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Research Paper

Cost implications of patient spending on heart failure medications in the US Medicare program

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Abstract

Objectives The aim of this study was to model the associations between patient spending on heart failure (HF) medications and Medicare and all-payer expenditures on health care services for participants in the Medicare prescription drug (Part D) program.

Methods Correlational analysis of pooled 2011–12 data from the Medicare Current Beneficiary Survey. Analysis was restricted to community-dwelling beneficiaries with self-reported HF at baseline, continuous Part D coverage, and no Low-Income Subsidy (LIS). The main predictor was mean patient expenditure on a HF-related prescription per 30-day supply. The outcomes were all-payer and Medicare-specific payments for inpatient and total health care services during the observation year.

Key findings Mean patient drug expenditure was not statistically associated with Medicare or all-payer inpatient payments or (after covariate adjustment) with total health care payments. However, patient expenditure was statistically associated with total Medicare payments, e^{γ} = 1.022, 95% CI [1.004 to 1.041]. Marginal effects analysis predicted an average rise in total Medicare payments of $190.32, 95% CI [$40.54 to $341.10], for each additional $1 of patient spending per prescription, $P = 0.013$. Given an average 2.4 HF-indicated drug classes per participant and assuming 12.2 copays per year, a hypothetical $1 increase in prescription copay predicted a net loss to Medicare of $160.90 per participant.

Conclusion Prescription drug spending by Medicare beneficiaries with HF was not associated with higher inpatient or all-payer costs. A modest association between patient drug spending and total Medicare costs was observed, but longitudinal and cost-effectiveness analyses are needed to support causal inference.

Keywords: Medicare; heart failure; cost sharing; health care costs; value-based insurance design

Introduction

In recent years, a growing body of research has documented the potential and limits of value-based insurance design (V-BID) for improving health outcomes and controlling costs.[1–10] Under a V-BID policy, cost sharing—the amount an insured patient pays for care—varies as a function of the clinical value of a given service and its potential to reduce net health care costs.[11] V-BID usually entails the reduction or elimination of cost sharing (e.g. copays) to promote adherence to treatments that are shown to reduce illness or death.[12] Therefore, V-BID policies are thought to be more cost-effective than

across-the-board cost-sharing requirements that do not account for value.

V-BID is already widespread for primary prevention services, such as vaccinations, in US health insurance plans. Simulation models have demonstrated the theoretical cost-effectiveness of V-BID for certain secondary prevention therapies as well, including angiotensin-converting enzyme (ACE) inhibitors for renal preservation in diabetes mellitus,[13] aromatase inhibitors in early-stage breast cancer,[14] and combination pharmacotherapy after myocardial infarction.[15, 16] Results from empirical studies are more mixed. A 2013 systematic review found that V-BID policies were not associated with significant changes in overall health care spending after one year.[12] However, two of the included studies showed a significant reduction in hospital admissions and emergency department use with V-BID policies.[3, 9]

Research on V-BID has focused largely on vascular disease and diabetes, yet heart failure (HF) is the most common cause of hospitalization among Medicare beneficiaries in the USA.[17] HF is also an expensive disorder, costing the US health care system an estimated $34 billion annually.[18] Prior studies have shown that higher prescription drug cost sharing is associated with non-adherence and hospital use in Medicare beneficiaries with HF,[19–21] but little is known about the effect of such cost sharing on overall health care costs in this population. This knowledge gap is important given the heterogeneity of cost-sharing requirements in Medicare Part D prescription drug plans.[22] Therefore, this study was designed to investigate the association between out-of-pocket spending on HF prescriptions and Medicare and all-payer expenditures on health care services for Part D subscribers. A positive association was hypothesized, because the rationale of V-BID is that lower copays for effective chronic disease medications have the potential to reduce costs by promoting adherence and preventing acute care episodes.[11, 12]

Methods

Data and study sample

The Medicare Current Beneficiary Survey (MCBS) is a national panel survey that enrolls about 12 000 new participants annually, and the sample is designed to represent the ever-enrolled Medicare population in a given year.[23] The survey consists of face-to-face interviews three times yearly, and health care use and payment data are collected for three calendar years.[24, 25] Health care encounters reported on the survey are matched to Medicare claims and records when possible.[25, 26] For this study, cost and use data were pooled from the 2011–12 files, the two most recent years available when the data use agreement was executed, and additional survey data were pulled from the 2010–11 files to identify beneficiaries with HF at baseline. MCBS data files exclude direct identifiers, and this study received Institutional Review Board approval with a waiver of additional informed consent documentation.

The subsample specified for this study consisted of all participants who had responded affirmatively to the survey questions, 'Has a doctor ever told you that you had congestive heart failure?' or 'In the past 12 months, has a doctor told you that you had congestive heart failure?' by the last interview round before the observation year (fall 2010 for the 2011 cohort, and fall 2011 for the 2012 cohort). Study participants also must have held Part D coverage in all 12 months of the observation year, because the intent was to study out-of-pocket spending in health plans with drug coverage, not drug prices generally. In addition, spending data are less likely to be imputed for the prescription events from Part D records (as opposed to the survey).[27]

Participants living in a facility for any part of the year were excluded, because facility staff may acquire or administer medications on behalf of residents.[28] Recipients of the Low-Income Subsidy (LIS) for Part D cost-sharing assistance also were excluded, because the LIS reduces out-of-pocket prescription spending to zero or near-zero, so a cost-sharing effect on medication adherence and downstream costs was unlikely. Finally, participants were excluded if they did not have at least one fill of a prescription from a HF-indicated class—defined as ACE inhibitors, angiotensin receptor blockers, non-ocular β blockers, diuretics, aldosterone antagonists, and cardiac glycosides—during the observation year. Isosorbide and hydralazine also were considered HF-related if both were filled during the same year, given the indication of combination isosorbide–hydralazine for African-American HF patients.[29] (See Supplementary Figure S1 for a sample selection flow chart.)

Measures

The primary predictor of interest was the average of out-of-pocket (OOP) expenditures on 30-day supplies of HF-related prescriptions, as defined above. MCBS does not include data on benefit structure, such as cost-sharing requirements. Therefore, medication cost sharing was approximated by computing average OOP payment for HF prescriptions in the Part D records. To obtain average cost, payments were first standardized to a 30-day supply by dividing 30 by the actual days supplied and multiplying the payment by the result.[19, 30] For example, a $12 payment for a 90-day supply would be converted to $4. An average of 30-day payments was then computed for each beneficiary. A secondary analysis was also conducted for total OOP drug expenditure, defined as the sum of all OOP payments for HF prescriptions in the observation year.

The outcome variables for both analyses were: (1) all-payer inpatient payments, (2) Medicare inpatient payments, (3) all-payer total payments, and (4) Medicare total payments, as reported in the MCBS person- and service-summary files for the observation year. All-payer expenditures were analyzed in addition to Medicare-specific payments, because Medicare benefits do not cover 100% of all health care services; substantial amounts may be paid by a private 'Medigap' policy, the Veterans' Administration, employer-sponsored health insurance, or Medicaid. MCBS derives these payment totals from Medicare claims records for covered services, and from survey responses—which include interviewer review of financial documents such as bills, receipts and explanations of benefits—for other services. For participants with incomplete survey participation during the survey year, payments for non-Medicare-covered services are imputed by the MCBS team.[23] Costs were converted to 2012 dollars using the Consumer Price Index for All Urban Consumers.

Multivariable analysis adjusted for gender, race/ethnicity, marital status, annual income, educational attainment, Census region, urbanicity and Medicare Advantage (MA) enrollment. Gender, race/ethnicity, marital status, urbanicity and MA enrollment were dichotomized. Census region was also dichotomized into South (including Puerto Rico) or other. Educational attainment was quasi-normally distributed and treated as continuous after the categories between high school diploma and four-year degree were combined. Income was converted to 2012 dollars and log-transformed due to a right-skewed distribution. Age was not included in the models due to collinearity with other predictors, especially reason for Medicare entitlement (see next paragraph).

The analysis also adjusted for self-rated health (compared to one year ago and to others the same age) and difficulty walking 2–3 blocks or ¼ mile, both reported on five-point scales; log-transformed body mass index (BMI); having a Medicare-qualifying disability (compared to qualifying by old age only); and number of HF drug classes used during the year (1, 2 or ≥3). Number of HF drug classes was included as a rough proxy for disease severity in the absence of HF-specific clinical measures. A comorbidity index was not computed, because records for Parts A and B-covered services are incomplete for Medicare Advantage enrollees.[26] Nonetheless, the analysis also adjusted for self-reported type 2 diabetes and depression, due to their clinical relevance for HF outcomes.[31, 32] Finally, all models contained indicators of death or attrition and year of observation as proxies for censoring and time effects, respectively.[25]

Analysis plan

Bivariate associations were explored using Spearman's correlation coefficient (r_s), because the cost variables were non-normally distributed. Statistically significant correlations were further investigated with design-adjusted gamma log-link regression models, which are recommended for non-negative and right-skewed variables.[33] Given the challenges of interpreting non-linear models, coefficients were exponentiated to represent the percent change in the outcome per one-unit rise in the predictor variable, and marginal effects analysis was performed to predict average change in the outcome, conditional on the covariates. Predicted values of the outcome at the 25th, 50th and 75th percentiles of the predictor variable are also reported for each model. MCBS sampling weights were applied to account for unequal probabilities of selection, post-stratification and nonresponse; for multi-year participants, an average of cross-sectional sampling weights was used.[24] Standard errors were computed with Taylor-series linearization to adjust for clustering and stratification in the sample design.[34] Univariate and bivariate analyses were performed in SAS version 9.4; multivariable models were built in Stata version 15.1.

Results

Sample characteristics

N = 252 participant-year records met the sample inclusion criteria, representing 204 unique MCBS participants. Without adjusting for sampling weights, this sample was 50.4% female; 11.1% non-white, Latino or multiracial; 30.6% non-metropolitan; and 44.0% unmarried at the time of survey (Table 1). About one-third (32.1%) did not finish high school. Mean (SD) age was 77.7 (8.8) years, and median (semi-interquartile range) annual income was $26 731 (8602) in 2012 dollars, which included Social Security, pension and retirement account payments for the participant and their spouse. Notably, MA plan enrollees made up 44.8% of the sample.

In terms of health status, 41.6% rated their health as fair or poor compared to others the same age, and 57.0% could walk 2–3 blocks or ¼ mile only with 'a lot' of difficulty or not at all (Table 1). Mean (SD) BMI was 28.7 (6.5), and about 8% were entitled to Medicare benefits because of a qualifying disability or disease (rather than age alone). No data on HF class or ejection fraction were available, but over a third (35.7%) rated their health as worse than one year before, and 43.6% used three or more HF-indicated drug classes during the year of observation. Prevalence of self-reported comorbid conditions was 27.0% for type 2 diabetes and 31.0% for depression.

Mean (SD) OOP payment for one HF-related prescription was $5.27 (5.99) for a 30-day supply (Table 1). Mean (SD) OOP payment

Table 1 Sample characteristics (*N* = 252)

Variable	Count	%
Gender		
Male	125	49.60
Female	127	50.40
Race/ethnicity		
Non-white[1] or Latino	28	11.11
White, non-Latino	224	88.89
Education		
8th grade or less	32	12.70
9th–12th grade	49	19.44
High school diploma	80	31.75
Vocational, some college or associate's	67	26.59
Bachelor's degree	13	5.16
Post-graduate	11	4.37
Marital status		
Married	141	55.95
Unmarried	111	44.05
Urbanicity		
Metropolitan area	175	69.44
Non-metro. area	77	30.56
Region		
South or PR	109	43.25
Other	143	56.75
Medicare plan type		
Medicare Advantage	113	44.84
Traditional (FFS)	139	55.16
Health versus others the same age		
Excellent	14	5.60
Very good	51	20.40
Good	81	32.40
Fair	72	28.80
Poor	32	12.80
Health now versus one year ago		
Much better	14	5.56
Somewhat better	25	9.92
About the same	123	48.81
Somewhat worse	72	28.57
Much worse	18	7.14
Difficulty walking ¼ mile or 2–3 blocks		
None	52	20.72
A little	29	11.55
Some	27	10.76
A lot	41	16.33
Unable	102	40.64
Medicare entitlement		
Disability/ESRD	20	7.94
Age only	232	92.06
Type 2 diabetes		
Yes	68	26.98
No	184	73.02
Depression		
Yes	78	30.95
No	174	69.05
No. of HF-indicated drug classes used		
1	51	20.24
2	91	36.11
3 or more	110	43.65
Censoring		
Died or LTFU	≤10	–
Alive, retained	≥242	–
Year of observation		
2011	122	48.41
2012	130	51.59
Variable	**Mean**	**SD**
Age (years)	77.70	8.84
Annual income (thousands of dollars)[2,3]	32.30	33.4
Body mass index	28.71	6.54
Average OOP payment per HF prescription[2,4]	5.27	5.99
Total OOP payments for HF prescriptions[2]	118.83	134.95
Inpatient costs (thousands), all payers[2]	4.25	10.47
Inpatient costs (thousands), Medicare[2]	3.12	9.44
Total costs (thousands), all payers[2]	19.24	26.14
Total costs (thousands), Medicare[2]	10.84	18.19

Cell sizes below 11 suppressed for participant privacy. ESRD, end-stage renal disease; FFS, fee-for-service; HF, heart failure; LTFU, lost to follow-up; OOP, out-of-pocket; PR, Puerto Rico; SD, standard deviation.

[1]Includes multiracial participants

[2]Adjusted to 2012 dollars

[3]Includes Social Security, pension and retirement account payments for participant and spouse

[4]Standardized to a 30-day supply

for all HF-related prescriptions during the year of observation was $118.83 (134.95). Again not adjusting for sampling weights, mean (SD) inpatient costs were $3127 (9441) per participant-year for Medicare and $4255 (10 470) per participant-year for all payers. Total health care costs per participant-year averaged $10 842 (18 191) for Medicare and $19 242 (26 145) for all payers.

Bivariate correlations

In primary analysis, there was a statistically significant correlation between mean OOP expenditure per HF prescription, adjusted to a 30-day supply, and total health care payments by all payers, $r_s = 0.16$, $P = 0.010$. Likewise, there was a significant correlation between mean OOP expenditure per HF prescription and total health care payments by Medicare, $r_s = 0.16$, $P = 0.011$. Both these associations were carried forward to multivariable analysis. Conversely, there was no statistically significant correlation between mean OOP expenditure on HF prescriptions and inpatient costs paid by all payers, $r_s = 0.08$, $P = 0.227$, nor was there a significant correlation between mean OOP expenditure on HF prescriptions and inpatient costs paid by Medicare, $r_s = 0.09$, $P = 0.158$. In secondary analysis, no statistically significant correlations were observed between annual OOP expenditures on all HF prescriptions and any of the health care cost outcomes (data not shown).

Multivariable models

In adjusted analysis, the association between mean OOP expenditure per 30-day HF prescription and total all-payer expenditures was no longer statistically significant, $e^{\gamma} = 1.000$, 95% confidence interval (CI) [0.983 to 1.017] (Table 2, Figure 1). Conversely, the adjusted association between mean OOP expenditure per 30-day HF prescription and total Medicare payments retained statistical significance, $e^{\gamma} = 1.022$, 95% CI [1.004 to 1.041] (Table 2, Figure 2). Analysis of marginal effects in the latter model showed that annual Medicare payments rose by an average of $190.32, 95% CI [40.54 to 341.10], for each additional $1 of OOP spending per prescription, $P = 0.013$ (Figure 2). Predicted values from this model are shown in Table 3.

Discussion

In this study of community-dwelling Part D subscribers with self-reported HF at baseline, OOP payment for the average 30-day HF prescription (in the absence of the LIS) was statistically significantly associated with total Medicare spending. A one-dollar increase in mean OOP spending per HF prescription was associated with an increase of 2.2%—or $190 on average—in total Medicare payments for the year. However, there was no evidence of an association between average OOP spending on HF prescriptions and Medicare inpatient payments, all-payer inpatient payments, or (after multivariable adjustment) total health care payments during the observation year.

A positive association between OOP prescription spending and heath care costs had been hypothesized, because the rationale of V-BID is that lower copays for effective chronic disease medications promote adherence and have the potential to reduce costs.[11, 12] Likewise, several studies have demonstrated a link between higher OOP drug payments and greater downstream health care costs.[35–38] Therefore, the finding that total Medicare payments are

Table 2 Adjusted associations with health care expenditures for heart failure patients, Medicare Current Beneficiary Survey (2011–12)

Parameter	Total payments, all payers (Model 1)		Total payments, Medicare (Model 2)	
	e^{γ}	95% CI	e^{γ}	95% CI
Mean OOP payment per HF Rx[1]	1.00	0.98 to 1.02	1.02[3]	1.00 to 1.04
Male gender	0.79	0.60 to 1.04	0.95	0.73 to 1.23
Non-white/Latino	1.47	0.97 to 2.23	1.06	0.71 to 1.60
Education level	1.10	0.98 to 1.22	1.06	0.95 to 1.19
Married	1.40[3]	1.06 to 1.86	1.08	0.85 to 1.39
Metro. Area	0.89	0.67 to 1.18	1.03	0.71 to 1.49
South or PR	0.82	0.66 to 1.04	0.85	0.65 to 1.11
Medicare Advantage	0.42[3]	0.34 to 0.53	0.14[3]	0.11 to 0.18
Health versus age group[2]	1.05	0.91 to 1.21	1.12	0.99 to 1.25
Health versus one year ago[2]	1.24[3]	1.06 to 1.45	1.04	0.90 to 1.20
Difficulty walking[2]	1.08	0.98 to 1.20	1.12[3]	1.03 to 1.23
Disability	2.98[3]	1.62 to 5.46	2.38[3]	1.39 to 4.08
Type 2 diabetes	1.13	0.86 to 1.49	1.20	0.90 to 1.61
Depression	1.47[3]	1.06 to 2.05	1.05	0.79 to 1.40
Drug classes used (*ref.* = 1)				
2	1.29	0.90 to 1.84	1.13	0.79 to 1.61
≥3	1.32	0.92 to 1.87	1.31	0.97 to 1.76
Died or lost to follow-up	1.02	0.20 to 5.11	0.23[3]	0.14 to 0.38
Year of survey (*ref.* = 2012)				
2011	0.96	0.76 to 1.21	1.00	0.80 to 1.26
Annual income in thousands, log	0.93	0.78 to 1.10	1.10	0.93 to 1.31
BMI, log	0.68	0.34 to 1.39	0.87	0.47 to 1.63
Intercept (thousands)	15.55[3]	1.47 to 164.06	3.84	0.47 to 31.34

BMI, body mass index; CI, confidence interval; HF, heart failure; OOP, out-of-pocket; PR, Puerto Rico; *ref.*, reference; Rx, prescription.

[1]Standardized to a 30-day supply

[2]Five-point scale; higher score reflects worse health or function

[3]Significant at the $P < 0.05$ level

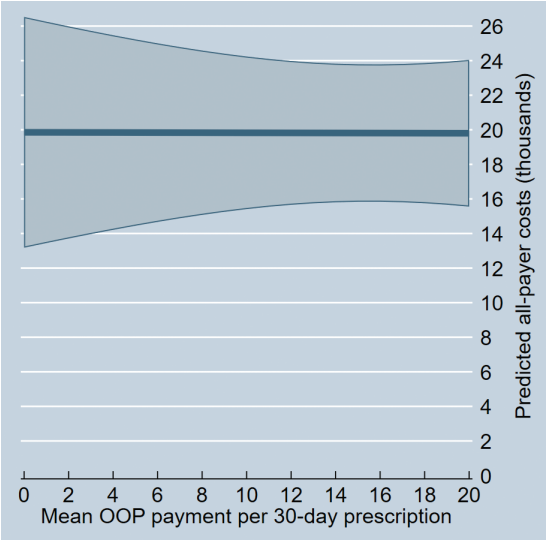

Figure 1 Model 1 (all payers) estimated marginal effects and 95% confidence intervals. Costs converted to 2012 dollars. OOP, out-of-pocket.

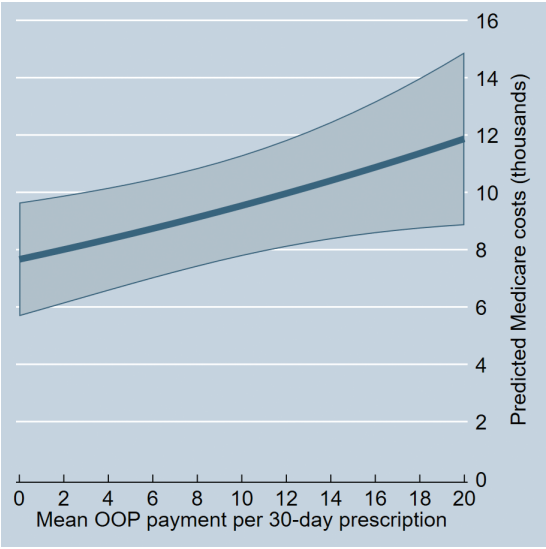

Figure 2 Model 2 (Medicare) estimated marginal effects and 95% confidence intervals. Costs converted to 2012 dollars. OOP, out-of-pocket.

associated with OOP spending on HF drugs supports the research hypothesis and is consistent with the logic of V-BID and prior literature. Although the effect size was small, predicted total Medicare payments per subscriber rose by $256 from the 25th to 50th OOP spending percentile ($2.60 versus $4.02 per prescription), and by $388 from the 50th to 75th percentile ($4.02 versus $6.09 per prescription; Table 3). These estimates could have significant financial implications for Medicare when multiplied by the hundreds of thousands of Part D subscribers with HF.

It is unclear why OOP drug payments were not associated with other cost outcomes, especially inpatient costs. HF-specific inpatient hospitalization was relatively uncommon in this sample (13% of fee-for-service beneficiaries). In addition, patients without inpatient use could still be costly to Medicare, as hospital-based outpatient treatment of HF patients with acute exacerbation in 24-hour observation units has become common. Regarding total payments by all payers, a prior study in a commercially insured HF population (including some Medicare beneficiaries) found no significant effect of medication copay on total health care costs,[19] and a systematic review of V-BID studies found no evidence of significant effects on total or non-drug costs after one year.[12] Our sample of Medicare beneficiaries with Part D coverage may have enjoyed overall good access to preventive medications, averting the need for some costly forms of care.

Compared with other chronic disorders, HF remains a serious illness with a generally poor prognosis.[39] Prior studies of the effect of prescription cost sharing on health outcomes have focused on subclinical or slower-onset conditions, such as hypertension, dyslipidemia and diabetes. In contrast, the clinical effects of non-adherence to HF treatment can quickly become serious, and the severity of HF and consequences of non-adherence may make some patients less price-sensitive. Adherence was not examined in this study, but previous studies of HF patients in and outside Medicare have shown modestly negative effects of drug copays on adherence,[19, 20, 30] suggesting that HF patients are not fully price-immune, and even modest gains in adherence among Medicare beneficiaries with HF have been linked to lower 3-year cumulative Medicare spending.[25] However, the one prior study to examine specifically copay-linked non-adherence failed to detect an effect on total health care costs.[19] Our results corroborate that finding for all-payer costs, but they seem to contradict it when Medicare costs are isolated.

Early studies suggested that health plans with higher cost-sharing requirements across all services may incur lower total health care costs. In the RAND Health Insurance Experiment of the 1970s–80s, participants assigned to health plans with cost sharing were cheaper to insure than participants with free care after 3–5 years of follow up.[40] Yet, subsequent analysis showed that almost all the reduction in hospital use in the cost-sharing plans could be attributable to greater attrition in those groups.[41] Moreover, low-income participants in the cost-sharing plans had higher predicted mortality in the presence of hypertension, and higher prevalence of serious symptoms if they began the study in poor health, compared to their free-care counterparts.[42, 43] Income was not a significant predictor of health care costs in our models, perhaps because most low-income MCBS participants were eligible for the LIS (and thus excluded from our sample).

OOP payments for HF medications were very low in this sample: just $5.27 for the average 30-day supply. Because of these low effective prices and the prevalence of multi-drug use, we conducted a secondary analysis to evaluate total OOP prescription spending over the observation year. This analysis returned no statistically significant associations with the cost outcomes. Similarly, number of HF drug classes used was not associated with health care costs in the multivariable models. It is possible that participants who used more drug classes or higher-cost medications were sicker and therefore less price-sensitive. Additionally, non-HF prescriptions and other OOP medical expenses may have been important factors in determining health care costs, but these effects were not modeled in this study.[26, 44, 45].

Limitations

Inferences from this study are limited by its correlational design: payments were aggregated over the year of observation, so inpatient and other health care costs may have accrued before the prescription drug costs, although HF was defined at baseline. In addition, OOP drug spending may take longer than 12 months to affect non-drug costs, which could have underestimated the main effects,

Table 3 Predicted annual Medicare expenditure by prescription drug spending quartile

Mean OOP payment per 30-day HF prescription	OOP payment percentile	Predicted total Medicare costs	95% CI	Difference in predicted costs per patient-year
$2.60	25th	$8109	$6255 to $9964	–
$4.02	50th	$8365	$6569 to $10 161	+$256
$6.09	75th	$8753	$7017 to $10 489	+$388

CI, confidence interval; HF, heart failure; OOP, out-of-pocket.

although as noted above, non-adherence to HF drug regimens can precipitate acute exacerbation more rapidly than in other conditions. Identifying HF cases with survey items may have led to misclassification, because some participants may not fully understand the questions or their diagnosis. Self-reported HF in the Atherosclerosis Risk in Communities (ARIC) study had 61% agreement with a Medicare claims-based definition,[46] but true agreement may have been higher since the ARIC investigators did not include hypertensive heart disease with heart failure (ICD-9-CM 402.x1, 404.x1 and 404.x3). Moreover, claims-based algorithms may result in false-negatives, due to more restricted reference periods, or false-positives, due to inclusion of erroneous or 'rule/out' diagnosis codes.[47]

Patients may evaluate the cost-sharing requirements of their prescription drug plan before a drug is prescribed or purchased, which could have been a source of endogeneity. Exclusion of survey-reported prescriptions that did not appear in Part D records may have biased spending estimates. However, only 6% of unmatched survey prescriptions reflect true out-of-plan use for Part D subscribers with common chronic disorders in MCBS data; many of the rest could be matched to Medicare records with a more sensitive algorithm.[27] Likewise, the inclusion of Medicare Advantage enrollees may have resulted in under-reporting of health care encounters and non-drug costs for that group, as explained above. And at least some portion of the higher Medicare costs observed at higher OOP drug expenditures could be attributable to coinsurance, which is percentage-based and a feature of many Part D plans.

The time period of this study may limit its immediate relevance, and lower out-of-pocket prices for HF drugs in 2011–12 could have biased our results toward the null. As noted above, no HF-specific clinical data were available, but adjustment for number of drug classes used and multiple health status variables likely captured some of this variation. Pooling data from two survey years could have underestimated standard errors, because observations from beneficiaries who participated both years are not truly independent. Yet, the necessity of correcting for this source of clustering in complex samples is unclear if the primary sampling unit is specified correctly.[24] Finally, as with any analysis of administrative datasets, results may be spurious because of omitted variables or sampling error.

Implications for policy or practice

With the discovery of new therapeutic drug classes and the addition of costly therapies (e.g. sacubitril and ivabradine) to the HF management arsenal, questions about the effects of prescription cost sharing are freshly relevant for HF patients. Given the growing use of V-BID, it is notable that our study of a national probability sample of Part D subscribers with HF found no evidence that higher OOP spending on essential medications resulted in greater inpatient or all-payer medical costs. However, we expect that future studies with more current data would show more significant associations due to the expense of newer HF therapies and the cost-sharing structures of Part D coverage. For example, a 2019 analysis of over 2800 Part D plans nationwide estimated the average cost sharing for a 30-day supply of sacubitril/valsartan to be $57, which is 10 times higher than the average OOP payment for a 30-day prescription in this study.[48]

Therefore, V-BID may have a role in optimal health coverage for this population. Our statistically significant finding that average OOP spending on HF prescriptions was associated with annual Medicare costs—even before the arrival of sacubitril—signals the need to consider value in future analyses. A hypothetical copay increase of $1, given a mean of 2.4 HF-indicated drug classes per beneficiary and assuming 12.2 copays per year (for continuous 30-day supplies), would equate to an average $29.28 in savings to a Part D plan sponsor per beneficiary per year. Yet these savings would be associated with a predicted loss to Medicare of $190.32, or a net loss of $160.90—an unfavorable return on investment when multiplied by the hundreds of thousands of Part D subscribers with HF. These estimates, together with high OOP costs for current therapies, suggest that longitudinal or cost-effectiveness studies of cost-sharing requirements for essential HF drugs in Medicare Part D are warranted. In addition, the impact of Part D coverage on overall Medicare costs should be evaluated in the HF population.

Conclusion

This study extends prior research on the effects of OOP prescription drug spending in HF and contributes to the body of knowledge on V-BID. The findings from this study offer preliminary evidence that, from the perspective of Medicare, cost sharing for essential HF medications in Part D plans may have unintended consequences in the form of higher costs for community-dwelling beneficiaries without the LIS. However, cost-sharing requirements for essential HF drugs were not linked to higher inpatient or all-payer costs. Longitudinal studies and formal cost-effectiveness analysis would better inform the optimal design of prescription drug coverage for HF patients, especially in a prospective sample given the recent availability of costly new HF therapies.

Supplementary Material

Supplementary data are available at *Journal of Pharmaceutical Health Services Research* online.

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Author Contributions

B.T.M. designed the study with input and oversight from V.P. B.T.M. conducted data analysis, with assistance from R.P., and V.P. contributed to the interpretation of results. B.T.M. drafted the manuscript, with substantive revisions by R.P. and V.P.

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Conflict of Interest

None declared.

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