In-Gap Discounts in Medicare Part D and Specialty Drug Use

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ABSTRACT

OBJECTIVES: Specialty drugs can bring significant benefits to patients, but they can be expensive. Medicare Part D plans charge relatively high cost-sharing costs for specialty drugs. A provision in the Affordable Care Act reduced cost sharing in the Part D coverage gap phase in an attempt to mitigate the financial burden of beneficiaries with high drug spending. We examined the early impact of the Part D in-gap discount on specialty cancer drug use and patients' out-of-pocket (OOP) spending.

STUDY DESIGN: Natural experimental design.

METHODS: We compared changes in outcomes before and after the in-gap discount among beneficiaries with and without low-income subsidies (LIS). Beneficiaries with LIS, who were not affected by the in-gap discount, made up the control group. We studied a random sample of elderly standalone prescription drug plan enrollees with relatively uncommon cancers (eg, leukemia, skin, pancreas, kidney, sarcomas, and non-Hodgkin lymphoma) between 2009 and 2013. We constructed 4 outcome variables annually: 1) use of any specialty cancer drug, 2) the number of specialty cancer drug fills, 3) total specialty drug spending, and 4) OOP spending for specialty cancer drugs.

RESULTS: The in-gap discount did not influence specialty cancer drug use, but reduced annual OOP spending for specialty cancer drugs among users without LIS by $1108.

CONCLUSIONS: In-gap discounts in Part D decreased patients' financial burden to some extent, but resulted in no change in specialty drug use. As demand for specialty drugs increases, it will be important to ensure patients' access to needed drugs, while simultaneously reducing their financial burden.

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Spending on prescription drugs has increased rapidly—by 14% in 2014—whereas spending on other medical care increased by only 4.1% to 4.6%.[1,2] A driver of this growth is the category of specialty drugs, in which spending increased by 30% in 2014.[1] Specialty drugs do not have a single definition, but generally have at least 1 of the following characteristics: high prescription price, identification as a biologic, use in the treatment of complex conditions, or requiring special handling and delivery.[3,4] Only a small share of the population is currently affected by conditions for which specialty drugs are used. However, specialty drugs account for a large share of total drug spending due to their high price alone.[1] Facing this cost pressure, payers place higher cost-sharing requirements for specialty drugs than traditional drugs, raising concerns about patients' access to needed specialty drugs and the financial burden associated with these drugs.[3,5,6]

Consumer cost sharing is commonly used to manage prescription drug use and spending, and prior studies suggest that patients are less likely to use traditional prescription drugs when cost sharing is higher.[7] For specialty drug use, the results of a recent study showed that commercial enrollees' responsiveness to cost sharing was relatively small.[8] Evidence regarding how elderly individuals in Medicare respond to cost sharing is sparse, although conditions for which specialty drugs are used are related to age. Part D plans use high cost sharing for specialty drugs as a way to manage utilization among beneficiaries without low-income subsidies (LIS).[9] However, high cost sharing would be counterproductive if those beneficiaries did not respond to price in specialty drug use due to potential benefits of specialty drugs or the absence of viable substitutes[3,8]—it would simply put patients at financial risk. Yet, few studies have examined the relationship between cost sharing and specialty drug use among elderly beneficiaries without LIS.

Studying responses to specialty drug benefits is challenging because Part D plan choice is voluntary, which can lead to biased estimates if specialty drug users are likely to enroll in plans with low cost-sharing benefits. We used a natural experimental design, leveraging an exogenous change in the Part D benefit, which enabled

TAKEAWAY POINTS

A provision in the Affordable Care Act provided discounts for prescription drug spending in the coverage gap in Medicare Part D. The effects of this in-gap discount among specialty cancer drug users were:

- The in-gap discount did not increase the likelihood of using a specialty cancer drug.
- The in-gap discount did not change the number of specialty cancer drug fills among users.
- Specialty cancer drug users' annual out-of-pocket spending for specialty cancer drugs decreased from $5533 to $4494 (–19%) after the in-gap discount.
- The financial burden of some cancer patients remains high, even with the in-gap discount.

us to avoid selection in plan choice to fill in the Part D coverage gap introduced by the Affordable Care Act (ACA). This provision led to a change in benefit generosity that particularly affected specialty drugs because it focuses on a large decrease in cost sharing for brand name drugs (and thus, specialty drugs).

The presence of a coverage gap in the standard Part D benefit, in which beneficiaries were responsible for the full drug spending prior to 2011, had been criticized for having posed a financial burden to enrollees.[10,11] In response, a provision in the ACA stipulated that the gap be gradually filled until it closes in 2020. This provision reduced the in-gap coinsurance rate to 50% for brand name drugs and 93% for generic drugs in 2011. In-gap cost sharing for brand name drugs gradually decreased to 47.5% between 2013 and 2014 and to 45% between 2015 and 2016, accumulating in a 5 percentage point decline per year thereafter. Similarly, coinsurance for generic drugs has decreased by 7 percentage points every year. In 2020, beneficiaries will be responsible for 25% of branded or generic drug spending until they reach the level of "catastrophic" coverage.

This Part D in-gap benefit change is designed to mitigate the financial burden of beneficiaries who reach the coverage gap due to increased drug spending. Among these are specialty drug users without LIS. Part D defines specialty drugs as those whose negotiated monthly price is greater than $600 and allows plans to place those drugs in a separate "specialty" tier in the pregap phase. The cost sharing of a specialty tier in the pregap phase is usually 33% coinsurance of the overall drug cost, higher than the standard of 25%. Further, specialty drug users often pass through the initial coverage stage and hit the gap with their first prescription fill due to the high prices of specialty drugs. The ACA discount is thus likely to relieve the financial stress of specialty drug costs among beneficiaries without LIS. Beneficiaries with LIS do not face financial burdens related to specialty drugs because their drug spending is mostly paid by Medicare. A prior study showed that patients with chronic myeloid leukemia (CML) with LIS were more likely to initiate specialty drugs after diagnosis than non-LIS patients, possibly due to the lack of financial barriers among patients who are prescribed specialty drugs.[12]

The 50% in-gap discount for branded drugs can be a sizable reduction in out-of-pocket (OOP) spending to specialty drug users without subsidies. It implies a decrease of $1860 in OOP spending for a beneficiary who had the Part D standard benefit in 2015 and passed through the gap in the year. Recent data showed that the average OOP spending on specialty drugs decreased from $2376 in 2010 to $1758 in 2011, a 26% reduction for Part D enrollees.[13] However, patients with cancer may face larger OOP spending due to the high cost of specialty cancer drugs, and 2 analyses of Part D plan formulary files suggested that OOP spending of specialty cancer drug users could reach up to $12,000 in 2016 even with the in-gap discount.[6,14]

Our study examined how the in-gap discount affected OOP spending for specialty cancer drugs among the elderly during the first 3 years of implementation. We focused on specialty cancer drugs, which comprise one-third of total specialty drug spending.[15] We also examined how the in-gap discount affected specialty cancer drug use because reduced in-gap cost sharing can encourage beneficiaries to continue to take recommended medications even when they have reached the gap. Beneficiaries may also begin taking specialty drugs if they make decisions regarding drug consumption based on total OOP spending. However, the ACA provision lowers cost sharing only in the coverage gap; it does not change cost sharing for the first fill. If patients cannot afford cost sharing in the initial coverage stage, they would be unlikely to use a specialty drug at all and the in-gap discount would be irrelevant. We examined this possibility by analyzing whether the in-gap discount changed the probability of using any specialty cancer drug and the number of specialty cancer drug fills among users.

METHODS

Sample and Data

The study population entailed randomly selected elderly Medicare beneficiaries with cancer between 2009 and 2013. We focused on 6 relatively uncommon cancer types (leukemia, kidney, pancreatic, skin, sarcoma, and non-Hodgkin lymphoma) for which specialty drugs are used, but understudied. Medicare claims data were searched to select a random sample of fee-for-service beneficiaries with these identified cancers, based on *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis codes and at least 1 inpatient or skilled nursing facility claim or 2 outpatient or carrier claims in a given year. Our analysis included beneficiaries who had both Part A and Part B coverage and stayed in the same standalone prescription drug plan (PDP) for the entire calendar year. We excluded beneficiaries in Medicare Advantage Prescription Drug Plans (MA-PDs) because their claims data were not available.

TABLE 1. Average Monthly Spending of Top 10 Specialty Cancer Drugs Frequently Used by Part D Enrollees With Selected Cancers[a]

Generic Name	Description	Average Monthly Spending, $[b] 2010	2013
Imatinib mesylate	Treats certain types of leukemia, bone marrow disorders, skin cancer, and certain tumors of the stomach and digestive system	4438	6418
Lenalidomide	Promotes immune responses to help slow tumor growth; treats multiple myeloma, mantle cell lymphoma, and anemia	8588	8994
Dasatinib	Treats chronic myeloid leukemia and acute lymphoblastic leukemia	6405	6915
Sunitinib malate	Targeted therapy; a receptor protein–tyrosine kinase inhibitor to treat late-stage kidney cancer, gastrointestinal stromal tumor, and metastatic pancreatic cancer	6075	6614
Nilotinib hydrochloride	Treats leukemia	7027	6934
Erlotinib hydrochloride	Interferes with the growth of cancer cells and slows their spread in the body; treats non–small cell lung and metastatic pancreatic cancer	4189	5222
Everolimus	Treats certain types of kidney cancer, breast cancer, or brain tumor	6776	8012
Pazopanib hydrochloride	Treats advanced kidney cancer and soft tissue sarcoma	5609	6069
Sorafenib tosylate	Treats liver cancer, thyroid cancer, and advanced renal cell carcinoma	5707	7764
Bexarotene	Treats cutaneous manifestations of cutaneous T-cell lymphoma	4852	8323

[a]Leukemia, kidney, pancreatic, skin, sarcoma, or non-Hodgkin lymphoma.
[b]Calculated based on the Gross Drug Costs in the Part D Prescription Drug Event records by the study sample, and adjusted to 2013 dollars based on the Consumer Price Index for prescription drugs.

The primary data were Part D Prescription Data Event (PDE) Files, which contained records on prescription drug fills by enrollees, including National Drug Code, days supplied, and spending (ie, beneficiary payment, plan payment, and subsidy amounts, where applicable). All drug spending variables were adjusted to 2013 dollars based on the Consumer Price Index for prescription drugs.

We augmented PDE files with Medicare Master Beneficiary Summary Files, which provided beneficiary information (ie, residence, demographic characteristics, and chronic condition indicators); Part D Plan Characteristics Files and Plan Formulary Files to get plan benefit attributes; and zip code-level income/education and county-level healthcare resource information from the 2010 American Community Survey and Area Health Resource Files, respectively. This study was approved by the Pennsylvania State University's institutional review board.

Identifying Specialty Cancer Drugs

We identified Part D specialty drugs as products placed in a specialty tier at least by 1 plan, based on Part D Plan Formulary Files.[13,16] To identify cancer drugs (antineoplastic agents, including chemotherapy, immunotherapy, and hormone therapy), we used 2 sources: 1) organizations supporting patients with cancer or cancer research (eg, the National Cancer Institute and the American Cancer Society) and 2) the Wolters Kluwer Health Medi-Span MED-file v.2,[17] which groups drugs by therapeutic class. By cross-walking the lists of Part D specialty drugs and antineoplastic agents, we identified Part D specialty cancer drugs. **Table 1** shows the top 10 specialty cancer drugs, by utilization, in the study population.

Empirical Approaches

We compared changes in specialty cancer drug use and OOP spending before and after the in-gap discount between non-LIS and LIS beneficiaries. LIS patients, who did not have a coverage gap, were used as the control group because they were not affected by the in-gap discount. This approach is known as a difference-in-differences method; it captures the in-gap discount effect on outcomes in the treatment group (ie, non-LIS beneficiaries) by controlling for secular trends.

We constructed 4 outcome measures: 1) use of specialty cancer drugs in a given year (a binary indicator), 2) the number of specialty cancer drug fills during the year, 3) annual total spending for specialty cancer drugs (ie, the sum of patient share, plan payment, and subsidy amounts for LIS enrollees), and 4) patient OOP spending for specialty cancer drugs.

Control variables included patient characteristics (ie, age, gender, race, buy-in status, and health status measured by the presence and number of chronic conditions), plan characteristics (ie, whether the plan offered more generous benefits than the standard package or in-gap coverage), and market factors (ie, median household income, percent college educated, hospital beds and admissions per capita, Medicare Advantage plan payment rates, the number of doctors per capita, and region indicators). We also included year dummies to control for time-specific effects that are common

TABLE 2. Descriptive Data of the Study Variables by LIS Status

	Mean (SD) or %	
	Non-LIS Sample (n = 117,260)	LIS Sample (n = 31,005)
Patient characteristics		
Age, years	76.54 (7.18)	77.28 (7.83)
Buy-in status, %	0.02	78.76
Female, %	48.60	65.20
White, %	96.80	74.97
Has diabetes, %	28.17	45.55
Has hypertension, %	69.43	81.95
Has ischemic heart disease, %	40.38	51.34
Has hyperlipidemia, %	58.92	56.63
Has depression, %	13.57	27.16
Has congestive heart failure, %	18.79	35.08
Has cataract, %	28.73	21.61
Has COPD, %	13.70	26.78
Number of chronic conditions	4.66 (2.60)	6.08 (2.89)
Plan characteristics		
Enhanced, %	43.75	8.09
Gap coverage, %	15.45	2.08
Market characteristics		
Zip code–level median household income, $	61,317 (25,041)	50,046 (20,285)
Zip code–level college educated, %	27.43	20.51
County-level factors		
Medicare Advantage payment, $	806.98 (133.51)	823.32 (136.93)
Hospital admission per 1000	124.16 (79.09)	126.27 (78.25)
Physician supply per 1000	2.94 (2.13)	2.87 (2.16)
Hospital beds per 1000	3.26 (2.59)	3.36 (2.43)
Census region		
Midwest, %	19.76	23.31
South, %	37.96	40.47
West, %	16.54	16.98
Northeast, %	25.74	19.24
Specialty cancer drug use, n (%)	3551 (3.03)	1769 (5.71)
Among specialty cancer drug users		
Reaching coverage gap, %	99.21	99.72
Reaching catastrophic coverage, %	94.40	97.06
Annual number of fills	7.71 (4.63)	7.67 (4.43)
Total annual spending, $	44,764 (30,307)	44,272 (30,201)
Total annual OOP spending, $	4870 (2099)	44 (187)
In-gap OOP spending, $	2689 (1215)	41 (176)

COPD indicates chronic obstructive pulmonary disease; LIS, low-income subsidy; OOP, out-of-pocket; SD, standard deviation.

to all study samples. Further, we used group-specific (ie, LIS vs non-LIS) year fixed effects to control for potential differential year effects between the 2 groups.

Our primary analysis included use of any specialty cancer drugs not limited to those approved to treat the patient's cancer type. This captures off-label drug use, which is common in cancer treatments,[18] and allowed us to examine the total demand for specialty cancer drugs in the study population. To check whether the results were sensitive to the selection of cancer-type specific drugs, we performed 2 additional analyses. First, we selected patients with CML and examined the use of tyrosine kinase inhibitors (ie, imatinib, dasatinib, and nilotinib), which are top Part D specialty cancer drugs (Table 1). Second, we limited the sample to patients with pancreatic cancer and examined use of erlotinib or sunitinib.

We used logit estimation for the analysis of specialty drug use and calculated marginal effects. For the interaction term between non-LIS and post indicators, the variable of interest, we obtained the average marginal effects.[19] For other dependent variables (eg, the number of fills and spending), we limited the analysis to specialty cancer drug users. Among users, the residuals from the regressions were approximately normally distributed. We then applied linear estimations to analyze those outcomes. Error terms were accounted for clustering within a plan in all analyses.

RESULTS

Table 2 presents the summary statistics of all study variables by LIS status. The table indicates that non-LIS beneficiaries were likely to be white, have fewer chronic conditions, and live in areas with relatively high income and education levels compared with LIS enrollees.

Approximately 3% of non-LIS patients used a specialty cancer drug in a given year, and each user spent an average of $4838 OOP per year; the average total annual spending for specialty cancer drugs was $44,460 per user. Most specialty cancer drug users reached the coverage gap (99%) and catastrophic coverage

level (94%) within a given year. In contrast, the LIS group had a higher specialty drug use rate (5.7%) than the non-LIS group, yet the average OOP spending for specialty cancer drugs among users was only $44.

Table 3 describes trends in specialty cancer drug use and OOP spending. The data indicate that the utilization rates of specialty cancer drugs increased over years, but to a small degree, and there was no differential increase following the in-gap discount. Among users, the number of specialty cancer drug fills remained stable. Despite little changes in utilization among users, total spending for specialty cancer drugs per user increased substantially over years in both groups—possibly due to rises in drug prices (Table 1). We found that non-LIS beneficiaries' OOP spending for specialty cancer drugs significantly decreased after the in-gap discount. Annual OOP spending of non-LIS beneficiaries for specialty cancer drugs sharply dropped between 2010 and 2011, from $5721 to $4254 (a 26% reduction). The average annual OOP spending in the postdiscount period (2011 to 2013) was $4494, which corresponds to a 19% decrease, from $5533.

TABLE 3. Specialty Cancer Drug Use and Spending by Year and LIS Status[a]

	Non-LIS Sample		LIS Sample	
	Specialty Cancer Drug Use			
	n	Specialty Cancer Drug Use (n, %)	n	Specialty Cancer Drug Use (n, %)
2009	19,294	575 (2.98)	5652	280 (4.95)
2010	20,734	599 (2.89)	5830	306 (5.25)
2011	23,496	689 (2.93)	6346	361 (5.69)
2012	25,515	764 (2.99)	6549	389 (5.94)
2013	28,221	924 (3.27)	6628	433 (6.53)
	Among Specialty Cancer Drug Users (mean, SD)			
	Number of Fills	Total Spending, $	OOP Spending, $	Number of Fills	Total Spending, $	OOP Spending, $
2009	7.44 (4.95)	34,327 (23,665)	5366 (2,184)	7.80 (4.80)	36,358 (24,507)	53 (200)
2010	7.61 (4.67)	38,479 (26,531)	5752 (2,156)	7.55 (4.39)	39,247 (26,569)	59 (222)
2011	7.85 (4.49)	44,308 (28,313)	4277 (1,840)	7.89 (4.55)	43,931 (28,416)	41 (181)
2012	7.98 (4.55)	50,044 (31,810)	4612 (1,965)	7.96 (4.37)	47,964 (31,725)	34 (159)
2013	7.63 (4.58)	51,309 (33,686)	4643 (2,054)	7.24 (4.12)	49,910 (34,161)	39 (180)

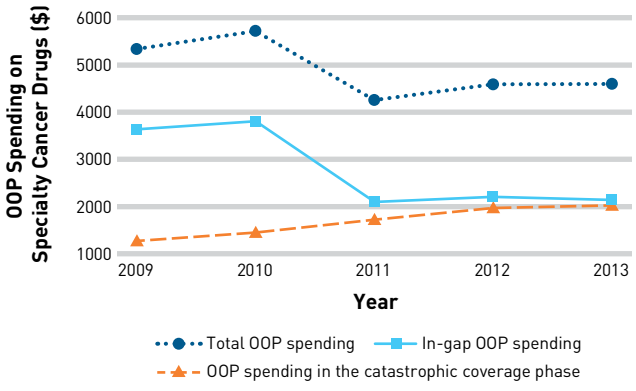
LIS indicates low-income subsidy; OOP, out-of-pocket; SD, standard deviation.
[a]All spending measures are limited to specialty cancer drugs, and they are adjusted to 2013 dollars based on the Consumer Price Index for prescription drugs.

The Figure depicts changes in OOP spending for specialty cancer drugs separately for the gap and catastrophic coverage phases in the non-LIS group. A large reduction in OOP spending occurred in the gap phase following the ACA discount (from $3725 to $2151, or a 42% decrease). However, OOP spending in the catastrophic coverage phase increased from $1363 to $1919 between pre- and postdiscount periods.

Table 4 presents results on key variables from regression analyses. We reported average marginal effects of the in-gap discount for specialty cancer drug use and OOP spending. Despite a seemingly large discount provided to beneficiaries, the decrease in the in-gap cost sharing had no significant effect on the use of specialty cancer drugs, either for use or the number of fills, among non-LIS beneficiaries with uncommon cancers. However, it significantly decreased OOP spending for specialty cancer among non-LIS patients by $1114. The results of all other covariates are reported in the eAppendix Table (eAppendices available at **ajmc.com**).

The results from the subgroup analyses were consistent with the primary analysis. In both CML and pancreatic cancer groups, specialty drug utilization did not change after the in-gap discount. Among non-LIS patients with CML, annual OOP spending for tyrosine kinase inhibitors declined by $970 after the in-gap discount. Non-LIS beneficiaries with pancreatic cancer also had a reduction in

FIGURE. OOP Spending for Specialty Cancer Drugs by Year Among Beneficiaries With No LIS



LIS indicates low-income subsidy; OOP, out-of-pocket.

TABLE 4. Regression Results on Selected Variables[a]

Variable	Specialty Cancer Drug Use	Marginal Effect (Robust SE)[b] Among Specialty Cancer Drug Users: Number of Fills	Total Spending	Out-of-Pocket Spending
All study sample				
Non-LIS	−0.92 (0.37)**	−0.63 (0.42)	−4654 (2575)*	4988 (135)***
POST	0.21 (0.25)	0.17 (0.35)	8144 (2018)***	51 (51)
Non-LIS × POST	−0.05 (0.05)	0.16 (0.43)	1503 (2462)	−1114 (126)***
N	148,265	5320	5320	5320
Subgroup analysis with specific cancer-type agents				
Patients with chronic myeloid leukemia				
Non-LIS	−0.70 (5.55)	−0.10 (0.46)	−3708 (3582)	5657 (191)***
POST	5.48 (4.22)	0.31 (0.38)	10,617 (2782)***	34 (67)
Non-LIS × POST	0.02 (0.18)	0.56 (0.47)	5060 (3327)	−970 (176)***
N	3541	2065	2065	2065
Patients with pancreatic cancer				
Non-LIS	1.30 (1.29)	−0.16 (1.76)	779 (6608)	3470 (442)***
POST	−1.32 (1.18)	−0.08 (1.74)	1033 (6956)	−230 (319)
Non-LIS × POST	−0.56 (0.60)	0.97 (1.87)	3920 (7768)	−704 (448)
N	8199	246	246	246

LIS indicates low-income subsidy; POST, post discount; SE, standard error.
"*" indicates $P < .10$; "**" indicates $P < .05$; "***" indicates $P < .01$.
[a]All spending measures are limited to specialty cancer drugs, and they are adjusted to 2013 dollars based on the Consumer Price Index for prescription drugs.
[b]All models control for patient, plan, and market characteristics; SEs are accounted for clustering within a plan.

OOP spending on erlotinib or sunitinib, but this effect was not statistically significant possibly due to the small sample size (n = 246).

DISCUSSION

We found that the ACA in-gap discount decreased patients' OOP spending for specialty cancer drugs but did not increase specialty cancer drug use in its early years. It is encouraging that the ACA's initiative to close the coverage gap in Part D mitigated the patients' financial burdens, to some extent. A $1114 decrease in annual OOP spending on specialty antineoplastic drugs (–19%) is not a small reduction; however, some patients with cancer without subsidies face a large financial burden even with the in-gap discount. The average annual budget of Medicare beneficiaries was reported to be $33,000 in 2012.[20] Thus, the mean OOP spending of $4494 implies that patients with cancer spent 15% of their budget for specialty cancer drugs. Further, about 14% of (non-LIS) these patients spent more than $6600—20% of their budget—for specialty cancer drugs. This suggests that the in-gap discount does not offer sufficient financial protection to certain patients using specialty cancer drugs without subsidies.

Our finding that the in-gap discount did not increase specialty cancer drug use might be because patients are not responsive to cost sharing in specialty drug use. Alternatively, it may be because the cost-sharing reduction kicks in after relatively high cost sharing for specialty drugs in the pregap phase.[12] Beneficiaries would not use specialty drugs regardless of the in-gap discount if they cannot afford cost sharing in initial coverage. Or some patients may not begin a specialty drug treatment due to high annual OOP spending required to complete a course of treatment. To these patients, the in-gap discount is irrelevant and unlikely to lead them to use specialty drugs.

In Part D, catastrophic coverage is a stop-loss mechanism. However, because of high prices of specialty drugs, even the 5% coinsurance in catastrophic coverage can bring a financial pressure on patients. Our data showed that the average OOP spending for specialty cancer drugs in catastrophic coverage increased from $1363 to $1919. This change reflects increases in drug prices given no change in drug fills among users. This high level of OOP spending even in the catastrophic coverage phase may have deterred patients from starting a specialty drug.

Demand for specialty drugs is expected to increase as more drugs become available.[4,21] Because specialty drugs do not usually have generic substitutes or alternative treatments,[3] high cost sharing for specialty drugs can create financial difficulties to patients, which can lead them to forgo specialty drugs. Some patients may use specialty drugs despite high cost sharing; however, high cost sharing puts these patients at financial risk. It will thus be critical to identify high-value specialty drugs and ensure patients' access to those medications. Reducing financial stress on beneficiaries who need expensive but effective drugs can help improve patients' access to needed drugs. Expanding eligibility for low-income cost-sharing subsidies for certain costly yet effective specialty drugs might be an option to explore. Setting an OOP spending maximum for Part D drugs, either a fixed amount or as a certain percentage of household income, could be another possibility to consider.

Limitations

Several limitations of this study should be noted. First, we do not have detailed clinical information, such as the stage of diseases,

which may predict patterns of specialty drug use. However, this limitation would result in any bias only if temporal changes in the distribution of cancer stages systematically differed by LIS status, which is unlikely. Second, we focused on the impact of a change only in the in-gap benefit. Our findings do not apply to patients' responsiveness to changes in overall or initial cost sharing in specialty cancer drug use, which is an important topic to pursue in future research. However, we were able to avoid selection in drug benefit choice, which could potentially lead to biased estimates, by exploiting an exogenous change in benefits. Finally, our study is limited to PDP enrollees with 6 uncommon cancers, and the results may not be generalizable to MA-PD enrollees or patients with other conditions.

CONCLUSIONS

The Part D in-gap discount decreased patients' OOP spending for specialty cancer drugs; however, even with the in-gap discount, the financial burdens of specialty cancer drug users without subsidies remain high. Approaches to reduce financial burdens for high-value specialty drugs may improve patients' access to needed drugs. ■

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eAppendix Table. Full Regression Results

	Marginal Effect (robust standard error)[a]			
	Specialty Cancer Drug Use	Among Specialty Cancer Drug Users		
Variables		**Number of Fills**	**Total Spending**	**Out-of-Pocket Spending**
Non-low income subsidy (Non-LIS)	-0.92(0.37)**	-0.63(0.42)	-4,654(2,575)*	4,988(135)***
Post-discount (POST)	0.21(0.25)	0.17(0.35)	8,144(2,018)***	51(51)
Non-LIS*POST	-0.05(0.05)	0.16(0.43)	1,503(2,462)	-1,114(126)***
Age	-0.16(0.01)***	0.01(0.01)	-260(73)***	-11.5(4.8)**
Buy-in status	0.15(0.30)	0.09(0.37)	381(2,626)	-162(47)***
Female	-0.319(0.15)**	0.08(0.16)	-2,236(1,123)**	-105(64)
White	-1.66(0.21)***	-0.21(0.23)	1,685(1,591)	-13(72)
Having diabetes	-0.35(0.14)**	0.03(0.18)	737(1,223)	-19(64)
Having hypertension	-0.14(0.19)	0.06(0.20)	483(1,326)	1.2(76.7)
Having heart disease	-0.18(0.16)	0.52(0.19)***	1,038(1,156)	51(61)
Having hyperlipidemia	-1.77(0.13)***	0.23(0.16)	241(1,081)	5.6(55.2)
Having depression	-0.93(0.16)***	-0.08(0.20)	182(1,369)	-119(68)*
Having congestive heart failure	0.09(0.17)	0.28(0.22)	833(1,272)	47(68)
Having cataract	-0.63(0.14)***	0.63(0.18)***	3,393(1,001)***	209(63)***
Having chronic obstructive pulmonary disease	-0.91(0.18)***	-0.54(0.20)***	-3,274(1,318)**	-166(75)**
Number of chronic conditions	0.52(0.05)***	-0.30(0.06)***	-1,251(348)***	-55(19)***
Enhanced (%)	-0.09(0.16)	-0.09(0.20)	-570(1,241)	107(84)
Gap coverage (%)	0.99(0.24)***	0.67(0.24)***	4,978(1,757)***	230(109)**
Median household income ($1,000)	0.01(0.01)	-0.00(0.01)	16.6(37.6)	0.54(2.32)
College educated (%)	-0.02(0.01)**	0.00(0.01)	1.4(54.5)	0.18(3.34)
Medicare Advantage payment ($)	0.00(0.00)***	-0.00(0.00)	-4.4(5.6)	-0.59(0.33)*
Midwest	-0.48(0.23)**	-0.07(0.27)	458(1,941)	-522(132)***
South	-0.09(0.19)	-0.14(0.21)	-507(1,519)	-0.45(77.30)
West	-0.37(0.22)*	-0.54(0.23)**	-1,802(1,734)	-39(92)
Hospital admission/1,000	-0.00(0.00)	-0.00(0.00)	4.3(9.8)	-0.43(0.60)
Physician supply/1,000	0.00(0.05)	0.00(0.6)	-331(371)	6.7(19.2)
Hospital beds/1,000	0.09(0.04)**	0.05(0.02)**	157(211)	7.8(11.9)
2010	0.09(0.22)	-0.28(0.32)	2,928(1,622)*	32(33)
2012	0.08(0.18)	0.06(0.27)	4,352(1,781)**	31(28)
2013	0.44(0.25)*	-0.65(0.28)**	6,629(2,006)***	29(39)
Non-LIS*2010	-0.02(0.05)	0.43(0.40)	1,347(1,983)	365(109)***
Non-LIS*2012	-0.02(0.05)	0.20(0.33)	2,404(2,259)	363(90)***
Non-LIS*2013	-0.11(0.08)	0.62(0.34)*	1,744(2,446)	371(91)***
N	148,265	5,320	5,320	5,320

[a]Standard error terms are accounted for clustering within a plan.

*P <.10; **P <.05; ***P <.01