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RESEARCH BRIEF

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Association between changes in prices and out-of-pocket costs for brand-name clinician-administered drugs

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Abstract

Objective: To determine whether annual changes in prices for clinician-administered drugs are associated with changes in patient out-of-pocket costs.

Data Sources and Study Setting: National commercial claims database, 2009 to 2018.

Study Design: In a serial, cross-sectional study, we calculated the annual percent change in manufacturer list prices and net prices after rebates. We used two-part generalized linear models to assess the relationship between annual changes in price with (1) the percentage of individuals incurring any out-of-pocket costs and (2) the percent change in median non-zero out-of-pocket costs.

Data Collection/Extraction Methods: We created annual cohorts of privately insured individuals who used one of 52 brand-name clinician-administered drugs.

Principal Findings: List prices increased 4.4%/yr (interquartile range [IQR], 1.1% to 6.0%) and net prices 3.3%/yr (IQR, 0.3% to 5.5%). The median percentage of patients with any out-of-pocket costs increased from 38% in 2009 to 48% in 2018, and median non-zero annual out-of-pocket costs increased by 9.6%/yr (IQR, 4.1% to 15.4%). There was no association between changes in prices and out-of-pocket costs for individual drugs.

Conclusions: From 2009 to 2018, prices and out-of-pocket costs for brand-name clinician-administered drugs increased, but these were not directly related for individual drugs. This may be due to changes to insurance benefit design and private insurer drug reimbursement rates.

KEYWORDS
clinician-administered drugs, drug prices, health policy, out-of-pocket costs, prescription drugs, private insurance

What is known on this topic

- High prices for pharmacy-dispensed prescription drugs are associated with higher out-of-pocket costs for patients, which can reduce medication adherence and negatively impact health outcomes.
- Clinician-administered drugs represent approximately one-third of all prescription drug spending, which has been rising in recent years.

What this study adds

- In this serial, cross-sectional study of privately insured patients using 52 brand-name clinician-administered drugs from 2009 to 2018, we observed increases in prices (4.4%/year) and median out-of-pocket costs (9.6%/year).
- There was no association between annual changes in drug prices and out-of-pocket costs for individual clinician-administered drugs.

Spending on prescription drugs in the US continues to increase, surpassing $600 billion in 2022.[1–5] Spending is concentrated among brand-name drugs, which are protected by periods of government-granted market exclusivity during which manufacturers freely set high prices. Launch prices for new brand-name drugs increased 13% per year from 2008 to 2021, with more than half of new drugs now costing more than $150,000 per year.[2,6,7] Additionally, manufacturers have frequently raised prices over time, averaging 4.5% per year from 2007 to 2018 after accounting for manufacturer discounts.[3]

Even for those with health insurance, brand-name prescription drugs can have high out-of-pocket costs, particularly for when insurance plans have high deductibles or coinsurance. High out-of-pocket costs are associated with financial toxicity, lower medication adherence, and worse clinical outcomes.[8–12] Unlike other healthcare services, out-of-pocket costs for prescription drugs are tied to manufacturer list prices, even if health insurers or pharmacy benefit managers negotiate sizeable discounts from drug manufacturers. Consequently, annual increases in manufacturer list prices for brand-name drugs are associated with higher out-of-pocket costs for those with private insurance or Medicare.[4,13,14] However, previous studies focused on drugs dispensed by retail or specialty pharmacies. This excludes clinician-administered drugs, such as injectable and infusion-based therapies. Spending on clinician-administered drugs now represents about one-third of all prescription drug spending in the United States.[15-17]

The relationship between drug prices and out-of-pocket spending for clinician-administered drugs may differ from pharmacy-administered drugs because clinician-administered drugs are typically purchased by provider organizations (e.g., clinics or hospitals) that are later reimbursed via their patients' medical insurance benefits. This arrangement is known as "buy-and-bill." Medicare reimburses providers based on the average sales price (ASP), which is the average price at which the drug is sold by manufacturers to wholesalers after discounts and rebates.[18,19] Private insurers frequently reimburse providers at substantial markups, ranging from 5% to 300% above ASP.[15,20]

For patients with private insurance, out-of-pocket costs for clinician-administered drugs typically include a combination of copayments, a flat fee based on the drug, or coinsurance—a percentage of the total drug cost—and may include a deductible, a specific dollar amount the patient is responsible for upfront before the insurer will cover any health care costs. Median annual out-of-pocket costs for the top seventy-five brand-name clinician-administered drugs in Medicare Part B were estimated at $4683 per person in 2018, but few studies have examined trends in out-of-pocket costs for clinician-administered drugs or how these costs are linked to drug prices.[21] To better understand the costs borne by patients for brand-name clinician-administered drugs, we evaluated the relationship between yearly changes in prices and out-of-pocket costs for privately insured patients.

1 | METHODS

We included brand-name drugs without generic or biosimilar competition from 2009 to 2018. Using a national commercial insurance claims database (Merative MarketScan), we identified the 200 clinician-administered drugs with the highest total spending in 2018. We excluded drugs with generic or biosimilar versions marketed prior to January 2009 and censored drugs after new generic or biosimilar competition, which was determined based on when generics or biosimilars were first included in the Medicaid Drug Rebate Program.[22] To minimize variations in pricing patterns, we excluded vaccines, diagnostic products (e.g., radiocontrast), plasma-derived products (e.g., immunoglobulins, albumin), intravenous fluids (e.g., sodium chloride), and drugs regulated as medical devices (e.g., hyaluronic acid). Drugs used by fewer than 50 individuals in 2018 were excluded to ensure stable estimates of out-of-pocket costs.

We determined each drug's route of administration using Lexicomp and therapeutic category based on the World Health Organization's Anatomic Therapeutic Classification system (see methods in Supplement).[23,24] We obtained approval from the Mass General Brigham Institutional Review Board to use deidentified claims data. This study followed the STROBE reporting guideline for cohort studies.

1.1 | Drug prices

We extracted the manufacturer's published list price (i.e., wholesale acquisition cost [WAC]) for each national drug code from SSR Health and AnalySource (with permission from First Databank). We identified ASP from public quarterly Medicare files.[25]

Each dosage form and strength of a drug have a separate WAC, while Medicare reports an average product-level ASP weighted by use. Additionally, different units can be used for WAC (e.g., mL, vials) versus ASP (e.g., mg). To facilitate direct comparison, we converted WAC unit prices to ASP units using the public cross-walk file.[25] We excluded drugs if the converted WAC differed by dosage form or strength because changes in the annual price could be confounded by changes in the relative use of different forms or strengths. All prices were averaged annually and converted to 2018 US dollars using the Consumer Price Index for All Urban Consumers (CPI-U).[26]

1.2 | Out-of-pocket costs

To measure out-of-pocket costs, we created annual cohorts of patients who used each drug from 2009 to 2018; drugs were only included during years when there was no generic or biosimilar competition. Each drug-year cohort included commercially insured patients with at least 1 outpatient medical claim for the clinician-administered drug using Healthcare Common Procedure Coding System (HCPCS) codes and continuous health insurance enrollment for the entire calendar year, allowing for 30 days of lapsed coverage (eFigure 1). We excluded inpatient claims and outpatient claims paid on a capitated basis, because costs for these claims may not be accurately recorded. We combined HCPCS codes for drugs that contain the same active ingredient (darbepoetin, epoetin, ferumoxytol, methoxy polyethylene glycol-epoetin).

For each patient, we identified baseline characteristics, including health insurance plan type (high-deductible health plan [HDHP] vs. non-HDHP) and place of service at which they received the clinician-administered drug during the calendar year (professional office, outpatient hospital facilities, or both). We summed each patient's annual out-of-pocket costs for all drug claims, including copayments, coinsurance, and deductibles.

The out-of-pocket cost data included a large share of patients for whom the drug's cost was fully covered by insurance, and so was right-skewed. To address this, we summarized out-of-pocket costs for each drug-year cohort based on the percentage of users with non-zero out-of-pocket costs and the median non-zero out-of-pocket costs. In a secondary analysis, we included out-of-pocket costs for any medication administration fees billed on the same day as the clinician-administered drug (eTable 2 in Supplement).

1.3 | Statistical analysis

For each drug-year, we calculated the annual percent change in the WAC and ASP compared to the prior year. We described these changes with medians, weighting drug-years based on the number of users in that year. We measured changes in out-of-pocket costs based on the absolute year-over-year change in the percentage of patients with any out-of-pocket costs and the relative percent change in the median non-zero out-of-pocket costs, compared to the prior year.

We used two-part modeling to determine the association between annual changes in price and out-of-pocket costs.[27] In our first linear model, price (WAC or ASP) was the exposure variable and the absolute change from the prior year in the percentage of individuals with any out-of-pocket costs was the outcome. In the second linear model, we used the same exposure variable and the year-over-year annual percent change in non-zero median out-of-pocket costs as the outcome (see Supplement). Models were performed at the drug-year level, and standard errors were clustered by drug. We removed extreme outliers, defined as exposure variables three times the interquartile range above or below the median.

For the secondary analysis, we repeated the two-part modeling using out-of-pocket costs including administration fees. We also repeated the analysis using median out-of-pocket costs for subgroups of patients, stratified based on insurance plan type (HDHP vs. non-HDHP) and place of service (all hospital vs. all office, excluding those with claims at both places; see Supplement).

2 | RESULTS

We included 52 drugs, which contributed 310 drug-years from 2009 to 2018, after removing 12 drug-years (4%) that were extreme outliers (eFigure 1). Eighteen drugs (35%) did not face generic or biosimilar competition during the entire study period; the remaining drugs entered the study after 2009 or faced competition before 2018 (eTable 1). Twenty-seven drugs (52%) were antineoplastic, 7 (13%) hematologic, 6 (12%) immunomodulating, and 5 (10%) antibiotics (eTable 1).

2.1 | Prices

The weighted median annual change in WAC and ASP during the study period was 4.4% (IQR, 1.1% to 6.0%) and 3.3% (IQR, −0.3% to 5.5%), respectively. Annual price changes were similar each year (Figure 1A). Forty-two drugs (81%) had at least one year in which both list and net prices increased above inflation.

2.2 | Out-of-pocket costs

The drug-year cohorts included 1.2 million commercially-insured individuals. The median age was 53 years (IQR, 44 to 59 years), 62% were female, and 5% were enrolled in a HDHP; 38% of individuals received the drug at an outpatient hospital facility, 44% at a professional office, and 18% at both sites during the calendar year (eTable 3a). From 2009 to 2018, the population had a higher percentage of females (60% to 66%), with more individuals enrolling in HDHPs (1% to 10%), and receiving clinician-administered drugs in hospital facilities (33% to 39%; eTable 3b).

The median percentage of individuals with any out-of-pocket costs increased from 38% in 2009 to 48% in 2018 (eFigure 7); median non-zero annual costs increased by 9.6% per year (IQR, 4.1% to 15.4%) (Figure 1). This corresponded with median non-zero out-of-pocket costs increasing from $351 (IQR, $223 to $987) in 2009 to $768 (IQR $619 to $1645) in 2018 (eTable 4). Among all patients, the median deductibles and coinsurance increased from $0 (IQR, $0 to $2) and $104 (IQR, $0 to $630) in 2009 to $0 (IQR, $0 to $460) and $236 (IQR, $11 to $1163), respectively, in 2018 (eTable 5). Out-

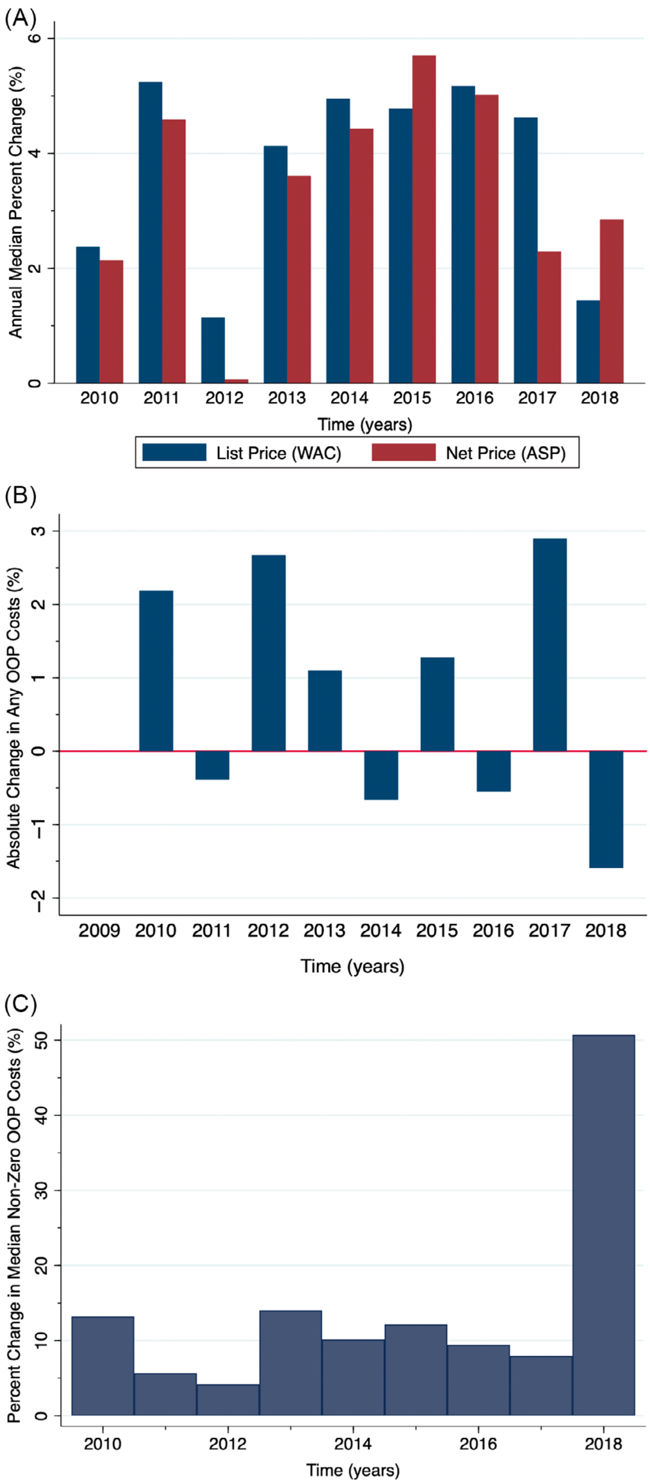

FIGURE 1 Panels A–C. Annual Change in Prices and Out-of-Pocket Costs of Clinician-Administered Drugs from 2009 to 2018. Panel A. Annual median percent change in wholesale acquisition cost (WAC) and average sales price (ASP) for 52 clinician-administered drugs in the cohort after eliminating extreme outliers (median +/− 3 × IQR). Panel B. Median frequency-weighted percentage of individuals with any out-of-pocket costs. Panel C. Among individuals with any non-zero out-of-pocket (OOP) costs, the frequency-weighted median annual percent change in out-of-pocket costs for clinician-administered drugs. All prices are reported in 2018 US Dollars and adjusted for inflation using the consumer price index for all urban consumers (CPI-U) from the Bureau of Labor Statistics.

of-pocket costs for the 10 most-used drugs in 2018 are presented in Table 1. Results were similar when including out-of-pocket costs for drug administration fees (eFigure 9) and trends were similar for subgroups by insurance plan type and place of service (eFigure 7).

2.3 | Association between prices and out-of-pocket costs

Overall, every 1% increase in WAC was associated with a decrease of 0.09% (95% CI, 0.03%–0.15%) in the proportion of patients paying non-zero out-of-pocket costs compared to the previous year ($p = 0.003$), but there was no association between changes in WAC and changes in median non-zero out-of-pocket costs (Figure 2; eFigure 2a–d). There was no association between changes in ASP and changes in out-of-pocket costs.

The results were similar when including out-of-pocket drug costs for administration fees and in the subgroups of patients enrolled in HDHPs (eFigure 3) and non-HDHPs (eFigure 4). Results were also similar among those who received drugs exclusively in hospital settings (eFigure 6). For patients who received clinician-administered drugs exclusively in office (eFigure 5), there was a positive relationship between changes in ASP and changes in median non-zero OOP costs; every 1% increase in ASP was associated with a 0.53% (IQR, 0.02–1.04) increase in median non-zero out-of-pocket costs. Subgroup results are summarized in Figure 2.

3 | DISCUSSION

Among 52 brand-name clinician-administered drugs, prices and median out-of-pocket costs paid by privately insured patients both increased from 2009 to 2018, but there was no association between changes in prices and out-of-pocket costs for individual drugs.

Similar to other analyses, we found that on average, prices for brand-name clinician-administered drugs increased faster than inflation.[17,20] These rising prices for existing drugs have raised concerns about medication affordability. However, unlike prior studies of retail prescription drugs, we found that rising out-of-pocket costs for clinician-administered drugs were not directly related to price changes for individual drugs.[4,12,13]

There are several potential reasons for this discrepancy between clinician-administered drugs and pharmacy-administered drugs. First, commercial insurance plans frequently reimburse clinics and hospitals at substantial markups over the drug's price. One study found that private insurers pay 11 top-performing US hospitals approximately 150% to 300% more than what Medicare pays for the same clinician-administered drug.[15] Another study found that private payors paid up to 50% more for high-spending clinician-administered drugs than Medicare in 2020.[20]

Second, this may reflect the complexities of benefit design for commercial insurance plans for which out-of-pocket costs for individual services (e.g., clinician-administered drugs) vary depending on the time of year and prior use of other services. For example, HDHPs

TABLE 1 Changes in drug prices and out of pocket costs for the 10 most commonly used clinician-administered drugs in 2018.

		Out-of-pocket (OOP) Costs during first and final study year[a]		Median annual changes in drug prices and out-of-pocket (OOP) costs			
10 most used drugs in 2018	Years included in study	N (%) with Any OOP costs	Median (IQR) non-zero OOP costs (USD)	List price (WAC) (%/year)	Net price (ASP) (%/year)	Any OOP Cost (%/year)	Non-zero OOP costs (%/year)
Denosumab (Prolia)	2012–2018	5384 (47) 6366 (48)	247 768	3.5	1.8	0.1	21.6
Ferric carboxymaltose (Injectafer)	2015–2018	2031 (47) 5480 (51)	346 685	2.9	−2.1	1.1	34.6
Bevacizumab (Avastin)	2009–2018	4364 (34) 4854 (46)	67 151	2.0	1.5	1.3	9.7
Rituximab (Rituxan)	2009–2018	3346 (38) 2676 (43)	967 2143	4.1	3.6	0.6	9.3
Ferumoxytol (Feraheme)	2010–2018	989 (44) 2598 (50)	119 487	8.9	1.1	0.8	21.0
Aflibercept (Eylea)	2013–2018	516 (47) 2744 (56)	730 1558	−1.7	−1.8	2.6	23
Leuprorelin (Eligard)	2010–2018	2649 (45) 2019 (48)	285 619	−0.7	−1.0	0.4	10.3
Trastuzumab (Herceptin)	2009–2018	2571 (43) 1564 (40)	818 1692	3.9	3.6	−0.5	7.8
Vedolizumab (Entyvio)	2016–2018	1325 (49) 2332 (61)	1686 2406	7.0	3.5	5.4	18.9
Omalizumab (Xolair)	2009–2018	832 (39) 1277 (39)	585 1325	5.7	5.8	−0.3	9.9

Note: Annual changes in drug prices and out-of-pocket costs are adjusted for inflation using the consumer price index for all urban consumers (CPI-U) and reported in 2018 US dollars.

Abbreviations: ASP, average sales price (i.e., net price after rebates and discounts); OOP, out-of-pocket, the total cost paid by patients for a prescription drug or the sum of deductibles, copayments, and coinsurance; WAC, wholesale acquisition cost (i.e., manufacturer list price).

[a]First number listed is each cell is the value during the first year in the study and the second value beneath it is from the final year in the study (2018).

require patients to bear the full cost of covered drugs until a deductible is reached. From 2009 to 2018, the percentage of patients enrolled in HDHPs increased from 1% to 10% in our study. Among privately insured patients nationally, enrollment in HDHPs increased from 7% in 2009 of all working adults to 26% in 2018.[28] In 2018, the median annual deductible for those in HDHPs was approximately $2000.[29,30] Because many clinician-administered drugs cost tens of thousands of dollars per dose, annual out-of-pocket costs may be more related to patient deductibles and insurance out-of-pocket maximums than the actual cost of individual drugs.[31-33] If patients reach their out-of-pocket maximum due to OOP spending on an expensive prescription drug, their costs may not change even if the drug price increases.

We also observed important differences based on the site where patients received clinician-administered drugs. Over the study, there was an increase in the frequency of outpatient hospital facility use with a corresponding decrease in outpatient clinic use. For patients who received drugs only at office locations but not hospitals, increase in net prices were modestly related to patient out-of-pocket costs. This may be because of higher reimbursements disconnected from drug prices in hospital outpatient settings.[34,35]

We observed variation in the year-over-year changes in out-of-pocket costs, with an outlier 50% increase in the median non-zero OOP cost 2017 to 2018. This result was not obviously explained by changes in the patient population between 2017 and 2018 (eTable 3b). While this result raises concerns about a trend by private insurers to increase cost-sharing by patients, more recent data should be analyzed in the future studies to determine if this trend persists.[36,37]

Our study has limitations. We measured the association between changes in prices and patient out-of-pocket costs, but we did not measure how changes in drug prices result in changes to premiums. For commercially insured patients, about 22% of premiums are spent on prescription drugs.[33] Our study focused on commercially-insured patients, and we could not evaluate the relationship between prices and out-of-pocket costs for publicly-insured individuals.[38] In Medicare, for example, reimbursement is directly related to the net price (ASP) and patients are responsible for 20% coinsurance, so prices and out-of-pocket costs may be more directly related. Our analysis was also limited to 52 brand-name, single-sourced clinician-administered drugs without generic and biosimilar competition and had strict inclusion criteria to enable direct comparisons of the list and

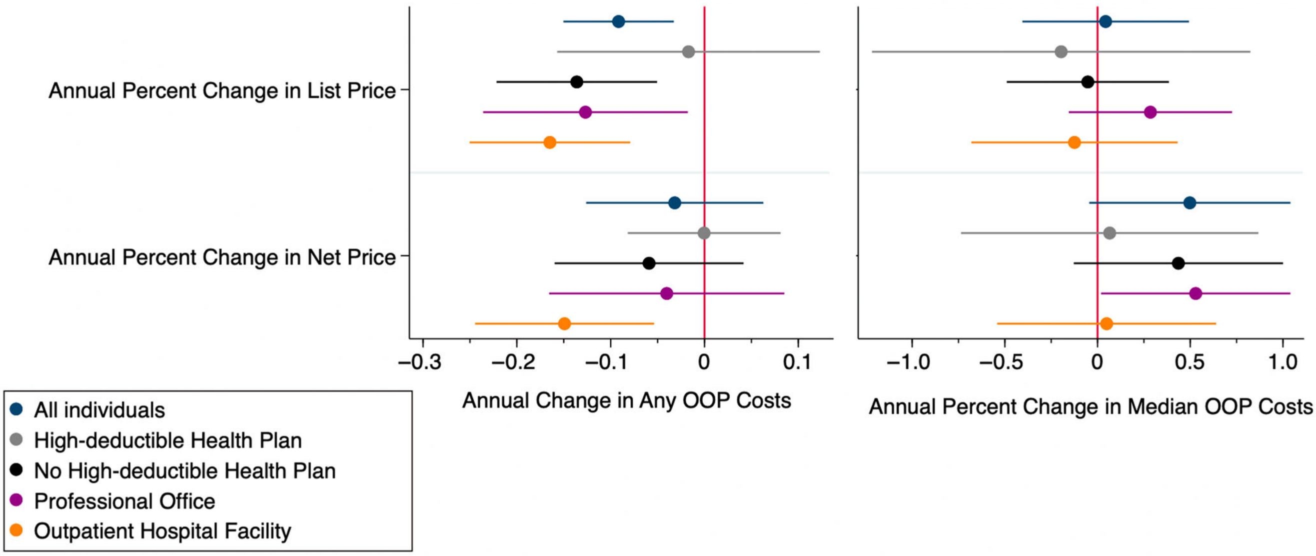

FIGURE 2 Relationship between annual percent change in drug prices and individual out-of-pocket costs for brand-name clinician-administered drugs. ASP, average sales price (i.e., net price after rebates and discounts); OOP, out-of-pocket, the total cost paid by patients for a prescription drug or the sum of deductibles, copayments, and coinsurance; WAC = Wholesale Acquisition Cost (i.e., manufacturer list price). Values are beta-coefficients from linear regression models with 95% confidence interval. Two-part linear modeling of percent change in annual prices, using wholesale acquisition costs (list price) or average sales price (net price) as the exposure, and the difference between having any out-of-pocket costs or the annual change in median out-of-pocket costs as the outcome. Results presented for all individuals and stratified by subgroups.

net prices, so our results may not be generalizable to all clinician-administered drugs. Finally, we could not account for patient assistance programs or copay cards that some patients use lower insurance-related out-of-pocket costs.[39,40]

4 | CONCLUSIONS

From 2009 to 2018, prices and out-of-pocket costs for privately insured patients increased for 52 high-spending clinician-administered drugs, but there was no association between changes in price and out-of-pocket costs for individual drugs. This is likely because private insurers frequently reimburse hospitals and clinics at substantial markups, and because insurance benefit design can de-link patient out-of-pocket costs from the cost of individual drugs. With clinician-administered drugs accounting for nearly one-third of all prescription drug spending annually, higher cost-shifting to patients is a concerning development that deserves careful scrutiny by policymakers to prevent adverse outcomes from cost-related non-adherence.

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CONFLICT OF INTEREST STATEMENT

Dr. Kesselheim reports serving as an expert witness on behalf of the FTC in 2023 for 2 cases related to pharmaceutical industry acquisitions covering physician-administered drugs (both now settled).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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