded from CVS Caremark’s standard formulary increased from 77 in 2014 to 366 in 2020, an annualized increase of 157% and a total increase of 375%. Over the study period, 421 drugs were excluded from CVS Caremark’s formulary for at least 1 year. In 2020, CVS Caremark added 100 additional medicines to their formulary exclusions list. Of this total, 68% were single-source medicines without a generic or biosimilar equivalent on the market.

Diabetes and related medicines were the most impacted by CVS Caremark’s formulary exclusions, representing nearly one quarter (23%) of all excluded products over the study period. Between 2014 and 2020, the number of diabetes and related products excluded from CVS Caremark’s formulary increased from 17 to 49, a 188% increase.

Figure 6. Number of Medicines Excluded From CVS Caremark’s Formulary Between 2014–2020, by Therapeutic Area (n=421)



Note: Excluded for at least 1 year between 2014 and 2020.

*Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, ear/nose/throat/mouth, obstetrical and gynecological, urological, and inflammatory conditions.

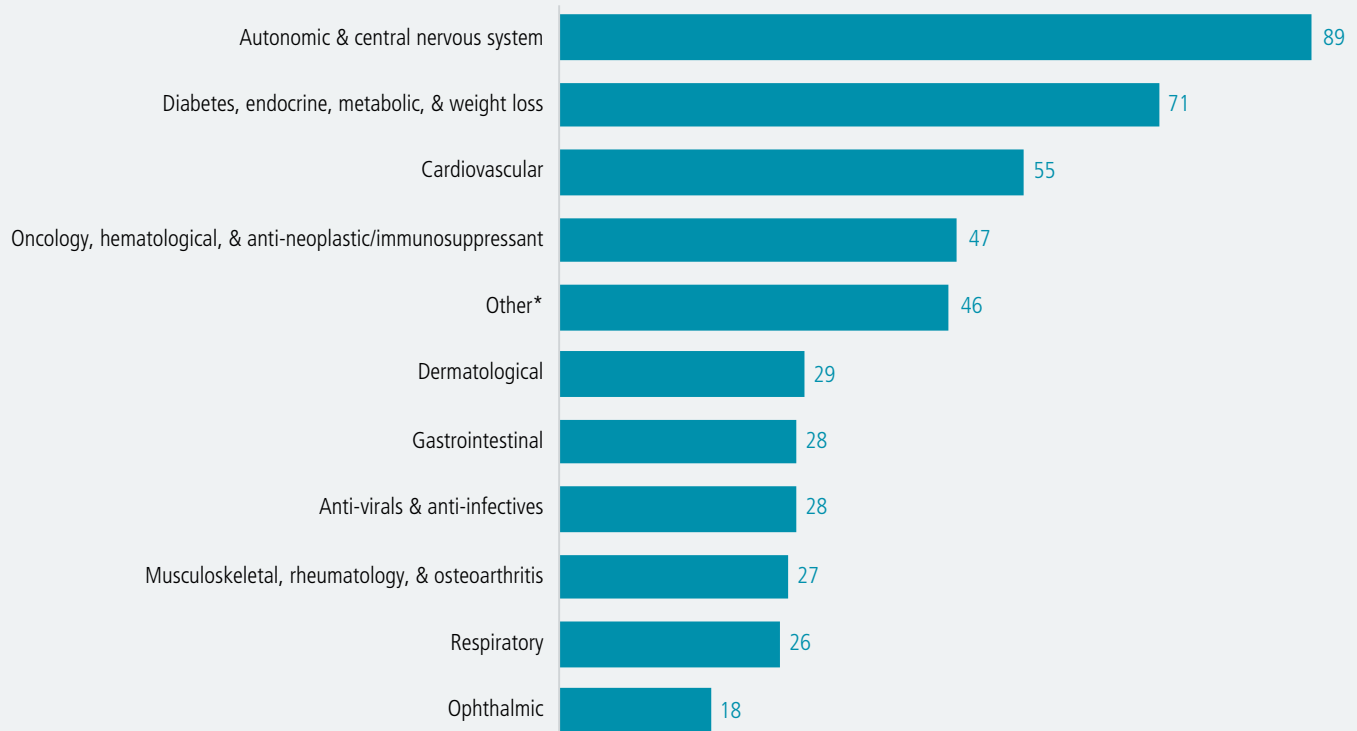
Source: Data shown in the figure above are based on a compilation of CVS Caremark’s formulary exclusion listings from 2014–2020.

Express Scripts

The number of medicines excluded from Express Scripts' standard formulary increased from 57 in 2014 to 380 in 2020, an annualized increase of 37% and a total increase of 567%. Between 2014 and 2020, Express Scripts excluded 464 unique drugs for at least 1 year.

Express Scripts increased the number of autonomic and central nervous system medicines excluded from 4 products in 2014 to 89 in 2020, an increase of more than 2,000%.

Figure 7. Number of Medicines Excluded From Express Scripts' Formulary Between 2014–2020, by Therapeutic Area (n=464)



Note: Excluded for at least 1 year between 2014 and 2020.

*Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, ear/nose/throat/mouth, obstetrical and gynecological, urological, and inflammatory conditions.

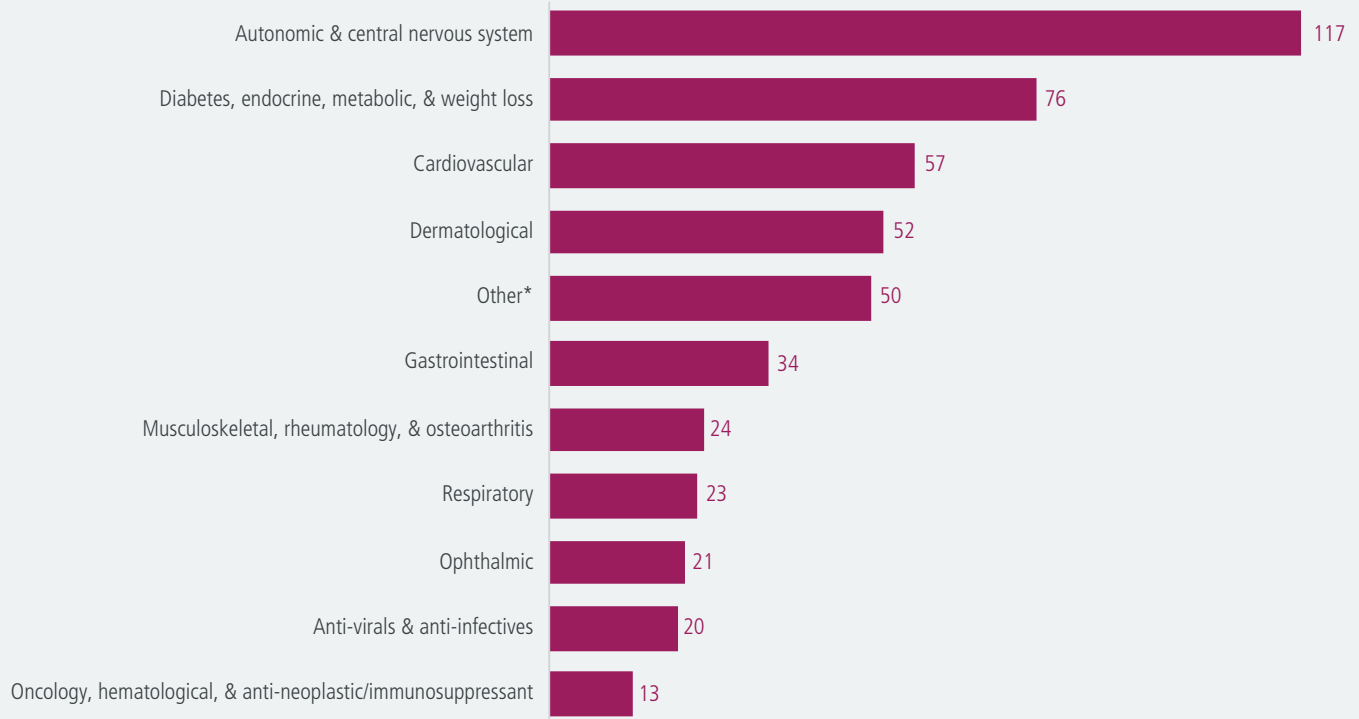
Source: Data shown in the figure above are based on a compilation of Express Scripts' formulary exclusion listings from 2014–2020.

Additionally, Express Scripts excluded 47 cancer medicines and supportive therapies,^e representing 10% of its total exclusions during the study period. In comparison, CVS Caremark excluded 25 cancer medicines, accounting for 6% of their exclusions, and OptumRx excluded 13 cancer medicines, accounting for 3% of their exclusions, from 2014 to 2020.

^e Medicines to treat cancer span several therapy areas, as defined by the National Cancer Institute.⁸

OptumRx did not exclude any medicines from its standard formulary during the first 2 years of the study period. However, due to dramatic year-over-year growth between 2016 and 2020, OptumRx has since surpassed the other 2 PBMs in terms of the most medicines excluded from their 2020 formulary. OptumRx increased the number of exclusions by 468% in just 5 years. In total, 487 medicines were excluded by OptumRx for at least 1 year between 2016 and 2020.

Figure 8. Number of Medicines Excluded From OptumRx’s Formulary Between 2016–2020, by Therapeutic Area (n=487)



Note: Excluded for at least 1 year between 2016 and 2020.

*Other includes hepatology, immunomodulators, transplant, nephrology, renal disease, allergies, ear/nose/throat/mouth, obstetrical and gynecological, urological, and inflammatory conditions.

Source: Data shown in the figure above are based on a compilation of OptumRx’s formulary exclusion listings from 2016–2020.

Implications

The number of medicines excluded from the standard formularies of the nation's 3 largest PBMs has skyrocketed in recent years, increasing by an astounding 679% since 2014. Patients who find their medicines suddenly excluded from formularies may be required to switch to different treatments in order to maintain coverage. With significant variation between the medicines excluded from each PBM's formulary, individuals who switch jobs or change health plans may also lose access to treatments covered by their previous plan, requiring them to pay out of pocket, begin a burdensome appeals process, and/or change their course of treatment.

Some PBMs have claimed that formulary exclusions only impact a small share of their enrollees.¹⁴ However, each of the 3 largest PBMs manage prescription drug coverage for tens of millions of commercially insured patients.¹⁵ 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.¹⁴ As the programs director of advocacy at Consumer Reports recently noted, "It's unfair to spring these changes on consumers at the pharmacy counter, especially when a consumer's health is at risk... People sign up for health plans expecting that the drugs they need will be covered. Insurers should be required to honor those promises."¹⁶

According to Harvard Medical School professor Aaron Kesselheim, formulary exclusions leave patients vulnerable, especially those with chronic conditions.¹⁶ Medicines to treat chronic diseases are among the most frequently targeted by formulary exclusions. Chronically ill patients typically require continuous, often life-long treatment to manage their conditions. Patients who unexpectedly find their medicines excluded from PBM formularies may experience treatment interruptions or delays, resulting in potentially adverse events, medication non-adherence, or premature discontinuation of therapy.¹⁶ Research has shown that medication non-adherence and discontinuation are associated with worsening health outcomes and increased utilization of costly emergency and hospital care.¹⁷

Formulary exclusions may also interfere with the patient-physician decision-making process to determine the best therapy for an individual's condition and circumstances. PBMs are increasingly imposing 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.¹⁸ When medicine choices are limited because of formulary exclusions, patients may experience delays in initiating treatment or be forced to switch to a different medicine that results in less optimal outcomes.¹⁹ Research shows that such "non-medical switching" is associated with higher healthcare costs and poorer clinical outcomes.²⁰

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 as their physician complies with prior authorization requirements, disruptions in continuity of care, or the payer may require the patient to fail on an alternative medication first (i.e., step therapy).²¹ 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.

Case Study

"Non-Medical Switching" and Diabetes



Non-medical switching has been shown to be particularly harmful for patients with diabetes who are stable on their treatment. According to the Diabetes Patient Advocacy Coalition (DPAC), "A seemingly 'simple' change in formulary can cause life-threatening alterations to the insulin levels of a patient with diabetes."²² For patients with diabetes who are stable on their treatment, non-medical switching has been associated with decreased disease management, increased physician and hospital visits, and higher overall healthcare costs.²³

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