

Comparing Patient OOP Spending for Specialty Drugs in Medicare Part D and Employer-Sponsored Insurance

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The pharmaceutical pipeline is moving toward more high-cost specialty drugs.¹ From 2008 until 2017, CMS defined specialty drugs as those with a monthly cost greater than \$600; beginning in 2017, the threshold became \$670.^{2,3} These drugs are primarily biologics and biosimilars used to treat complex chronic conditions such as rheumatoid arthritis (RA), multiple sclerosis (MS), cancer, and hepatitis C. Patients with these conditions have few other clinical options, forcing them to pay high cost-sharing rates or forgo treatment.⁴⁻⁶

Care for these diseases can begin around age 40 years and continue throughout life, making health insurance coverage likely to span across employer-sponsored insurance (ESI) and Medicare prescription drug (Part D) coverage.⁷⁻¹⁰ Few studies have examined whether the financial burden placed on patients who take specialty drugs differs among those with ESI, Medicare fee-for-service (FFS), and Medicare managed care (Medicare Advantage [MA]) drug coverage.¹¹⁻¹³ Given the policy and clinical concerns that high cost sharing may lead to nonadherence and financial burden, it is important to understand the levels of cost sharing across insurance types and the role that benefit design may play.

ESI and Medicare Part D prescription drug plans are administered via private insurance plans and typically involve the same 3 pharmacy benefit managers that have the greatest market share. The design of the insurance benefit, however, may result in differences in out-of-pocket (OOP) spending.¹⁴⁻¹⁶ We examine if there are differences in specialty drug choice and OOP spending across 3 populations: ESI enrollees, enrollees in stand-alone Medicare Part D plans (for FFS beneficiaries), and enrollees in an MA plan that offers prescription drug coverage. First, we compared Medicare spending with ESI spending, and then we examined Medicare FFS and MA populations separately. We analyze FFS and MA plans separately because MA plans are paid an annual, capitated amount to provide a beneficiary's inpatient and outpatient medical benefits, whereas FFS drug plans do not have inpatient and outpatient benefits under their auspices. Thus, MA plans have an incentive to minimize total health care spending of their enrollees and encourage greater adherence to drug regimens by having lower

ABSTRACT

OBJECTIVES: Per capita spending on specialty drugs increased 55% between 2014 and 2018. Individuals aged 55 to 75 years using specialty drugs make the transition from employer-sponsored insurance (ESI) to Medicare Part D coverage. We compared out-of-pocket (OOP) spending across ESI, Medicare fee-for-service (FFS), and Medicare Advantage (MA) prescription drug plans to examine the impact of benefit design on OOP spending.

STUDY DESIGN: Analyses consisted of Truven MarketScan and Medicare Part D prescription drug claims from 2013 to 2017 for individuals enrolled in ESI, FFS, and MA drug plans taking at least 1 drug among the top 4 specialty drug classes: rheumatoid arthritis (RA), multiple sclerosis (MS), cancer, and hepatitis C.

METHODS: Multivariate regression analyses with fixed effects were used to assess whether there are differences in OOP spending by insurance type and the impact of benefit design differences. A secondary outcome was drug choice within a therapeutic class.

RESULTS: There were small differences in drug choice between Medicare and ESI but significant differences in OOP spending. Monthly OOP spending for ESI relative to FFS was \$108 less for RA drugs, \$288 less for MS drugs, \$504 less for cancer drugs, and \$1437 less for hepatitis C drugs. Spending was slightly greater for beneficiaries in MA plans compared with FFS. Higher Medicare spending was driven by gaps in coverage in the Part D benefit phases because beneficiaries pay a percentage of list price.

CONCLUSIONS: OOP spending was substantially higher for Medicare enrollees compared with ESI enrollees as a result of the Part D benefit structure.

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cost sharing. Although Part D is outside the MA capitated payment, adherence to prescription drug regimens is often a low-cost substitute for medical spending in the management of common chronic conditions.^{17,18}

The standard Part D benefit is the same for beneficiaries in FFS and MA drug plans and typically requires beneficiaries to pay a percentage of a drug's list price. The Part D benefit has 4 phases—deductible, initial coverage period, coverage gap (“donut hole”), and catastrophic coverage—with varying levels of cost sharing. Beneficiaries are responsible for all costs during the deductible period (a maximum of \$400 in 2017), 25% of gross drug costs up to the initial coverage limit (\$3700 in 2017), and 40% of their branded drug costs and 50% of their generic drug costs in the coverage gap. Once OOP expenses reach \$4950 (2017 limit), beneficiaries enter catastrophic coverage, in which they pay 5% of drug costs. There is no OOP maximum. There is wide variation in the benefit structure of ESI plans and no comprehensive data on the benefit structure for drugs across all ESI plans. Anecdotal evidence suggests that ESI plans do not have coverage gaps like Medicare plans (although some have separate tiers for specialty drugs that can utilize coinsurance, rather than co-payments) and most have an OOP cap.¹⁹

Per capita spending on specialty drugs increased 55% from 2014 to 2018, driven primarily by a 57% increase in the price of branded specialty drugs and more drugs entering the market.²⁰ High and rising prices of specialty drugs may have adverse implications for patient financial and clinical outcomes because adherence to specialty drugs is negatively correlated to the level of cost sharing.²¹ This is especially important for a subset of specialty drugs, some of which have list prices above \$50,000 and for which the cost sharing can be 25% to 33% of the list price. An improved understanding of how differences in benefit design affect OOP spending is important for patients, physicians, payers, and Medicare policy makers. This study examines differences in OOP costs and drug choice among enrollees with ESI, FFS, and MA.

METHODS

Data and Sample

We analyzed prescription drug claims from 2013 to 2017. We used Medicare Part D claims for a 20% random sample of FFS and MA beneficiaries to capture OOP spending by Medicare beneficiaries. The data included information on beneficiary cost sharing, starting and ending benefit phases for each prescription fill, and the plan's formulary. Part D claims were linked with age, gender, race, and state and county of residence from the Master Beneficiary Summary File. Individuals receiving low-income subsidies were excluded from the analysis because they have

TAKEAWAY POINTS

Medicare beneficiaries pay substantially higher out-of-pocket (OOP) costs for specialty drugs than employer-sponsored insurance enrollees, primarily because of the lack of an OOP cap and the “donut hole.”

- ▶ This study examines differences in OOP spending as individuals age from employer-sponsored insurance into Medicare Part D coverage.
- ▶ Based on specialty drug class, average OOP spending for Medicare fee-for-service (FFS) enrollees was \$108 to \$1437 greater than spending by employer-sponsored insurance enrollees. Medicare Advantage beneficiaries had slightly higher OOP spending than FFS beneficiaries.
- ▶ The benefit structure of Part D results in Medicare enrollees paying substantially higher OOP costs for specialty drugs than employer-sponsored insurance enrollees, primarily due to the absence of an OOP cap in Medicare and the donut hole.

limited cost sharing that does not follow the standard Medicare benefit structure.

To assess drug spending in ESI, we used data from Truven MarketScan, a claims and encounter database encompassing approximately 25% of the commercially insured population (not nationally representative).²² The data come from employers and commercial insurers and include active employees, early retirees, and dependents insured by employer-sponsored plans (including but not limited to Employee Retirement Income Security Act/self-insured plans), but they do not include those insured by individual marketplace plans. We merged prescription drug claims with enrollee characteristics including age, gender, metropolitan statistical area (MSA) of residence, and plan type (eg, health maintenance organization [HMO], preferred provider organization [PPO], FFS, capitated, high deductible).

In both the ESI and Medicare settings, the sample consisted of individuals who filled a prescription for a specialty drug between 2013 and 2017. Based on existing literature, we focused on 16 drugs within the 4 specialty drug classes with the highest per capita annual spending in the United States: those for RA, MS, cancer, and hepatitis C.^{6,10,23} Due to the focus on outpatient drug use, physician-administered therapies for RA and cancer were not examined.

The primary outcome of interest was monthly OOP spending. Both databases define OOP spending as the dollar amount paid by the beneficiary, including co-payments, coinsurance, and the deductible, per prescription fill. We divided OOP spending by days supplied and multiplied the daily amount by 30 to create a standardized monthly OOP cost per drug. The main independent variable of interest was whether an individual had coverage through ESI, FFS, or MA.

Statistical Analyses

First, to test for differences in drug choice among enrollees with ESI, FFS, and MA, we conducted *t* tests for rates of utilization and average OOP costs for each drug within a therapeutic class.

Second, to estimate whether there were differences in OOP spending on specialty drugs among ESI, FFS, and MA enrollees, we conducted multivariate ordinary least squares regressions with fixed effects at the therapeutic class level. We controlled for patient

TABLE 1. Descriptive Statistics for Individuals Taking Specialty Drugs by Insurance Type and Disease Category*

	Rheumatoid arthritis			Multiple sclerosis			Cancer			Hepatitis C		
	FFS	MA	ESI	FFS	MA	ESI	FFS	MA	ESI	FFS	MA	ESI
Individuals ^a	10,837	5738	191,567	5093	3289	46,042	16,960	8401	14,284	8090	7072	31,227
Prescription fills ^a	162,613	87,634	2,371,983	114,827	75,611	602,695	211,436	100,343	167,197	26,913	23,456	100,856
Beneficiary characteristics												
Proportion female	0.67 (0.47)	0.69 (0.46)	0.58 (0.49)	0.77 (0.42)	0.76 (0.43)	0.76 (0.43)	0.35 (0.48)	0.34 (0.48)	0.40 (0.49)	0.39 (0.49)	0.37 (0.48)	0.37 (0.48)
Average age in years	71.1 (7.5)	69.0 (8.8)	46.1 (13.0)	64.0 (8.8)	61.1 (9.0)	47.0 (10.5)	75.3 (7.8)	75.3 (7.9)	54.3 (9.5)	66.8 (7.2)	66.0 (7.0)	53.4 (10.1)
Drug characteristics												
Annual number of drugs	16.5 (9.6)	17.1 (10.2)	12.2 (9.2)	14.6 (9.3)	14.9 (9.4)	10.7 (8.4)	17.2 (9.4)	16.7 (9.2)	14.7 (10.8)	14.2 (9.0)	13.5 (8.9)	11.6 (8.8)
Proportion of total drugs that are generic	0.66 (0.18)	0.67 (0.19)	0.58 (0.25)	0.63 (0.22)	0.64 (0.21)	0.54 (0.26)	0.72 (0.18)	0.72 (0.18)	0.64 (0.25)	0.73 (0.21)	0.73 (0.22)	0.64 (0.25)
Proportion who reached coverage gap threshold	0.38 (0.49)	0.51 (0.50)	-	0.69 (0.46)	0.81 (0.39)	-	0.70 (0.46)	0.75 (0.43)	-	0.76 (0.42)	0.86 (0.34)	-
Proportion who reached catastrophic threshold	0.30 (0.46)	0.38 (0.49)	-	0.59 (0.49)	0.68 (0.47)	-	0.67 (0.47)	0.70 (0.46)	-	0.76 (0.43)	0.84 (0.37)	-

ESI, employer sponsored insurance; FFS, Medicare fee-for-service; MA, Medicare Advantage.

*Sample size for FFS and MA represents the number of people in the 20% random Medicare claims data. The Medicare sample includes only individuals who do not receive a low-income subsidy. Unadjusted SDs are reported in parentheses.

Data source: Medicare Part D and Truven MarketScan claims, 2013-2017.

age and sex and included a set of fixed effects: MSA of residence (to account for geographic variation, using a county-MSA crosswalk to identify MSAs for Medicare enrollees), year (to account for unobservable, time-invariant characteristics [ie, changes in drug use because of new clinical studies, the ongoing phase-out of the coverage gap in Medicare, and changes in ESI benefit design]), month (to capture differences in OOP spending over the course of a year because of movement through the benefit phases), and branded drug (to ensure that each drug was being compared with itself across different insurers and results were not affected by differing proportions of drug use across insurers). Robust standard errors clustered at the beneficiary level were used to allow for individual heterogeneity. We conducted several sensitivity analyses to examine the robustness of our results (described later).

RESULTS

Sample Characteristics

The analytic data set included 348,600 individuals and 4,045,564 claims; 80% of the claims were covered by ESI (283,120 enrollees) (Table 1). Among specialty drug users in the Medicare sample, FFS made up the majority of the sample, 63%, compared with 37% enrolled in MA, reflective of national MA enrollment. Additional details regarding the ESI sample are in eAppendix Tables 1 and 2 (eAppendix available at ajmc.com). The gender distribution was similar between ESI and Medicare. The average age difference was 20 years between ESI and Medicare enrollees in the RA, MS, and cancer samples; however, there was only a 13-year age difference for hepatitis C.

Drug-Level Utilization and Spending

There were significant differences (Table 2) in drug choice for RA but not MS, cancer, or hepatitis C. Among RA drugs, the most commonly taken drug by ESI beneficiaries was Humira, by 60% of patients, but the most common drug taken by Medicare beneficiaries was Enbrel, taken by 54% and 53% of FFS and MA beneficiaries, respectively. Despite differences in drug choice, OOP costs were similar within an insurance type. In ESI, OOP costs for the 2 brand name drugs were nearly identical, \$103 for Enbrel compared with \$102 for Humira, suggesting that OOP cost was not the primary reason for branded drug choice. For FFS patients, average OOP costs were \$219 for Enbrel compared with \$225 for Humira, whereas for MA patients, average OOP costs for Enbrel were \$218 (not statistically different from FFS) compared with \$192 for Humira (\$40 lower than FFS; $P < .01$). Compared with Medicare, ESI OOP costs were significantly lower ($P < .01$) across both drugs.

Among the other 3 disease groups, differences in drug choice were fewer. The majority of MS patients took Copaxone in both ESI and Medicare. For the cancer population, the most commonly used drug was Revlimid (used by 48% of Medicare beneficiaries and 46% of ESI enrollees). Average monthly OOP spending on Revlimid was \$111 for ESI patients compared with more than \$700 for Medicare (\$734 for FFS patients and \$757 for MA patients). Finally, for hepatitis C drugs, drug choices were not substantially different between Medicare and ESI, but average OOP costs were higher in Medicare. The most commonly taken drug was Harvoni, with average OOP costs of \$448 for ESI patients compared with more than \$1900 for Medicare (\$1981 for FFS patients and \$1995 for MA patients). Given the limited differences in OOP spending among

TABLE 2. Costs and Utilization of Specialty Drugs by Insurance Type

	n (%) of drug population taking each drug			Mean (SD) OOP spending per month, \$		
	FFS (reference)	MA	ESI	FFS (reference)	MA	ESI
Rheumatoid arthritis						
Enbrel	6276 (54)	3269 (53)	76,067 (36)***	219 (379)	218 (411)	103*** (246)
Humira	4495 (39)	2326 (38)	125,804 (60)***	225 (423)	192*** (445)	102*** (258)
Orencia	832 (7)	570 (9)	8734 (4)***	175 (391)	196*** (904)	110*** (327)
Multiple sclerosis						
Avonex	885 (16)	556 (16)	6716 (13)**	379 (533)	384 (508)	92*** (252)
Copaxone	3004 (54)	1839 (52)	24,986 (49)***	423 (562)	440*** (806)	102*** (289)
Tecfidera	1660 (30)	1175 (33)	19,409 (38)***	410 (588)	459*** (600)	105*** (378)
Cancer						
Gleevec	2100 (12)	1105 (13)	4687 (30)***	523 (694)	494*** (695)	104*** (459)
Imatinib mesylate	1166 (7)	551 (6)	1868 (12)	464 (733)	363*** (667)	50*** (198)
Revlimid	8666 (49)	4182 (48)	7041 (46)***	734 (911)	757*** (955)	111*** (474)
Venclexta	151 (0.9)	47 (0.5)	97 (0.6)	594 (691)	520 (672)	67*** (251)
Zytiga	5512 (31)	2813 (32)	1762 (11)***	552 (767)	545 (785)	90*** (326)
Hepatitis C						
Epclusa	601 (7)	614 (9)	2104 (7)	1881 (1381)	1685*** (1413)	488*** (2049)
Harvoni	5182 (63)	4800 (67)***	18,148 (57)***	1981 (1441)	1995 (1517)	448*** (2410)
Sovaldi	1930 (23)	1425 (20)*	8917 (28)***	1616 (1206)	1723*** (1260)	317*** (2024)
Viekira Pak	186 (2)	125 (2)	2494 (8)***	1216 (1345)	1707*** (1325)	275*** (1738)
Zepatier	349 (4)	206 (3)	336 (1)	1445 (1245)	1447 (1257)	389*** (1754)

ESI, employer-sponsored insurance; FFS, Medicare fee-for-service; MA, Medicare Advantage; OOP, out-of-pocket.

P* < .1; *P* < .05; ****P* < .01.

Data source: Medicare Part D and Truven MarketScan claims, 2013-2017.

drugs within a given therapeutic class, we conducted subsequent analyses at the therapeutic class level, rather than the drug level.

Therapeutic Class Utilization and Spending

Table 1 compares ESI and Medicare differences in drug utilization. Across all 4 drug classes, Medicare beneficiaries, both FFS and MA, took a similar number of drugs per year (16.1 vs 15.6), about 25% more than the ESI population. Among all classes, a substantial proportion of Medicare enrollees reached catastrophic coverage over the course of the year, with MA patients being more likely to reach the coverage gap and catastrophic coverage than FFS patients (Table 1). Due to the significant difference between FFS and MA beneficiaries in movement through the Part D benefit phases, we continue to separately assess these 2 populations.

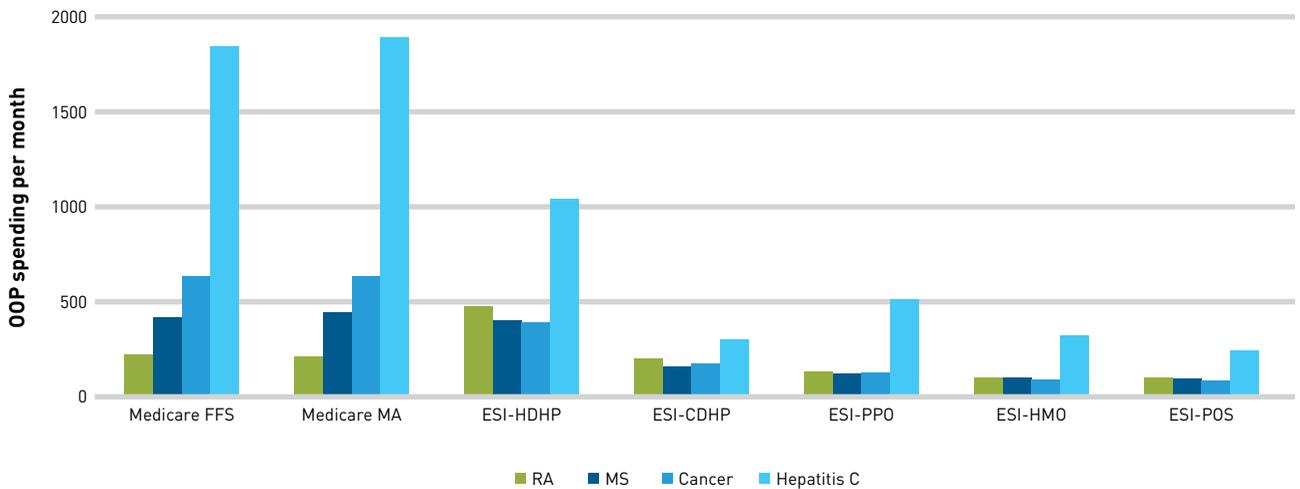
The Figure shows average monthly OOP spending by insurance and disease type. There were substantial differences between ESI and Medicare but little variation within ESI (across plan types [eg, PPOs vs HMOs]) or within Medicare (FFS vs MA). Average OOP spending for all Medicare beneficiaries was significantly higher than in ESI, approximately \$200 for RA drugs, \$400 for MS drugs, \$600 for cancer drugs, and \$1700 for hepatitis C drugs (Figure), with spending just slightly higher in MA than FFS. OOP spending was consistent across all types of ESI plans for RA, MS, and cancer, about \$100 per month, with differences of \$30 or less (except for

high-deductible health plans [HDHPs]). The 1 exception among ESI plans was for hepatitis C drugs; average spending varied from approximately \$200 in point of service (POS) plans to greater than \$1000 in HDHPs.

The main finding of this paper can be found in Table 3, which shows adjusted differences in OOP spending by insurance type. The large differences in average OOP spending between Medicare and ESI, seen in the unadjusted data, persist after controlling for beneficiary characteristics. Compared with Medicare FFS (the larger of the 2 Medicare populations), individuals in ESI paid, on average, \$108 (*P* < .01) less per month for RA drugs, \$288 (*P* < .01) less for MS drugs, \$504 (*P* < .01) less for cancer drugs, and \$1437 (*P* < .01) less for hepatitis C drugs. Differences in OOP spending existed between Medicare FFS and MA plans; however, they were smaller in magnitude. Compared with FFS, MA beneficiaries paid, on average, \$28 (*P* < .01) more per month for RA drugs, \$36 (*P* < .01) more for MS drugs, \$38 (*P* < .01) more for cancer drugs, and \$75 (*P* < .01) more for hepatitis C drugs. Full regression results are shown in eAppendix Table 3.

To understand how variation in Medicare OOP spending occurred, we examined differences between FFS and MA by benefit phase. As shown in Table 4, we found large variation in OOP spending during the coverage gap. Relative to FFS, MA beneficiaries paid \$117 (*P* < .01) less for RA drugs, \$87 (*P* < .01) less for MS drugs, \$374 (*P* < .01)

FIGURE. Average OOP Spending per Month for Specialty Drugs by Insurance and Plan Type^a



CDHP, consumer-directed health plan; ESI, employer-sponsored insurance; FFS, fee-for-service; HDHP, high-deductible health plan; HMO, health maintenance organization; MA, Medicare Advantage; MS, multiple sclerosis; OOP, out-of-pocket; POS, point of service; PPO, preferred provider organization; RA, rheumatoid arthritis. ^aThere are 515,789 claims in Medicare FFS; 231,954 claims in MA; 143,513 claims for HDHPs; 233,440 claims for CDHPs; 1,556,668 claims for PPO plans; 178,121 claims for POS plans; and 308,375 claims for HMO plans. Data source: Medicare Part D and Truven MarketScan claims, 2013-2017.

TABLE 3. Differences in Monthly OOP Spending for Specialty Drugs by Insurance Type^a

	Rheumatoid arthritis	Multiple sclerosis	Cancer	Hepatitis C
FFS	Reference			
MA	28*** [5]	36*** [6]	38*** [7]	75*** [20]
ESI	-108*** [23]	-288*** [4]	-504*** [8]	-1437*** [25]
Prescription fills, n	2,495,689	730,248	394,656	136,678

ESI, employer-sponsored insurance; FFS, Medicare fee-for-service; MA, Medicare Advantage; OOP, out-of-pocket.

* $P < .1$; ** $P < .05$; *** $P < .01$.

^aThe coefficients represent dollar differences for ESI and MA beneficiaries compared with FFS beneficiaries. The Medicare samples do not include individuals who receive a low-income subsidy. Regressions include controls for age and gender of individuals and fixed effects for year, metropolitan statistical area of residence, and branded drug choice. Standard errors are clustered at the beneficiary level and reported in parentheses.

Data source: Medicare Part D and Truven MarketScan claims, 2013-2017.

less for cancer drugs, and \$671 ($P < .01$) less for hepatitis C drugs. In contrast, MA plans required significantly higher cost sharing than FFS in the initial coverage period (differences ranged from \$33 to \$106, depending on therapeutic class). During catastrophic coverage, differences were less than \$25. It would appear that most of the difference in MA and FFS spending occurs during the donut hole period. Two possible explanations are that MA plans are filling in the donut hole (which has been phased out as of 2020; there is a uniform 25% coinsurance rate in the initial coverage limit and coverage gap phases) and that MA plans have greater use of high, fixed-dollar co-payments instead of coinsurance.²⁴

TABLE 4. Differences in OOP Specialty Drug Spending per Prescription Month by Insurance Type and Medicare Benefit Phase^a

	Rheumatoid arthritis	Multiple sclerosis	Cancer	Hepatitis C
Initial coverage limit				
FFS	Reference			
MA	33*** [3]	50*** [11]	83*** [11]	106*** [40]
Prescription fills, n	121,202	34,038	65,109	7855
Coverage gap ("donut hole")				
FFS	Reference			
MA	-117*** [21]	-87** [39]	-374*** [60]	-671** [311]
Prescription fills, n	15,150	11,500	5127	516
Catastrophic coverage				
FFS	Reference			
MA	-16*** [4]	-1 [2]	-8 [6]	-25** [12]
Prescription fills, n	79,451	102,897	164,391	31,092

FFS, Medicare fee-for-service; MA, Medicare Advantage; OOP, out-of-pocket. * $P < .1$; ** $P < .05$; *** $P < .01$.

^aThe sample includes only individuals who do not receive a low-income subsidy. Regressions include controls for gender, age, year, metropolitan statistical area of residence, days supply of prescription, and branded drug choice. Standard errors are clustered at the beneficiary level and reported in parentheses.

Data source: Medicare Part D claims, 2013-2017.

We also examined variation within ESI plan types. Consistent with the descriptive analysis in the Figure, little variation existed among OOP costs in PPO, HMO, consumer-directed, POS, and comprehensive plans, but there was significantly higher OOP spending in HDHPs (eAppendix Table 4).

Sensitivity Analyses

One concern is that the ESI population may be different from the Medicare population, and so we restricted the sample to enrollees aged 55 to 64 years for ESI and 65 to 75 years for Medicare, allowing for increased homogeneity (eAppendix Table 5). We found that differences in OOP spending by insurance type were consistent with those observed in the full population.

To better understand what was driving observed differences in OOP spending among insurers, we examined annual days supplied to assess whether there were differences in the intensity of drug utilization. As shown in eAppendix Table 6, there were no statistically significant differences in the number of days supplied among ESI, FFS, and MA for MS and hepatitis C drugs and differences of 20 days or less per year ($P < .01$) for RA and cancer drugs. This suggests minimal differences in utilization.

Finally, we examined gross drug spending, total spending on the prescription claims by all payers, to understand whether insurers were steering patients toward certain drugs. We found that gross drug costs were not statistically different between insurers for MS and cancer drugs and that the differences that existed for RA and hepatitis C drugs were financially small relative to the total cost of the drugs (eAppendix Table 7). Important to note is that these gross costs do not include rebates and so may not be wholly reflective of the actual cost paid by the insurer or employer.

DISCUSSION

Our main finding is that OOP spending for specialty drugs treating RA, MS, cancer, and hepatitis C was significantly higher in Medicare compared with ESI from 2013 to 2017. This was likely due to the standard Medicare Part D benefit structure, which determines OOP spending as a percentage of the drug's list price rather than a fixed co-payment, which is more common in ESI (although some plans treat specialty drugs differently and can use coinsurance).²⁵ We found that the differences between ESI and Medicare arose primarily during the coverage gap (donut hole) phase. Despite a closing of the coverage gap over the course of our study period, the persistent difference in OOP spending between ESI and Medicare points to fundamental differences in design between the 2 insurance types, with implications for enrollees. Small but statistically significant differences were seen between FFS and MA plans, with the MA plans having slightly higher OOP spending.

Current policy debates in Congress around Medicare Part D reform are focused on limiting OOP spending for Medicare beneficiaries: most importantly, an OOP maximum.^{26,27} Although an OOP maximum would not decrease OOP spending per prescription fill, it would

slightly reduce spending over the course of a year, reducing OOP differences between Medicare and ESI. This is particularly important because the OOP maximums proposed by Congress occur prior to the coverage gap, so implementing such a policy would eliminate cost sharing for the majority of specialty drug fills. It will be important to continue to monitor ESI plan design because commercial plan changes are reported to be occurring in 2020 and 2021.²⁸

Limitations

This study has several limitations. First, standardizing plan design across plans within FFS, MA, and ESI is difficult given the level of variability in both Medicare and commercial plan design. Second, these insurers may make different trade-offs between medical vs prescription drug spending, which could influence OOP spending. Third, we do not know the prices that FFS, MA, and ESI plans actually pay; some of these effects have been mitigated, but some remain.

A significant limitation is the lack of data on patient assistance programs (PAPs) and coupons. For specialty drugs in particular, PAPs often reimburse some or all of beneficiaries' OOP costs. Thus, it is possible that individuals have co-payments reported in claims data that are reimbursed outside of their insurance. There are no drug- or individual-level data on these programs, and so no data are available to discern how frequently this is occurring and the amount of OOP burden eased by these programs. The incentive to use PAPs is the same for FFS, MA, and ESI, so it should not bias the results in either direction; however, federal guidance makes the use of PAPs different in Medicare vs ESI, and ESI beneficiaries also have the option to use coupons, which could lower their OOP spending further.

Another limitation is that the MarketScan data disproportionately include claims from large self-insured employers, which tend to offer relatively generous benefits. Thus, estimates of OOP spending may not be representative of the entire employer-sponsored market.

Finally, there is far more clinical variation in cancer than in the other diseases being studied, and these differences could be age-related and thus affect the Medicare-ESI comparisons.

CONCLUSIONS

We compared prescription drug spending between ESI and Medicare and found that OOP spending was substantially higher among Medicare enrollees compared with ESI enrollees, because Medicare is structured for beneficiaries to pay a percentage of a drug's list price. Higher OOP spending in Medicare is likely to pose a challenge for individuals as they make the transition into Medicare, with potential implications for management of their diseases and, ultimately, health outcomes. Rethinking the design of the Part D benefit given the growth in specialty drugs to move toward fixed costs, rather than a percentage of drug costs, may be necessary to ensure that Medicare beneficiaries receive seamless care as they enter the program. ■

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eAppendix: Comparing Patient OOP Spending for Specialty Drugs in Medicare Part D and Employer Sponsored Insurance

eAppendix Table 1. Method of Qualifying for Truven MarketScan Database

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Active full time	244,024	59,358	13,343	20,461
Active part time or seasonal	4,145	1,066	307	356
Early retiree	24,985	5,896	3,226	23,339
Medicare eligible retiree	3,724	1,232	337	421
Retiree	1,702	529	219	123
COBRA continuee	3,951	1,180	478	388
Long term disability	1,575	1,448	344	236
Surviving spouse/ dependent	1,004	306	113	145
Other/ unknown	91,660	23,915	6,748	9,795
Total	376,770	94,930	25,115	35,264

Data Source: Truven MarketScan claims, 2013-2017

eAppendix Table 2. Industry of Work for Individuals in the Truven MarketScan Database

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Oil & Gas Extraction, Mining	3,919	841	278	347
Manufacturing, Durable Goods	58,111	14,824	3,909	5,727
Manufacturing, Nondurable Goods	23,393	5,503	1,528	1,813
Transportation, Communications, Utilities	38,919	9,819	2,798	3,843
Retail Trade	13,658	3,004	719	1,211
Finance, Insurance, Real Estate	35,420	9,976	1,965	2,192
Services	69,319	17,906	4,357	5,554
Agriculture, Forestry, Fishing	309	62	18	15
Construction	1,169	224	62	123
Wholesale	3,185	723	205	270
Total	247,402	62,882	15,839	21,095

Data Source: Truven MarketScan claims, 2013-2017

eAppendix Table 3. Differences in Monthly OOP Spending for Specialty Drugs by Insurance Type with all Control Variable Coefficients (excluding 439 MSA fixed effects)

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Medicare Fee-for-Service		<i>Reference</i>		
Medicare Advantage	27.7*** (4.71)	35.7*** (6.29)	37.8*** (7.13)	74.7*** (20.2)
Employer Sponsored Insurance	-108*** (2.78)	-288*** (4.40)	-504*** (7.92)	-1,437*** (24.7)
Age	-1.01*** (0.046)	-1.02*** (0.12)	-1.78*** (0.28)	-5.39*** (1.11)
Female	-4.88*** (1.22)	-5.16* (2.85)	-6.35 (5.59)	-19.1 (18.0)
Enbrel	<i>Reference</i>	-	-	-
Humira	-10.5*** (1.26)	-	-	-
Orencia	-1.46 (3.24)	-	-	-
Avonex		<i>Reference</i>		
Copaxone	-	18.2*** (3.60)	-	-
Tecfidera	-	25.7*** (3.76)	-	-
Gleevec	-	-	<i>Reference</i>	-
Imatinib Mesylate	-	-	-38.0*** (7.90)	-
Revlimid	-	-	132*** (6.01)	-
Venclexta	-	-	28.4 (22.6)	-
Zytiga	-	-	6.28 (7.00)	-
Epclusa	-	-	-	<i>Reference</i>
Harvoni	-	-	-	75.7 (47.4)
Sovaldi	-	-	-	-73.4 (54.1)
Viekira Pak	-	-	-	-140** (58.0)
Zepatier	-	-	-	-227*** (75.7)
2013		<i>Reference</i>		
2014	20.8*** (0.86)	6.42*** (2.43)	3.03 (3.84)	-135 (85.7)

2015	30.2*** (1.09)	7.03** (2.79)	29.9*** (4.54)	-99.0 (94.0)
2016	57.4*** (1.44)	27.7*** (2.87)	53.1*** (5.12)	-32.9 (93.5)
2017	94.5*** (1.52)	37.9*** (3.59)	52.4*** (9.11)	39.4 (99.5)
January		<i>Reference</i>		
February	-148*** (3.51)	-250*** (5.75)	-902*** (11.2)	-571*** (30.7)
March	-226*** (3.60)	-396*** (6.55)	-1,040*** (11.2)	-716*** (33.8)
April	-272*** (3.64)	-451*** (6.74)	-1,076*** (11.1)	-752*** (32.5)
May	-293*** (3.67)	-468*** (6.80)	-1,084*** (11.2)	-759*** (41.3)
June	-299*** (3.71)	-478*** (6.83)	-1,094*** (11.2)	-784*** (33.1)
July	-298*** (3.74)	-465*** (7.21)	-1,092*** (11.2)	-767*** (33.9)
August	-313*** (3.74)	-479*** (6.91)	-1,099*** (11.1)	-759*** (34.4)
September	-320*** (3.72)	-485*** (6.89)	-1,106*** (11.1)	-783*** (37.1)
October	-322*** (3.85)	-485*** (6.90)	-1,101*** (11.1)	-717*** (41.8)
November	-330*** (3.57)	-490*** (6.88)	-1,115*** (11.1)	-710*** (36.2)
December	-333*** (3.72)	-494*** (6.85)	-1,120*** (11.0)	-734*** (34.0)
Constant	541*** (5.79)	868*** (11.8)	1,682*** (23.9)	3,000*** (138)
N, Prescription Fills	2,495,689	730,248	394,656	136,678

Data Source: Medicare Part D and Truven MarketScan claims, 2013 - 2017

Notes: The coefficients represent dollar differences for Medicare Advantage and employer sponsored insurance beneficiaries compared to Medicare fee-for-service beneficiaries. The Medicare samples do not include individuals who receive a low-income subsidy. Regressions also included 439 MSA fixed effects that are not shown here. Standard errors are clustered at the beneficiary level and reported in parentheses. Statistical significance *p<0.1 **p<0.05

***p<0.01

eAppendix Table 4. Differences in OOP Specialty Drug Spending Per Month by Employer Sponsored Insurance Plan Type

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Preferred Provider Organization (PPO)				
Health Maintenance Organization (HMO)	-42*** (2)	-33*** (4)	-48*** (5)	-196*** (24)
Consumer Directed Health Plans (CDHP)	118*** (2)	77*** (4)	96*** (11)	133*** (18)
Point of Service (POS)	-34*** (2)	-25*** (4)	-24** (11)	-100*** (33)
High Deductible Health Plans (HDHP)	356*** (6)	289*** (7)	287*** (14)	761*** (32)
Comprehensive	-26*** (3)	-23*** (6)	-47*** (12)	-124*** (29)
N, Prescription Fills	1,433,968	360,366	98,642	56,805

Data Source: Medicare Part D and Truven MarketScan claims, 2013 - 2017

Notes: The Medicare sample only includes individuals that do not receive a low-income subsidy. Regressions include controls for gender, age, year, MSA of residence, day supply of prescription, and branded drug choice. Standard errors are clustered at the beneficiary level and reported in parentheses. Statistical significance *p<0.1 **p<0.05 ***p<0.01

eAppendix Table 5. Differences in Monthly OOP Spending on Specialty Drugs for Individuals Ages 55-75 years By Insurance Type

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Medicare Fee-for-Service		<i>Reference</i>		
Medicare Advantage	24.2*** (5.22)	36.8*** (7.46)	16.5* (9.68)	89.2*** (21.8)
Employer Sponsored Insurance	-132*** (3.98)	-284*** (6.28)	-509*** (11.3)	-1,469*** (28.2)
N, Prescription Fills	934,529	289,811	228,265	97,185

Data Source: Medicare Part D and Truven MarketScan claims, 2013 - 2017

Notes: The Medicare sample only includes individuals that do not receive a low-income subsidy. Regressions include controls for gender, age, year, MSA of residence, day supply of prescription, and branded drug choice. Standard errors are clustered at the beneficiary level and reported in parentheses. Statistical significance *p<0.1 **p<0.05 ***p<0.01

eAppendix Table 6. Differences in Annual Days Supplied as a Measure of Utilization and Intensity for Specialty Drugs by Insurance Type, 2013-2016

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Medicare Fee-for-Service		<i>Reference</i>		
Medicare Advantage	-20.4*** (1.6)	1.5 (1.9)	1.6 (2.3)	-0.5 (0.6)
Employer Sponsored Insurance	-3.2*** (1.1)	0.7 (1.6)	8.3*** (2.1)	0.8 (0.6)
N, Prescription Fills	394,560	109,530	58,971	47,281

Data Source: Medicare Part D and Truven MarketScan claims, 2013 - 2017

Notes: The Medicare sample only includes individuals that do not receive a low-income subsidy. Regressions include controls for gender, age, year, MSA of residence, day supply of prescription, and branded drug choice. Standard errors are clustered at the beneficiary level and reported in parentheses. Statistical significance *p<0.1 **p<0.05 ***p<0.01

eAppendix Table 7. Differences in Monthly Gross Specialty Drug Spending Per Month by Insurance Type

	<i>Rheumatoid arthritis</i>	<i>Multiple sclerosis</i>	<i>Cancer</i>	<i>Hepatitis C</i>
Medicare Fee-for-Service				
Medicare Advantage	-143*** (21.4)	29.2 (46.0)	-34.1 (44.5)	-486*** (56.0)
Employer Sponsored Insurance	-98.3*** (16.0)	3.41 (73.5)	46.6 (62.2)	-1,393*** (103)
N, Prescription Fills	2,495,689	730,248	394,656	136,678

Data Source: Medicare Part D and Truven MarketScan claims, 2013 - 2017

Notes: The coefficients represent dollar differences for Medicare Advantage and employer sponsored insurance beneficiaries compared to Medicare fee-for-service beneficiaries. The Medicare samples do not include individuals who receive a low-income subsidy. Regressions include controls for age and gender of individuals and fixed effects for year, MSA of residence, and branded drug choice. Standard errors are clustered at the beneficiary level and reported in parentheses. Statistical significance *p<0.1 **p<0.05 ***p<0.01