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Abstract

Introduction Access to prescription drugs is an enduring challenge in patient care. Payers often rely on coverage restrictions to balance access and cost.

Methods We assessed coverage restrictions for a comprehensive set of branded retail drugs without generic competitors from 2011 to 2019 across the four largest US market segments (Medicare, Medicaid, employer-sponsored, and health insurance exchanges) using CMS and Managed Market Insight and Technology (MMIT) data.

Results Between 2011 and 2019, for the nationally representative beneficiary, the share of drugs excluded from formularies increased from 7.5% to 13.4%, the share of drugs subject to administrative restrictions such as prior authorization or step therapy increased from 18.1% to 43.7%, and the share of drugs on non-preferred tiers decreased from 57.8% to 42.2%. The share of drugs with any coverage restriction increased from 69.7% to 79.0%. Health plans and drugs subject to federal coverage mandates saw much larger increases in prior authorization and increases in non-preferred status.

Conclusion These dynamics suggest that future research should study the tradeoffs between partial and full coverage restrictions for patient utilization, spending, and well-being.

Keywords pharmaceutical policy, benefit design, coverage restrictions, access to care, utilization management, prior authorization

Key points

- Formulary exclusions and administrative restrictions increased substantially, and drugs on non-preferred tiers decreased for branded retail prescription drugs without a generic competitor from 2011 to 2019.
- Coverage mandates, such as those imposed on all Medicaid formularies and on drugs in Medicare protected classes, are associated with higher rates and growth of other coverage restrictions.
- Understanding the scope of coverage restrictions and differences across insurance types is important

for targeting policy and may have implications for pharmaco-equity.

Introduction

Access to prescription drugs is an enduring challenge in patient care.^{1,2} The high and rising cost of prescription drugs has prompted insurers to curb utilization through various coverage restrictions.^{3–5} Coverage restrictions include financial restrictions (eg, cost-sharing), administrative restrictions (eg, prior authorization and step therapy), and exclusions. The growth of

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coverage restrictions has prompted increased attention to these policies from policymakers and clinicians.^{3,6-11}

Coverage restrictions aim to restrain spending by discouraging avoidable, low-value care and by improving plans' negotiating leverage with manufacturers.^{12,13} Cost-sharing is meant to provide financial incentives to influence patient decision-making.^{14,15} Conversely, administrative restrictions like prior authorization are designed to modulate prescribing by requiring physicians to justify clinical decision-making before approving coverage for a treatment.¹⁶ The ability to exclude drugs from coverage and, to a lesser extent cost-sharing and administrative restrictions, helps plans to negotiate rebates with manufacturers.^{12,17} However, there are tradeoffs associated with coverage restrictions.^{1,18,19} Research suggests cost-sharing may result in adverse health effects,²⁰⁻²² and that prior authorization contributes to care delays and physician burnout.^{6,23,24}

Concern regarding potential adverse effects of coverage restrictions partially motivates coverage mandates in government-sponsored markets such as Medicare and Medicaid.²⁵ To mitigate risks associated with interrupted medication access for vulnerable beneficiaries, Medicare Part D requires that plans cover at least two drugs in the most commonly prescribed categories and designates six protected classes in which plans must cover "all or substantially all" drugs.²⁶ As a condition of the Medicaid Prescription Drug Rebate Program, Medicaid covers all FDA-approved drugs that abide by the program's rules—that is, virtually all of them. Moreover, the Medicaid program imposes strict caps on out-of-pocket costs.²⁷

Despite significant policy and public interest in prescription drug access, evidence characterizing the scale and scope of coverage restrictions has been limited to certain conditions, institutions, or insurance segments; there is no systematic quantitative evidence characterizing the scale of coverage restrictions and their evolution over time.^{3,5,7-9,28-30} Understanding the scope of coverage restrictions and differences across insurance types is important for targeting policy and may have implications for pharmacoequity.^{31,32}

This analysis examines national trends in formulary coverage restrictions for a comprehensive set of branded drugs without generic competitors (which have the highest spending and access burden) dispensed in retail settings from 2011-2019 across the four largest insurance segments in the US: Medicare, Medicaid, employer-sponsored, and Affordable Care Act (ACA) Health Insurance Exchange (HIX) plans.

Methods

Sample and data sources

To quantify national trends in retail drug (ie, drugs covered under Medicare Part D) coverage restrictions for on-patent branded drugs without generic competitors across the four largest insurance segments from 2011 to 2019 we combined two data sources.

First, for Medicare beneficiaries in Part D Plans (PDPs) and Medicare Advantage Part D plans (MA-PDs), we used formulary data from Research Identified Files (RIF) from the Center for Medicare and Medicaid Services (CMS). The CMS formulary files cover 100% of beneficiaries obtaining retail drug coverage through Medicare (approximately 75% of Medicare beneficiaries as of 2022).³³

Second, for non-Medicare patients, we used formulary data from Managed Market Insight and Technology (MMIT). The MMIT formulary data encompasses Medicaid (both state and managed care plans), employer-sponsored insurance, and ACA HIX plans. Prior analyses comparing MMIT against the American Community Survey (ACS) indicate MMIT covers over 90% of commercial lives.³⁴

We defined drugs at the brand name level (eg, Lantus for insulin glargine), inclusive of all formulations. To select the set of drugs for analysis, we used the Medicare Drug Dashboard Public Use Files to identify drugs sold primarily through the retail channel, defined as those for which at least 95% of their 2011-2019 Medicare spending occurred under Part D.³⁵ Then, from this set, we used the Medicare excluded drug list to remove drugs excluded from standard Medicare coverage, such as cosmetics, fertility, cough/cold, vitamins, and over-the-counter drugs.³⁶ We used the same set of drugs across all insurance segments to enable consistent cross-insurance comparisons.

We used Anatomical Therapeutic Category (ATC)-3 codes to identify drugs in the six Medicare protected classes. CMS identifies six "categories and classes of clinical concern" and requires Part D plans to cover "all or substantially all drugs" six "categories and classes of clinical concern": antineoplastics, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and immunosuppressants for the prevention of organ transplant rejection (Appendix A).¹² In addition to the protected categories, we grouped drugs by several common clinical areas, including cardiovascular/metabolic, central nervous system, psychiatric, immunologic, and respiratory drugs (Appendix B).

Finally, we used SSR Health, a proprietary dataset of prescription brand drug pricing information, to identify the date of generic entry, which we used to exclude drugs in their post-exclusivity years.

Measures

For each drug and formulary, we tracked three main measures of formulary coverage restrictions: (i) whether a drug was included or excluded from coverage, (ii) whether a drug was subject to an administrative restriction (prior authorization or step therapy), and (iii) whether a drug was included on a non-preferred tier (which imposes higher cost-sharing relative to preferred tiers in the same formulary). We tracked each restriction separately, as well as the share of drugs subject to any coverage restriction. We used previously established approaches for categorizing coverage restrictions and tiers in the MMIT and CMS formulary data.^{37,38}

Statistical analysis

For each year, we first calculated the share of drugs experiencing each type of coverage restriction (exclusion, administrative restriction, placement on a non-preferred tier) in each plan. Then, we estimated a yearly average restriction rate across plans, weighing by that plan's enrollment. Finally, we used ACS coverage estimates to weight each insurance segment to match national enrollment. This approach ensures that our estimates aren't influenced by plans with very low enrollment and represent the exposure of a representative patient to coverage

restrictions. We plotted year-by-year trends overall and by market segment. We further explored trends within Medicare (PDPs vs MA-PDs) and Medicaid (state-administered vs Medicaid managed care [MMC]). Finally, to study the role of coverage mandates, we examined coverage restrictions in Medicare Part D formularies for drugs in Medicare-protected and non-protected classes.

Sensitivity analyses

We conducted four sets of sensitivity analyses. First, to ensure our results are robust to different weighting approaches, we recalculated our coverage metrics using (i) an unweighted average of plan-level coverage and (ii) weighing each drug by sales and (separately) by units sold.

Second, to study the role of changes in the US insurance landscape, we used our plan enrollment data to decompose the change in formulary coverage trends over time and separately quantify the effect of (i) plans becoming less generous, and (ii) patients switching to different types of plans. Intuitively, our procedure exploits plan-level data to simulate how coverage trends would have changed from year-to-year holding enrollment constant at previous year levels.

Third, to check that any differences in Medicare coverage between protected and non-protected classes were due to Medicare regulation we compared coverage restrictions for the same set of Medicare protected and non-protected drugs in Medicaid, and commercial plans.

Finally, we examined trends across several common clinical categories (oncology, cardiovascular/metabolic, central nervous system, psychiatric, immunotherapy, and respiratory drugs) to explore whether trends in coverage restrictions were driven by drugs in specific therapeutic classes.

Limitations

Our analysis has several limitations. Our data only includes branded drugs without a generic competitor and does not incorporate coverage of generics or off-patent branded drugs. However, our sample includes the vast majority of molecules facing significant coverage restrictions, as restrictions on generic drugs are generally thought to be far less onerous.¹⁹

Our data does not include cost-sharing, though we can still infer relative financial burden by comparing tiers. Relatedly, our data includes binary indicators for whether a drug had a coverage restriction, but we do not observe details of prior authorization policies, such as required documentation, diagnoses, or prescriber credentials.

Our data ends in 2019. As a result, we have limited ability to speak to more recent trends in formulary coverage. However, our analysis remains informative about the transformations that formularies underwent during a crucial period that encompassed the introduction of the ACA. Studies using more recent data, albeit with more limited sample breadth, indicate the trends we observe here have persisted.^{3,5,39,40} More recently, patient and physician surveys related to prescription drug access and utilization management suggest coverage restrictions are a prominent issue today.^{41,42} Therefore, while we recommend

future research to update our numbers, we believe our insights remain valid today.

Finally, our dataset excludes a few smaller, but important insurance segments, such as Tricare and military-related coverage, Indian Health Service, Veteran Affairs, etc. Future research should study whether the trends we uncover apply to those segments as well.

Results

Sample size and characteristics

In 2019, our sample included 408 unique drugs and 5044 unique plans covering 302 334 065 lives. We weighted each insurance segment by ACS enrollment for that year to reflect the national population ([Appendix C](#)).

Overall coverage trends over time

The share of drugs subject to any coverage restriction increased from 69.7% in 2011 to 79.0% in 2019. However, this general trend hid substantial heterogeneity in the trends of specific types of restrictions. From 2011 to 2019, for the nationally representative beneficiary, the percentage of on-patent brand drugs subject to formulary exclusions increased slightly, from 7.5% to 13.4%. At the same time, the percent of drugs subject to administrative restrictions increased dramatically from 18.1% to 43.7%, while the percent of drugs on non-preferred tiers decreased from 57.8% to 42.2% ([Figure 1](#)).

Coverage trends across insurance segments

We observed large heterogeneity across insurance segments in both the level and growth of specific restrictions.

Commercial formularies had a lower proportion of drugs subject to any coverage restriction and less growth in coverage restrictions over time (from 67.9 in 2011 to 74.6 in 2019) compared to Medicare, Medicaid, and HIX plans. From 2011 to 2019, the share of excluded drugs on commercial formularies increased from 5.2% to 9.2%, and the share subject to administrative restrictions increased from 14.0% to 37.4%. The share of drugs on non-preferred tiers decreased from 57.9% to 46.9% ([Table 1](#)).

Among Medicare plans, the share of drugs subject to any coverage restriction increased from 68.9% in 2011 to 82.1% in 2019. The share of excluded drugs rose from 30.3% to 41.6%, while the share subject to coverage restrictions increased from 15.5% to 25.4%, and the share of drugs on non-preferred tiers increased from 38.6% to 40.5%. On average, PDPs were more restrictive than MA-PD plans with respect to exclusions (44.2% to 38.3% in 2019), similar in terms of administrative restrictions (25.6% vs 25.2%), and less restrictive with respect to non-preferred tier placement (38.4% vs 43.3%) ([Table 1](#)).

Among Medicaid plans, the share of drugs subject to any coverage restriction increased from 75.1% in 2011 to 86.5% in 2019. Exclusions were consistently low over the study period (2.0%-1.4% from 2011 to 2019) ([Table 1](#)). In the absence of

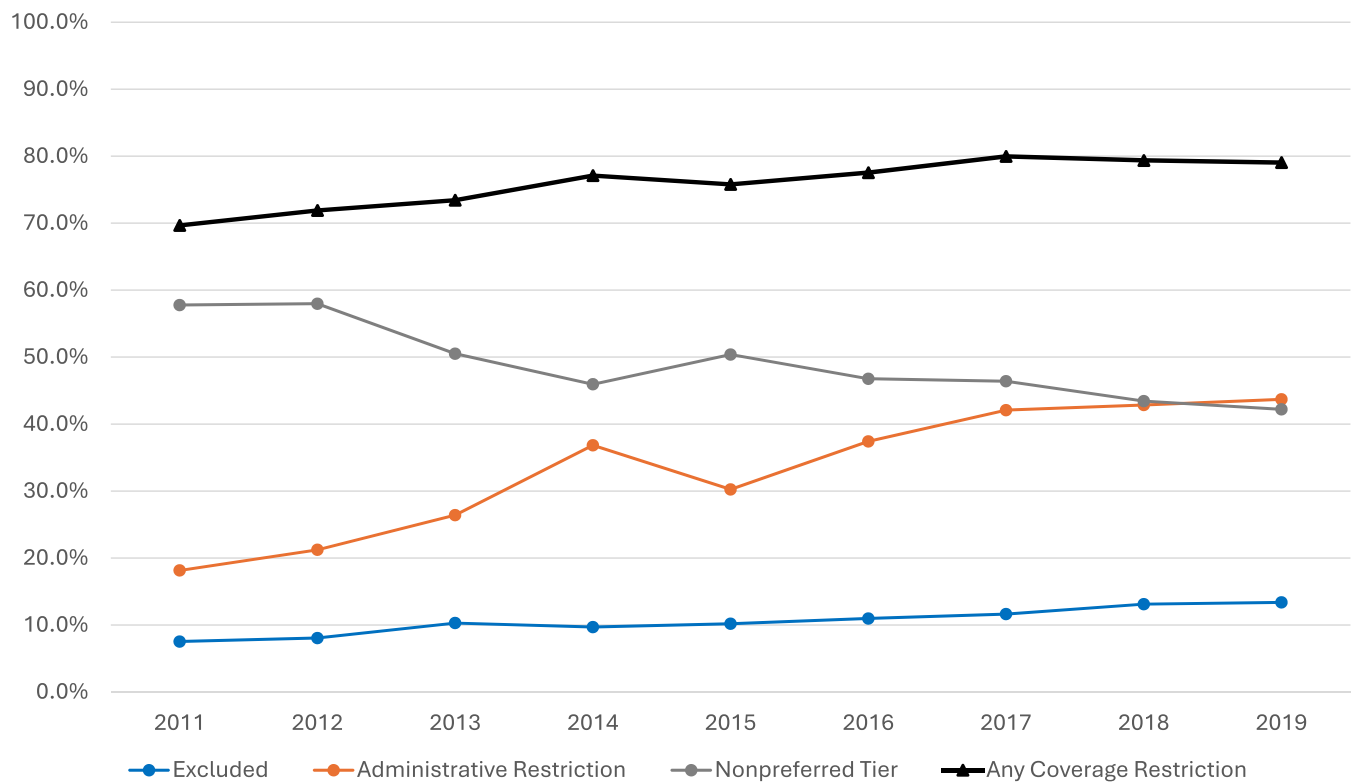


Figure 1 Formulary exclusions, administrative restrictions, and non-preferred tiers 2011-2019. Notes: Figure shows the percent of drugs subject to formulary exclusion, administrative restriction, non-preferred tier, or any combination of these three coverage restrictions. Figure includes all drugs and market segments in the sample, weighted by plan enrollment. Source: Authors' Analysis.

Table 1 Formulary coverage restrictions, by payer segment 2011-2019.

Coverage Type	Any coverage restriction			Restriction type								
				Non-preferred Tier			Exclusions			Administrative restrictions		
	2011 ^a	2019 ^a	change ^b	2011 ^a	2019 ^a	change ^b	2011 ^a	2019 ^a	change ^b	2011 ^a	2019 ^a	change ^b
Commercial	67.9	74.6	6.7	57.9	46.9	-11.0	5.2	9.2	4.0	14	37.4	23.4
Medicaid	75.1	86.5	11.4	67.8	31.7	-36.1	2	1.4	-0.6	31.5	72.6	41.1
State	75	86.5	11.5	67.7	67.1	-0.6	2	0.8	-1.2	31.5	55.9	24.4
MMC ^c	87.2	86.5	-0.7	75.4	21.4	-54.0	1.4	1.5	0.1	27	77.5	50.5
Medicare	68.9	82.1	13.2	38.6	40.5	1.9	30.3	41.6	11.3	15.5	25.4	9.9
PDP ^d	69.7	82.6	12.9	37.6	38.4	0.8	32.1	44.2	12.1	15.6	25.6	10
MAPD ^e	67.4	81.6	14.2	40.3	43.3	3.0	27.1	38.3	11.2	15.3	25.2	9.9
	2015	2019		2015	2019		2015	2019		2015	2019	
HIX^f	85.8	87.6	1.8	56	41.4	-14.6	17.6	26.8	9.2	34.3	43.2	8.9

Source: Authors' Analysis.

^aShare of drugs, weighted by plan enrollment.

^bPercentage point change from 2011-2019.

^cMedicaid managed care.

^dStandalone prescription drug plan.

^eMedicare Advantage prescription drug plan.

^fHealth Insurance Exchange.

exclusions, administrative restrictions increased substantially more in Medicaid than in other insurance categories, from 31.5% in 2011 to 72.6% in 2019. At the same time, the share of drugs

on non-preferred tiers decreased markedly from 67.8% to 31.7% over the same period, perhaps because cost-sharing caps limit the effectiveness of non-preferred tiers in Medicaid.

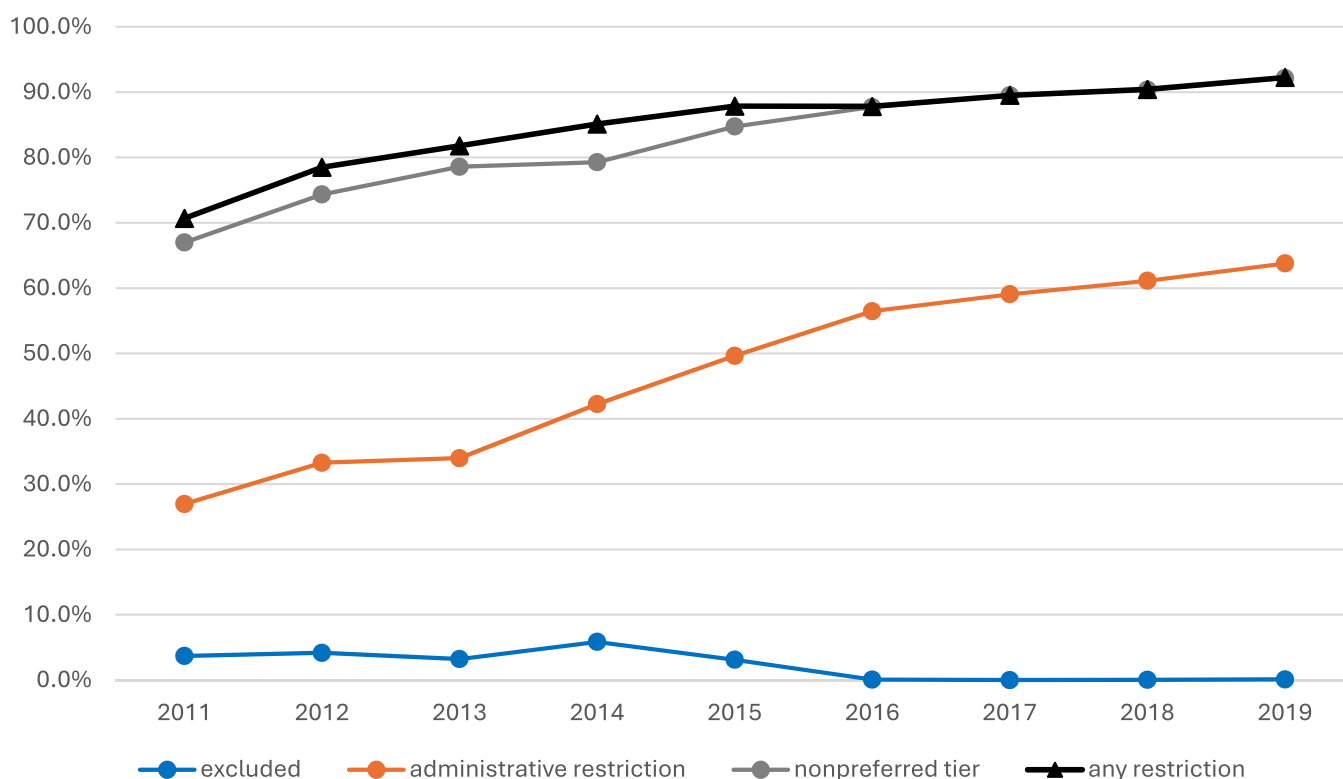


Figure 2 Coverage restrictions for Medicare Part D protected class drugs. Notes: Medicare plans only. Source: Authors' Analysis.

HIX formulary data were reported beginning in 2015, the first year for which data were reliably available (Table 1). From 2015-2019, the share of drugs subject to any coverage restriction increased from 85.8% to 87.6%, the share of drugs excluded by HIX formularies increased from 17.6% to 26.8%, while drugs subject to coverage restrictions increased from 34.3% to 43.2%. The share of drugs on non-preferred tiers decreased from 56.0% to 41.4% from 2015-2019.

Coverage mandates

Medicaid plans, which are generally not allowed to exclude drugs and have limited ability to steer utilization using financial barriers, experienced a much more dramatic increase in administrative restrictions than any other plan type. Administrative restrictions increased more sharply in MMC relative to state-administered formularies. From 2011 to 2019, administrative restrictions increased 50.5% points in MMC (27.0% to 77.5%) vs 24.4% points in state-administered Medicaid (31.5% to 55.9%) (Table 1).

In Medicare, there was a marked difference in exclusions among protected vs non-protected class drugs (0.1% vs 52.5% in 2019). However, drugs in protected classes were subject to a much higher rate of administrative restrictions (63.8% vs 15.3% in 2019), and placement on non-preferred tiers (92.1% vs 26.9% in 2019) relative to non-protected drugs (Figures 2 and 3).

Sensitivity analyses

Alternative approaches to weighting did not change temporal trends but did change the proportion of drugs subject to coverage

restrictions. Compared to our main specification, the unweighted proportion of drugs subject to exclusions was slightly higher (15.8% in 2019), while administrative restrictions (43.5%) and non-preferred tiers (45.4%) were slightly lower. Weighting by gross sales slightly decreased the proportion of exclusions (6.5%), increased the proportion of administrative restrictions (53.1%), and decreased the proportion of non-preferred drugs (39.4%). Weighting by units sold decreased the proportion of exclusions (8.9%), administrative restrictions (24.9%), and non-preferred drugs (28.6%) (Appendix D).

Our decomposition found that formulary coverage trends were largely driven by preferred drugs plans becoming less generous, with only a minor role played by the movement of patients across plans. The three main enrollment trends were: (i) the shifting of commercial patients to HIX and Medicaid after the ACA; (ii) increased market share for MA-PDs relative to PDPs within Medicare; and (iii) the replacement of State Medicaid with MMC. However, none of these trends contributed significantly to our overall formulary coverage trends, though the shift from State Medicaid to MMC did significantly contribute to the increase in the use of administrative restrictions within Medicaid (Appendix E).

Within the six Medicare Part D protected classes, both administrative restrictions and non-preferred tier placement were highest among antineoplastics and lowest among antiretrovirals (Appendix F). When we applied Medicare protected class categories to commercial plans, which do not face the same coverage mandates, we found differences between protected vs non-protected drugs were substantially attenuated compared to Medicare (Appendix G).

Coverage trends were broadly consistent across clinical categories (Appendix H). Exclusions, administrative restrictions,

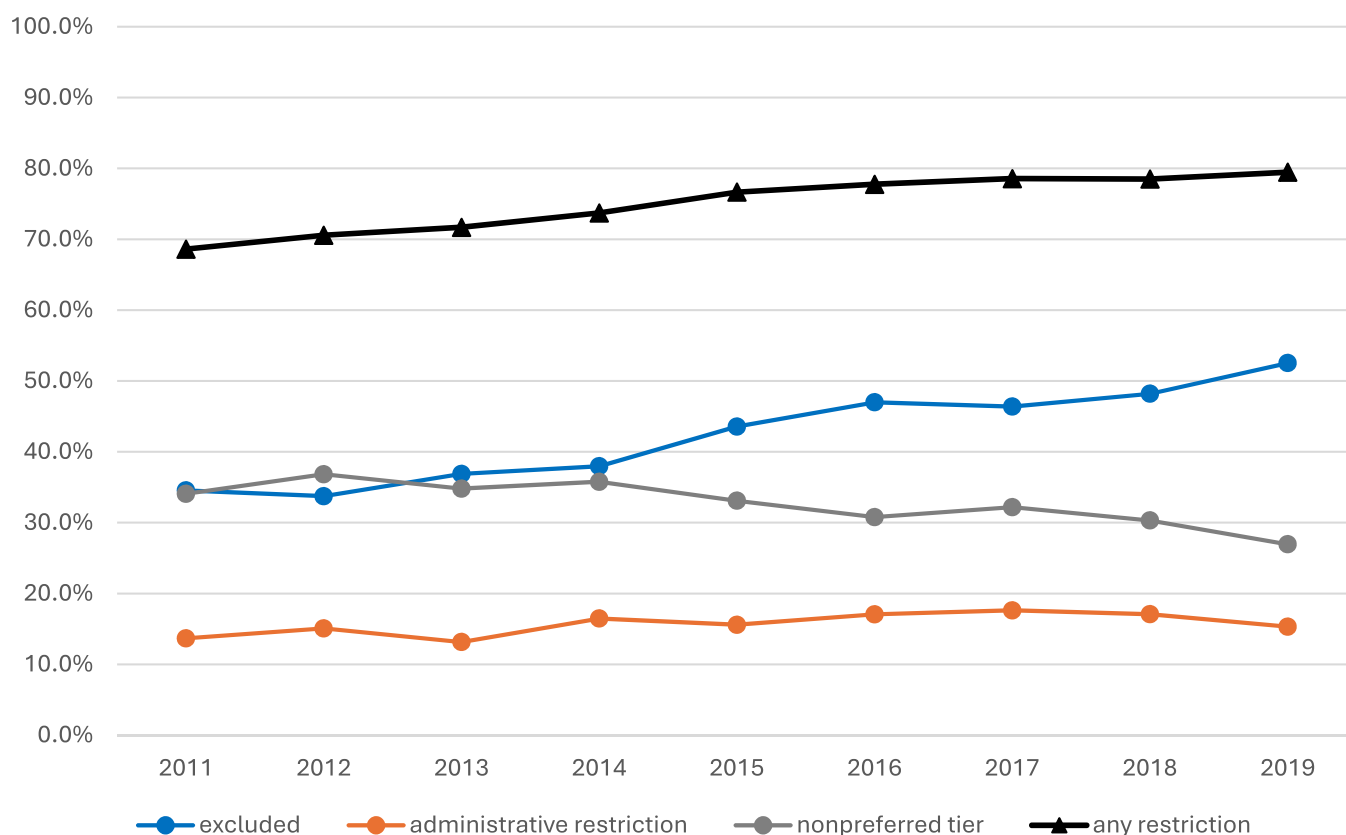


Figure 3 Coverage restrictions for Medicare Part D non-protected class drugs. Notes: Medicare plans only. Source: Authors' Analysis.

and non-preferred tier placement increased across all categories and insurance segments.

Discussion

From 2011 to 2019, overall formulary generosity declined, as formulary exclusions—and especially administrative restrictions—increased substantially for branded retail prescription drugs without a generic competitor. However, at the same time, the share of these drugs on nonpreferred tiers decreased. Two elements of this trend appear particularly interesting. First, we detect a systemic shift from *financial* to *non-financial* barriers. Second, this shift implies that the burden of access barriers has shifted from patients (who bear the burden of cost sharing) to providers (who share the administrative burden of prior authorization with patients).^{6,43}

Within this broader trend, our analysis also uncovered two important patterns. First, formularies in different insurance segments differ vastly in generosity, and rely on different types of coverage restrictions, likely due to a combination of market incentives and regulation.

Commercial formularies were more generous than Medicare, Medicaid, and HIX, perhaps because employer-sponsored plans are group plans (and thus less affected by adverse selection), generally enroll healthier patients, and face pressure from employees to provide generous benefits. Medicare Part D plans relied on formulary exclusions more than other insurance segments, although exclusions were also high among HIX plans. Medicare and HIX plans sell individual coverage and thus face

stronger adverse selection, both of which could motivate less generous coverage.⁴⁴

Second, across segments and over time, we uncovered evidence that coverage mandates, such as those imposed on all Medicaid formularies and on drugs in Medicare protected classes, are associated with higher rates and growth of other coverage restrictions. By design, coverage mandates mean that the strictest coverage restriction—formulary exclusion—is used very sparingly. However, coverage mandates do not prevent plan sponsors from imposing other coverage restrictions, and we found evidence that, between 2011 and 2019, both Medicare and Medicaid responded to coverage mandates by dramatically increasing administrative barriers. Medicare plans, which are less constrained than Medicaid in use of cost-sharing strategies, placed drugs protected by coverage mandates on non-preferred tiers at increasingly high rates.

Policy implications

Coverage restrictions influence utilization and create an administrative burden.¹⁹ Evidence shows that patients cut back on both high- and low-value care when faced with financial or administrative barriers.^{20,21,24,45,46} At the same time, payers need to use restrictions to negotiate drug prices and keep spending down, which is crucial for the overall affordability of pharmaceutical products. Policy efforts to improve patient access to prescription drugs must therefore balance cost containment and access to care.

US regulation of formulary coverage is currently confined to a few limited, but important settings, including coverage

mandates for Medicaid and some drug classes in Medicare Part D, and caps on out-of-pocket costs for Medicaid, and more recently, Medicare patients. Our work suggests that coverage mandates have spurred the growth of non-exclusionary restrictions, both financial and non-financial. The proliferation of these restrictions means that the need to understand their implications for patients is higher than ever.

Understanding the tradeoffs and implications of prescription drug coverage matters for state and federal policy. While prescription drug policy has focused on the financial burden of prescription drugs, growing evidence suggests that administrative restrictions warrant more attention. Evidence on the relative effects of exclusion, administrative burdens, and cost-sharing is scarce, even as recent reforms have begun adding more limits to what formularies can do. For example, the Inflation Reduction Act (IRA) implemented a \$2000 yearly OOP cap on Medicare Part D patients, and a narrower \$35 monthly OOP cap on insulin prescriptions.⁴⁷ Medicaid programs have also expressed interest in formulary innovation, such as Massachusetts' 2017 Section 1115 waiver (denied by CMS), requesting permission to implement a closed formulary.^{48,49}

Conclusion

Reducing administrative burden related to coverage restrictions will require revisiting opportunities for policy innovation. Just as value-based insurance design leveraged cost-sharing to promote access to high-value medications, similar tailoring of administrative restrictions will be needed to balance access and cost. Individual insurers have experimented with changing coverage policies, but larger-scale policy experimentation is needed.

Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

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Conflicts of interest

Please see ICMJE form(s) for author conflicts of interest. These have been provided as supplementary materials.

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