ORIGINAL RESEARCH

Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon"

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Recent pharmaceutical advances hold the promise of transforming the medical care of serious life-threatening, chronic, and/or rare diseases and significantly improving the lives of those afflicted. Yet, these advances may be out of reach for many Americans because of high out-of-pocket (OOP) costs.[1] Financial barriers to treatment access are particularly acute for Medicare Part D patients requiring specialty drug treatments. Since Part D's creation in 2006, patients who do not receive low-income subsidies (non-LIS beneficiaries) have been subject to high coinsurance requirements for specialty drugs, which are placed on a "specialty tier." Unlike co-payments of a fixed dollar amount, coinsurance payments vary based on the cost of the medication. Furthermore, under Part D, the required coinsurance percentage fluctuates across the coverage year (**Figure 1**), with the highest costs concentrated at the beginning of the year. The cycle resets on January 1 of the following year.[2] In addition, because Medicare Part D plans are not required to have an annual maximum OOP spending limit, patients who are prescribed continuous specialty drug treatment continue to face substantial OOP costs, even during the catastrophic coverage phase.[3] These fluctuating costs have been characterized as a "cost-sharing rollercoaster."[2]

A growing body of evidence links higher cost sharing with reduced utilization of specialty drugs.[1,4-8] In the Medicare population, studies of several specialty drug classes have documented that beneficiaries not receiving LIS (ie, those responsible for high cost sharing) have lower rates of treatment initiation, greater incidence of gaps in treatment, and more frequent interruptions in treatment compared with counterparts who receive full LIS (and thus face low, relatively stable costs across the coverage year).[9-11] Although further research is needed, it is likely that the high cost sharing for specialty drugs under Medicare Part D may place patients at risk for compromised treatment outcomes due to reduced or delayed initiation, poor adherence, and higher discontinuation rates.

Strategies to address financial barriers must balance access to treatment with very real financial constraints. Based on the accumulating data, and in keeping with our prior recommendations,[5]

ABSTRACT

OBJECTIVES: Medicare Part D specialty drug users not qualifying for low-income subsidies (non-LIS beneficiaries) face high and variable cost sharing during the calendar year. We examined their out-of-pocket (OOP) cost patterns under the existing Part D cost-sharing policies and proposed changes to these policies.

METHODS: Using 100% Medicare claims data from 2012, we examined mean annual and monthly OOP drug costs for Medicare Part D patients who were full-year users of Part D specialty drugs for rheumatoid arthritis (RA) (n = 1063), multiple sclerosis (MS) (n = 2256), or chronic myeloid leukemia (CML) (n = 1135) under existing policy. Using the same data, we simulated costs under both proposed Medicare Payment Advisory Commission (MedPAC) policy recommendations and our own recommendations.

RESULTS: In 2012, our sample faced mean annual cumulative OOP drug costs (for all medications) of $3949 (RA), $5238 (MS), and $6322 (CML). Mean OOP costs were $977 (RA), $1613 (MS), and $2456 (CML) in January alone. A substantial proportion of total annual OOP prescription spending also occurred during the catastrophic coverage phase (RA: $1229 [31%]; MS: $2456 [47%]; CML: $3546 [56%]). Under proposed MedPAC changes, patients would have faced maximum annual OOP spending of $4700, but mean OOP costs in January and February would have been higher compared with the existing policy. Under our proposed strategy, OOP costs would have been spread evenly over 12 months (≤$392 per month). The potential incremental costs of our proposed strategy would have been $23.55 per non-LIS Part D beneficiary per year.

CONCLUSIONS: The existing Part D cost-sharing structure creates a substantial financial burden for specialty drug users, especially early in the year. Implementing both annual and monthly OOP maximum spending limits would result in lower, more consistent OOP costs, potentially increasing patients' ability to access treatments for life-threatening, chronic, and rare diseases.

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TAKEAWAY POINTS

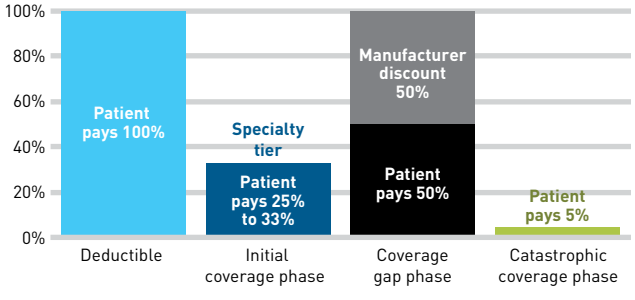
We analyzed out-of-pocket (OOP) prescription drug costs for real-world Medicare Part D specialty drug users under existing policy, then simulated how their costs would change based on recent Medicare Payment Advisory Commission (MedPAC) recommendations and our own proposed strategies.

- Patients face a substantial financial burden under existing policy, especially early in the coverage year.
- MedPAC's proposal would reduce the total cost burden for many patients and increase it for others, but it would exacerbate the burden early in the year.
- Incremental costs of our proposed strategies of annual and monthly OOP spending limits are manageable and likely to increase patients' ability to meet cost-sharing obligations.

we propose the introduction of 2 key changes to the Part D cost-sharing requirements that would provide additional protection for Medicare beneficiaries. First, the introduction of an annual OOP maximum spending limit—which is commonplace in private insurance plans and in health insurance exchange plans—would protect beneficiaries from unmanageable cumulative OOP costs. Indeed, the Medicare Payment Advisory Commission (MedPAC) recently recommended policy changes that would effectively establish an annual OOP maximum for Medicare Part D beneficiaries.[12] Second, more stable and consistent timing of OOP spending requirements—effectively introducing a monthly OOP maximum as well—would avoid the major fluctuations in monthly expenses that characterize the current cost-sharing structure and would be more appropriate for seniors, many of whom are on a fixed income. Previously, we have cited programs that offset the burden of high winter heating bills by distributing energy costs across the calendar year as a model for this approach.[5]

In order to test the impact of our proposed strategies on real-world OOP costs for non-LIS Medicare Part D beneficiaries, we undertook a 3-part investigation. First, using actual 100% Medicare claims from 2012, we illustrated the real-world OOP cost patterns and burden under the existing Part D cost-sharing structure for continuous users of specialty drugs for 3 chronic conditions that rank among the top spending categories for specialty drugs.[13,14] Second, we used the same Medicare claims data on drug utilization and costs to simulate the OOP cost patterns that these specialty drug users would face if recent MedPAC recommendations related to Part D cost sharing were to be implemented. Third, we simulated OOP costs for these patients under our proposed strategies and compared them with those under existing policy and the MedPAC recommendations. Finally, we discuss the incremental costs of our proposed strategies and how they could be funded.

FIGURE 1. Medicare Part D Cost-Sharing Requirements for Specialty Drugs, 2012[a]



[a]Coverage cycle begins on January 1, ends on December 31, and then resets on January 1 of the next year. Beneficiary movement through coverage phases is based on prescription drug spending.

METHODS

Estimation of OOP Cost Patterns Under the Existing Part D Cost-Sharing Structure

To estimate the impact of current policy, we used a data extract from the 2012 Chronic Conditions Data Warehouse 100% Medicare claims files, which contain data on all fee-for-service (FFS) Medicare beneficiaries. (Part D's cost-sharing structure has not changed since 2012.) We included non-LIS beneficiaries who had: 1) continuous FFS Medicare and stand-alone Part D plan coverage throughout 2012; 2) a diagnosis of rheumatoid arthritis (RA), multiple sclerosis (MS), or chronic myeloid leukemia (CML); and 3) prescription claims reflecting continuous use of a disease-specific Part D-covered specialty drug (listed in the **eAppendix Table** [eAppendices available at **ajmc.com**]) over the course of the coverage year (ie, a prescription fill for the specialty drug in January and total days' supply for any disease-specific specialty drug ≥360 days in 2012). For example, if an individual switched from one disease-specific specialty drug to another but had no gap in treatment (eg, a CML patient had 180 days' supply of bosutinib and 180 days' supply of dasatinib), then he or she was classified as a continuous user. After these criteria were applied, the resulting sample consisted of 1063 patients with RA, 2256 patients with MS, and 1135 patients with CML. Using actual 2012 claims data for these disease samples, we calculated annual cumulative OOP drug costs and OOP costs by calendar month and benefit phase for patients in each disease group.

We opted to restrict our sample to continuous users for several reasons. First, in the absence of specific reasons for discontinuation (eg, intolerable side effects, poor response), consistent treatment is typically recommended for each of the conditions we examined.[15-17] Thus, we wished to examine the OOP costs associated with optimal treatment patterns. Second, inclusion of individuals who used the specialty drugs during only part of the year could have artificially depressed our mean estimates of

annual and monthly costs. Third, high OOP costs are associated with interruptions in treatment and discontinuation of treatment; thus, including individuals who may have used medications inconsistently due to financial burden would have led to further underestimation of the true OOP costs associated with optimal use of these treatments.

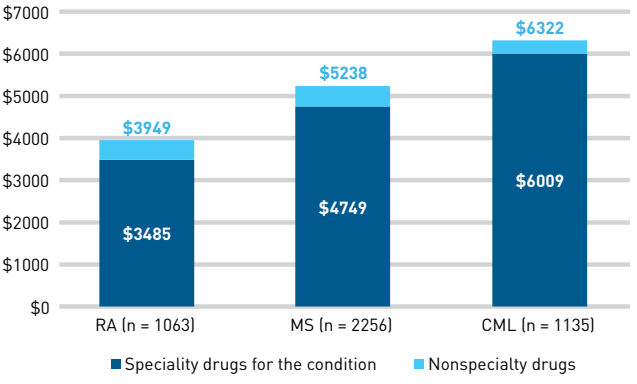
Simulation of OOP Cost Patterns Under Proposed MedPAC Changes to Part D Cost Sharing

Next, using the same drug utilization and cost information from the 2012 Medicare claims data, we simulated the OOP cost patterns for the 3 disease samples if recent MedPAC recommendations were to be applied to the 2012 Part D benefit. This involved simulating the impact of 2 key changes proposed by MedPAC.[12] The first involved the elimination of the 5% cost-sharing requirement during the catastrophic coverage phase, resulting in an effective annual OOP maximum equal to the annual true OOP (TrOOP) spending limit that triggers catastrophic coverage. In 2012, the TrOOP was $4700. Second, under existing Part D policies, brand name prescription drugs purchased by Part D beneficiaries during the coverage gap phase include a 50% manufacturer discount that is credited toward beneficiaries' TrOOP spending. Under the MedPAC proposal, these manufacturer discounts would no longer be credited toward patients' TrOOP spending. Given that movement through the coverage gap is based on TrOOP costs, elimination of the manufacturer discount credit under the MedPAC proposal would effectively extend the time patients spend in the coverage gap and increase the amount they must spend OOP before reaching catastrophic coverage. Then, only patients whose spending was sufficient to trigger entry into the catastrophic coverage phase would benefit from the elimination of cost sharing during that phase.

Simulation of OOP Cost Patterns Under Our Proposed Changes to Part D Cost Sharing

We estimated OOP costs under our proposed policy changes following the same procedure used for the MedPAC simulation, with 2 key differences. First, our proposal does not include a change to the current policy of crediting manufacturer discounts toward patients' TrOOP spending; we maintained the $4700 spending threshold that triggers catastrophic coverage as our proposed annual OOP spending limit, counting both beneficiary OOP spending and manufacturer discounts. (As in the MedPAC proposal, this spending limit would mean elimination of 5% cost sharing during Part D's catastrophic coverage phase.) Second, to spread the OOP costs more evenly across the year, we divided the annual OOP maximum spending limit number (ie, $4700) by 12 months to derive a maximum monthly OOP spending limit. This monthly limit also includes both beneficiary OOP spending and manufacturer discounts, meaning that actual beneficiary spending may be lower than the monthly OOP spending limit during the month(s) of the coverage gap.

FIGURE 2. Annual Out-of-Pocket Prescription Drug Spending for Medicare Beneficiaries Utilizing Disease-Specific Specialty Drugs for RA, MS, or CML, 2012



CML indicates chronic myeloid leukemia; MS, multiple sclerosis; RA, rheumatoid arthritis.

Estimating the Incremental Cost of Our Proposed Changes and Financing Strategies

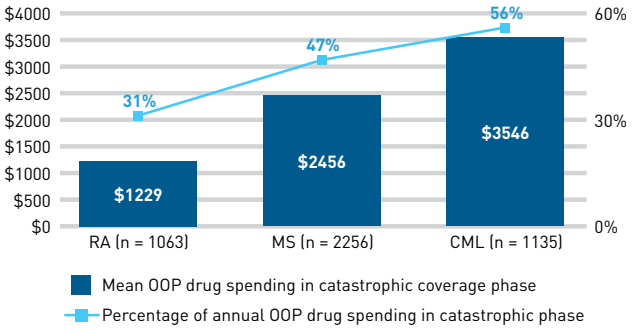
To estimate the incremental costs of our proposed policy changes, we identified publicly available data from the year closest to our 2012 utilization data (ie, 2013) to identify: 1) estimates of the total number of non-LIS beneficiaries who entered catastrophic coverage during that year and 2) the average OOP spending among these beneficiaries during the catastrophic coverage period.[18] The product of the 2 estimates provides the total OOP costs borne by these beneficiaries that would be foregone (ie, the incremental costs of our proposed policy of instituting an annual OOP spending maximum at the catastrophic coverage threshold level). We then divided the incremental cost of our proposed changes by the total number of non-LIS beneficiaries enrolled in the Part D program in 2013 to identify the per-beneficiary cost of the proposed policy change.[18] The per-beneficiary cost is approximate because, whereas the additional cost would be priced out through the Part D plan bidding process, our proposed financing strategy estimates the cost as if it were passed through to beneficiaries directly.

RESULTS

OOP Cost Patterns Under the Existing Part D Cost-Sharing Structure

In 2012, specialty drug users in the RA group faced mean annual cumulative OOP drug costs of $3949 for all their Part D medications, whereas those in the MS and CML groups paid an average of $5238 and $6322, respectively. The majority of these costs were due to specialty drug spending (ie, 88% for the RA group, 91% for the MS group, and 95% for the CML group) (**Figure 2**). A significant propor-

FIGURE 3. Out-of-Pocket Prescription Drug Spending During the Part D Catastrophic Coverage Phase, 2012[a]



CML indicates chronic myeloid leukemia; MS, multiple sclerosis; OOP, out-of-pocket; RA, rheumatoid arthritis.

[a]Data reflect out-of-pocket spending on all prescription drugs, not just the disease-specific specialty drug.

tion of the MS (84%) and CML (87%) groups had annual specialty drug OOP costs of $5000 or more (data not shown). Because OOP spending pushed specialty drug users through the deductible, initial coverage phase, and coverage gap quite quickly in 2012, patients continued to have substantial OOP spending requirements during the catastrophic coverage phase, despite the fact that their coinsurance obligation dropped to 5%. Across disease areas, a substantial proportion of total annual OOP prescription spending occurred during the catastrophic coverage phase (RA: $1229 [31% of annual OOP costs]; MS: $2456 [47%]; CML: $3546 [56%]) (**Figure 3**). At the same time, specialty drug users had to bear large mean OOP costs in January alone (RA: $977; MS: $1613; CML: $2456). Once again, specialty drug costs were driving this OOP spending (see **eAppendix Figures A** and **B**). These January OOP costs represented a substantial portion of spending for the entire year (RA: 25% of annual spending; MS: 31%; CML: 40%) (**Figure 4**), and about half of total OOP costs were paid out by February.

OOP Cost Patterns Under Proposed MedPAC Changes to Part D Cost Sharing and Under Our Proposed Strategies

Simulated analyses examining the impact of proposed MedPAC recommendations showed that the policy changes would have mixed effects on beneficiaries' OOP burden (**Figure 5** and **eAppendix Figure C**). Because manufacturer discounts for brand name drugs during the coverage gap phase would no longer be credited toward patients' TrOOP spending, patients using brand name specialty drugs would have taken longer to reach the TrOOP spending limit, leading them to remain in the coverage gap phase for a greater period of time. Because of this widened coverage gap, they would have been subject to 50% cost sharing until they reached the TrOOP spending limit that triggers entry into the catastrophic coverage phase. As such, only patients whose cumulative annual spending (excluding manufacturer discounts) would have exceeded the designated spending limit ($4700 in 2012) would have seen overall savings from the elimination of 5% cost sharing during the catastrophic coverage phase. Under current policy, manufacturer discounts can effectively reduce OOP spending in the coverage gap by up to half, depending on an individual beneficiary's drug utilization patterns. This differential impact was apparent across our 3 diagnostic subgroups. Although patients in the MS and CML groups would have seen a decrease in cumulative mean annual OOP costs under the proposed changes, the RA group would have experienced an increase in costs ($4540 under MedPAC vs $3949 in 2012; data not shown) due to fewer beneficiaries reaching the OOP limit.

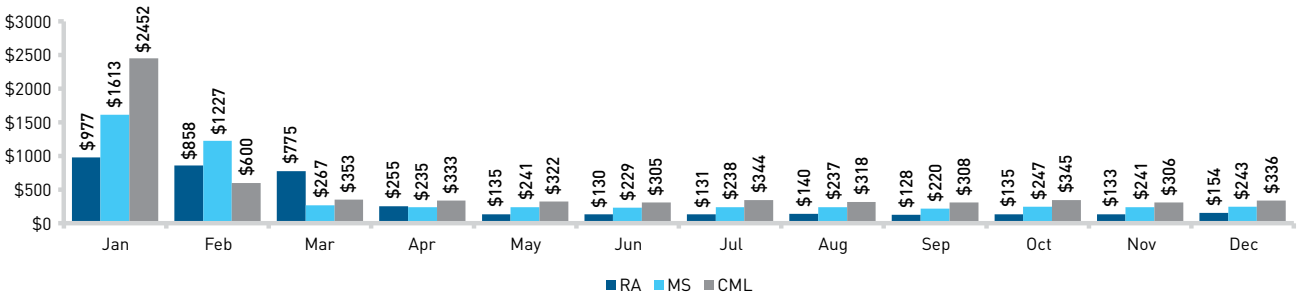
Given that patients in all disease samples had OOP costs that pushed them into the coverage gap early in the coverage year (often with the first fill of their disease-specific specialty drug), and they would have faced a higher threshold to exit the coverage gap under the MedPAC recommendations, the proposed policy changes would ultimately subject patients to even higher, more concentrated OOP costs during these early months (Figure 5). Patients would have faced maximum annual OOP spending of $4700 in 2012, but this entire OOP cost burden would have to be borne by most patients in the first 3 to 4 months of the calendar year. Furthermore, under the MedPAC changes, the mean OOP costs in January and February would be even higher than under existing policy (eg, $994 under MedPAC vs $977 in January 2012 for RA; $1685 under MedPAC vs $1613 for MS; $2814 under MedPAC vs $2452 for CML) (Figures 4 and 5).

Instituting a monthly OOP maximum based on an annual OOP maximum of $4700—which also counts the 50% manufacturer discounts for brand name drugs in the coverage gap—under our proposed strategies, in contrast, would result in a maximum of $392 in OOP costs to be borne by the patient in any given calendar month, as indicated by the dotted line in Figure 5.

Incremental Cost of Our Proposed Changes and Financing Strategies

Based on Medicare utilization numbers,[18] approximately 700,000 (2.8%) of the 24.2 million non-LIS beneficiaries enrolled in Part D plans reached the catastrophic coverage phase in 2013. They paid mean OOP costs of approximately $814 during that phase, for a total of approximately $569.8 million in patient OOP spending during the catastrophic coverage phase. Dividing that cost among all non-LIS beneficiaries, implementation of our proposal would have cost an additional $23.55 for each non-LIS beneficiary per year (ie, $1.96 per month).[12,18] In practice, the increased costs of $23.55 per beneficiary per year would not be straight pass-through costs via premiums, but would instead be borne out through the Part D plan bidding process, ultimately reducing the amount by which beneficiaries are directly impacted. Nevertheless, the incremental costs of our proposed changes are minimal when averaged over all non-LIS beneficiaries, regardless of the ultimate financing mechanism.

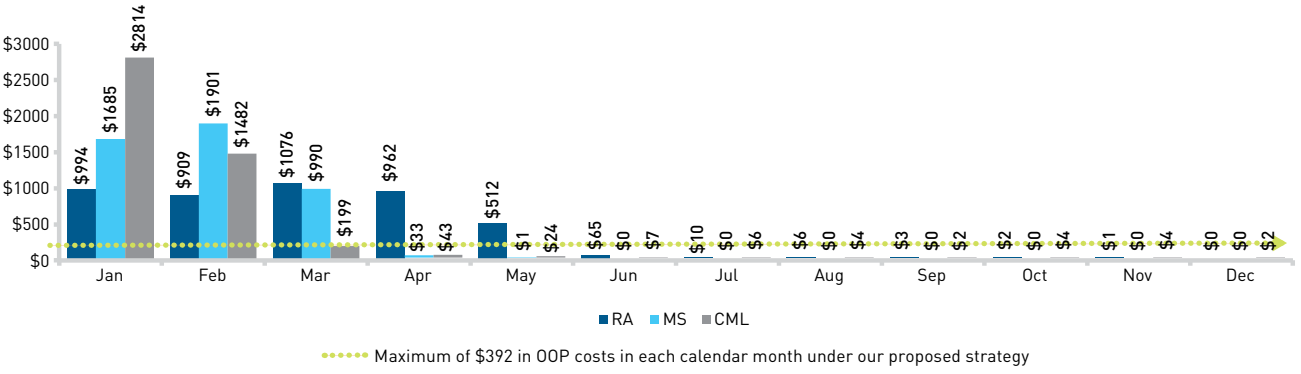
FIGURE 4. Mean Monthly Out-of-Pocket Prescription Drug Spending for Patients Utilizing Disease-Specific Specialty Drugs for RA, MS, or CML, 2012[a]



CML indicates chronic myeloid leukemia; MS, multiple sclerosis; RA, rheumatoid arthritis.

[a]Data reflect out-of-pocket spending on all prescription drugs, not just the disease-specific specialty drug.

FIGURE 5. Simulated Mean Monthly Out-of-Pocket Prescription Drug Spending Under the Proposed MedPAC Changes to Part D Cost Sharing and Under Our Proposed Strategies[a,b,c]



CML indicates chronic myeloid leukemia; MedPAC, Medicare Payment Advisory Commission; MS, multiple sclerosis; OOP, out-of-pocket; RA, rheumatoid arthritis.

[a]Analyses were based on 2012 data.

[b]The corresponding $4700 OOP threshold that triggered catastrophic coverage for that year was used as the annual OOP maximum for estimating the impact of the proposed MedPAC changes and our proposed strategies.

[c]Our proposed strategy counted both beneficiary OOP spending and the 50% manufacturer discounts on brand name drugs in the coverage gap toward this $4700 limit, whereas MedPAC changes only account for beneficiary OOP spending. Hence, patients' OOP payments may be less than $392 during the month(s) spent in the coverage gap.

DISCUSSION

Our analyses demonstrate that Medicare beneficiaries using high-cost specialty drugs face variable and high OOP cost obligations under the existing Part D cost-sharing structure, with a majority of these expenditures concentrated at the beginning of the calendar year. In 2 of our 3 disease samples (MS and CML), the average OOP cost of the first disease-specific specialty drug fill for the calendar year nearly equaled or exceeded the average monthly Social Security benefit.[19] This benefit provides a substantial portion of income for many Medicare beneficiaries.[20] In all 3 disease areas we examined—RA, MS, and CML—the required 5% coinsurance payments during the catastrophic coverage phase also resulted in considerable cumulative OOP spending during the remainder of the year, consistent with findings reported elsewhere.[3] Our simulation found that changes proposed by MedPAC, which effectively introduce an annual OOP spending maximum via elimination of cost sharing during the catastrophic coverage phase, would provide some relief later in the year for patients facing the highest specialty drug costs. Yet, the changes would actually exacerbate the problem of front-loaded costs at the beginning of the coverage year and fewer beneficiaries would likely benefit from the annual OOP spending limit, as many patients would remain in the coverage gap longer under the proposal to exclude manufacturer discounts for brand name drugs from TrOOP spending. This would exacerbate their total OOP costs and the timing of these costs. Excluding the discounts would also effectively double OOP costs paid by these beneficiaries in the coverage gap by widening the gap; this under-

mines the goal of better managing the timing and magnitude of OOP costs and ensuring appropriate access to care.

Such high and variable spending requirements are disruptive to monthly budgets, and our data highlight the fact that evaluation of the financial burden related to OOP spending should pay attention to both the magnitude and the timing of OOP expenditures. Our proposed strategies would institute both an annual and a monthly OOP maximum spending limit, which would spread OOP costs more evenly across the year. This would have resulted in OOP costs closer to $400 per month in our 2012 sample (inclusive of manufacturer discounts in the coverage gap); although the amount would increase slightly in 2017 due to an increase in the TrOOP spending limit, it would remain more manageable than existing OOP obligations. This would most likely improve patients' ability to meet their OOP cost-sharing obligations, especially early in the year. In addition, maintaining the current policy to count manufacturer discounts toward TrOOP would effectively lower overall OOP spending below the $4700 limit for beneficiaries requiring brand name medications. The proposed OOP spending limit would also increase the predictability of monthly OOP obligations, much like how payment options provided by energy companies enable more consistent budgeting despite seasonal variability in consumption. In light of a growing body of evidence that links high cost sharing among Medicare Part D beneficiaries with delayed initiation of treatment, increased gaps in treatment, and reduced adherence (compared with beneficiaries who receive LIS and face more stable, low cost sharing), reducing the OOP burden associated with specialty drug use would likely improve access to and optimal use of these treatments.[5,10]

It should be noted that our analyses provide a snapshot of the impact of both existing and proposed policies utilizing a sample year of prescription fill data from 2012. This is in line with MedPAC's own analysis of their proposed changes, which also used a single year of data (from 2013). However, the Part D benefit is dynamic; each year, there are changes to the designated spending limits that trigger entry into each benefit phase, and additional changes related to provisions of the Affordable Care Act (ACA) are scheduled to be implemented over the next 5 years, further impacting OOP costs. Most importantly, the catastrophic coverage threshold is scheduled to increase significantly by 2020, and 2 main factors will lead to additional widening of the coverage gap phase, making it harder for beneficiaries to reach the OOP threshold for catastrophic coverage (and thus, the proposed annual OOP spending maximum).

First, Part D plans will offer more generous plan coverage, which will displace previous beneficiary OOP spending during the coverage gap with payments that will not count toward patients' TrOOP—thereby indirectly widening the gap. Second, the growth rate of the TrOOP threshold that triggers catastrophic coverage was slowed from 2014 through 2019 under the ACA. As the coverage gap closes, however, the TrOOP threshold for 2020 will be set as if growth had not been artificially slowed.[21] This will lead to a $1200 increase in the TrOOP threshold from 2019 to 2020, a phenomenon known as the "OOP cliff."[22] Consequently, the beneficiary OOP burden documented in our analyses will intensify over time. Furthermore, a larger number of beneficiaries are likely to be affected over time. Ongoing developments in pharmaceutical treatments are likely to increase the number of non-LIS beneficiaries who are prescribed medications associated with the highest levels of OOP spending; for example, the past few years have seen a dramatic increase in the use of new treatments for hepatitis C, a trend that began after our 2012 data. This underscores the urgent need for strategies to alleviate OOP costs and burden.

Limitations

Our analysis had several limitations. First, as with all administrative databases, Medicare claims may be subject to errors or omissions. Second, we examined 2012 data and applied policy changes that took effect under the ACA in that year. As noted above, if the ACA remains in effect, the coverage gap will be phased out by 2020 and the catastrophic coverage limit will be higher; thus, the catastrophic coverage limit (and our proposed annual OOP spending maximum) will increase and the figures presented here will represent an underestimate of patient OOP spending. Our analysis is not able to account for future changes to the ACA that may impact Medicare policy. Third, given the availability of claims data, we limited our sample to FFS Medicare Part D beneficiaries; to illustrate the real-world OOP cost burden in patients prescribed continual treatment throughout the year, we further limited our sample to full-year users of specialty drugs. However, our proposed strategies are recommended for, and our incremental cost and financing calculations apply to, all Medicare Part D beneficiaries (FFS and Medicare Advantage) regardless of whether they were full- or part-year users of specialty drugs. Our calculations do not account for any increases in specialty drug utilization and spending that would occur among part-year users in response to lower and more stable monthly cost sharing under our proposed strategies. Similarly, as the number of beneficiaries eligible for and requiring specialty drug treatments increases over the years, the incremental cost of our proposed strategies would further increase. It is notable that our estimated costs begin at a relatively modest amount (less than $2 per month per beneficiary), however.

As with most aspects of healthcare, the fine-grained logistical details of implementing our proposed strategies will be straightforward in some cases and more complex in others. Redistribution of annual OOP costs in the form of a stable monthly payment is least complicated for individuals who are prescribed medications for continuous use throughout the coverage year (as in our sample), whereas protocols would have to be developed for those who initiate treatment later in the year. For example, if a patient fills a prescription in September that would have carried a $1500 coinsurance payment, he or she may need to continue to pay the remaining

balance on that prescription into the following year. Although this does increase the complexity somewhat, much of the rest of the healthcare system bills patients for remaining OOP costs after a service is rendered (eg, imaging tests, surgeries, hospitalizations). Developing adjustments in pharmacy and insurance procedures that are more in step with the advances in pharmaceutical treatments is a worthwhile goal.

Indeed, the expanding role of self-administered pharmaceutical treatments in the management of serious life-threatening, chronic, and/or rare diseases also argues for a less siloed approach and greater attention to overall OOP costs for patients. Our analysis addresses prescription drug OOP costs only, yet patients are also responsible for OOP costs related to premiums, medical deductibles, and medical co-pays and coinsurance. Unlike most employer and health insurance exchange plans, which integrate medical and prescription drug expenses into a combined annual OOP maximum spending limit,[23,24] all Medicare beneficiaries currently lack an annual OOP maximum limit for their Part D prescription drug spending and the majority have no annual maximum for other OOP medical spending. Our proposal represents an important first step toward addressing these issues.

CONCLUSIONS

Specialty drugs represent vital treatments for patients who often have few or no effective alternatives available, and consistent use can often help to prevent disease progression and other costly complications. Yet, these treatments can only be effective if patients can afford to utilize them. Thus, Medicare Part D policies that support access and adherence are critically important. Our analyses indicate that efforts to alleviate financial barriers to specialty drug adherence should include attention to both the amount and timing of OOP costs. ■

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Authorship Information: Concept and design (JAD, PL, ARP, JSD, AF); acquisition of data (JAD, PL, VPL); analysis and interpretation of data (JAD, PL, ARP, VPL); drafting of the manuscript (JAD, PL, ARP, JSD, AF); critical revision of the manuscript for important intellectual content (JAD, PL, ARP, JSD, AF, VPL); statistical analysis (PL); obtaining funding (JAD); administrative, technical, or logistic support (VPL); and supervision (JAD, PL).

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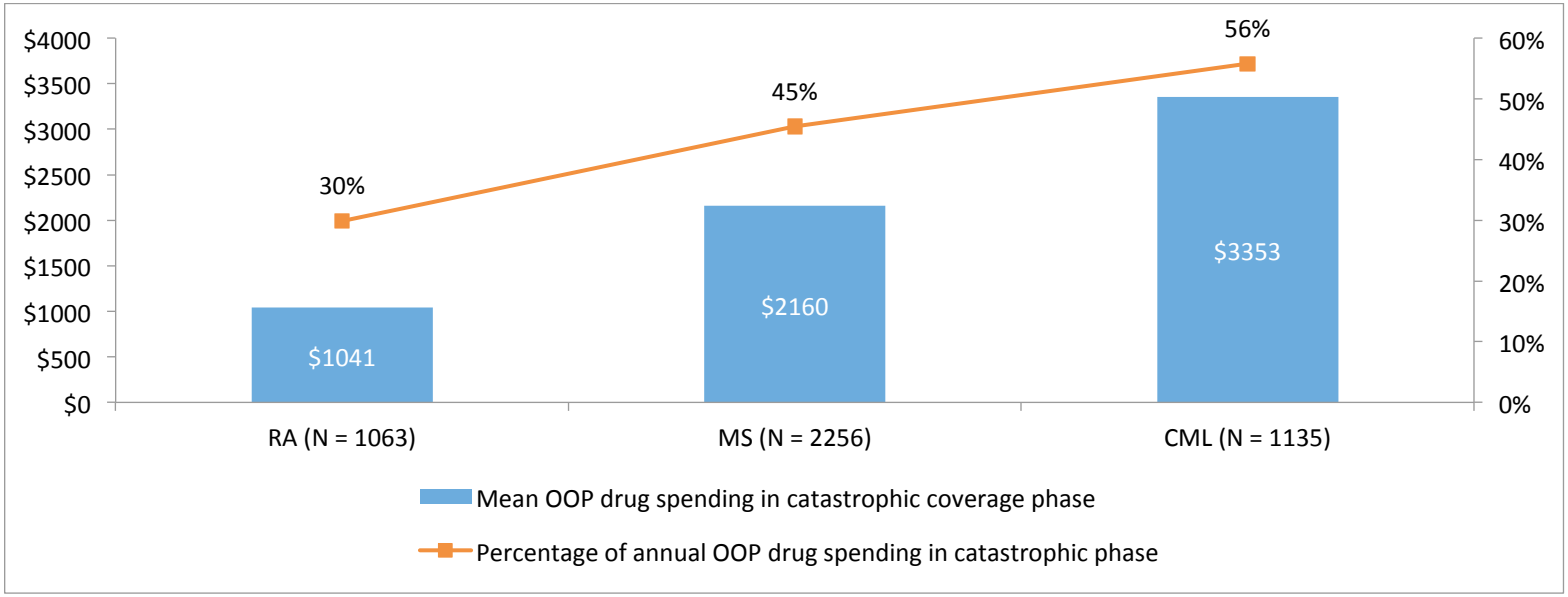
eAppendix

eAppendix Table. Part D Specialty Drugs for Rheumatoid Arthritis, Multiple Sclerosis, and Chronic Myeloid Leukemia

Condition	Generic Name
RA	
	adalimumab
	anakinra
	certolizumab pegol
	etanercept
	golimumab
	tocilizumab
	tofacitinib citrate
MS	
	dimethyl fumarate
	fingolimod
	glatiramer
	interferon beta-1a
	interferon beta-1b
	teriflunomide
CML	
	bosutinib
	dasatinib
	imatinib
	nilotinib
	ponatinib

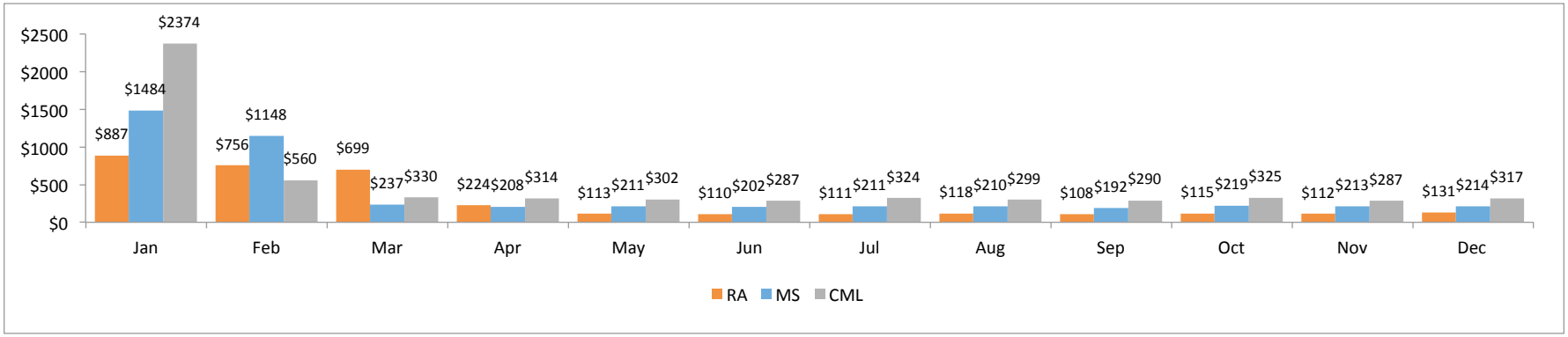
CML indicates chronic myeloid leukemia; MS, multiple sclerosis; RA, rheumatoid arthritis.

eAppendix Figure A. Out-of-Pocket Disease-Specific Specialty Drug Spending During the Part D Catastrophic Coverage Phase, 2012



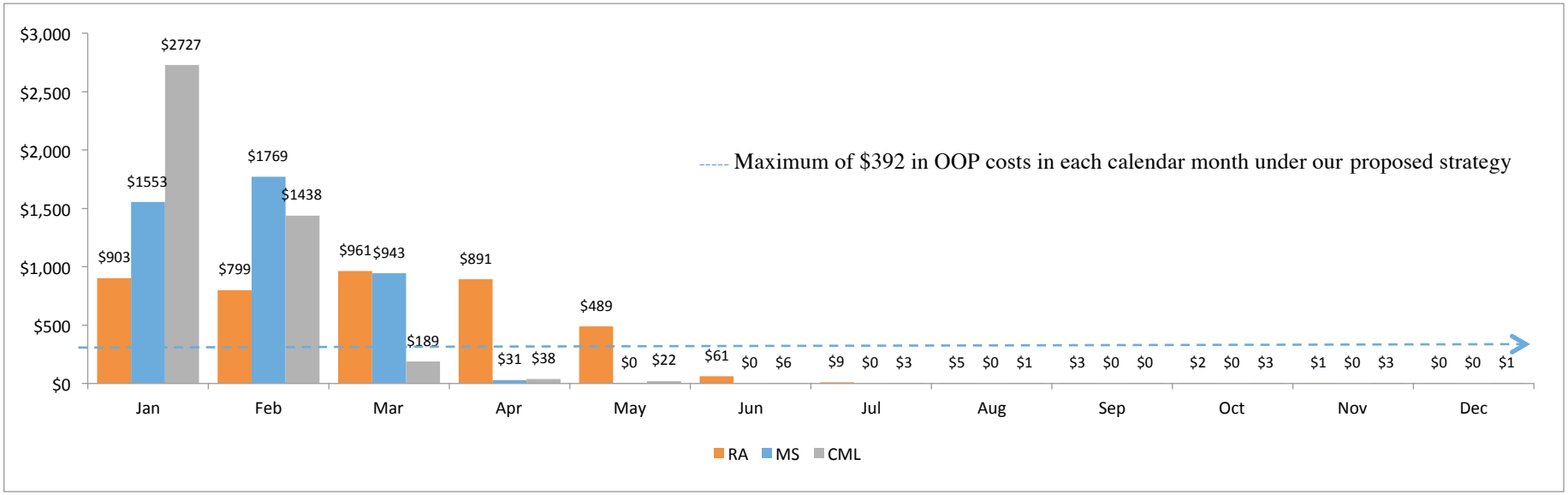
CML indicates chronic myeloid leukemia; MS, multiple sclerosis; OOP, out-of-pocket; RA, rheumatoid arthritis.

eAppendix Figure B. Mean Monthly Out-of-Pocket Disease-Specific Specialty Drug Spending for Patients With Rheumatoid Arthritis, Multiple Sclerosis, or Chronic Myeloid Leukemia, 2012



CML indicates chronic myeloid leukemia; MS, multiple sclerosis; RA, rheumatoid arthritis.

eAppendix Figure C. Simulated Mean Monthly Out-of-Pocket Disease-Specific Specialty Drug Spending Under the Proposed MedPAC Changes to Part D Cost Sharing and Under Our Proposed Strategies[a]



CML indicates chronic myeloid leukemia; MS, multiple sclerosis; OOP, out-of-pocket; RA, rheumatoid arthritis.

[a]Analyses were based on 2012 data. The corresponding $4700 OOP threshold that triggered catastrophic coverage for that year was used as the annual OOP maximum for estimating the impact of the proposed MedPAC changes and our proposed strategies. Our proposed strategy counted both beneficiary OOP spending and the 50% manufacturer discounts on brand name drugs in the coverage gap towards this $4700 limit, whereas MedPAC changes only account for beneficiary OOP spending. Hence, patients' OOP payments may be less than $392 during the month(s) spent in the coverage gap. Estimates of mean monthly OOP specialty drug spending for specialty drug users who were not receiving low-income subsidies reflect disease-specific specialty drug use only. Individuals using additional drugs would move through coverage phases more quickly.