Proposed Policies to Modify Medicare Part D Cost-Sharing Requirements: Potential Impact on Out-of-Pocket Costs and Access to Specialty Drugs

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BACKGROUND

- Medicare beneficiaries who do not qualify for low-income subsidies (non-LIS) face an enormous **out-of-pocket (OOP)** cost burden, especially early in the year, for specialty drugs under Part D. Prior research has shown that high costs are associated with treatment abandonment and interruptions in treatment.
- Recent Congressional bills have proposed solutions primarily via (1) An annual Part D OOP cap, with maximum OOP costs varying between $2,000 (H.R.3) and $3,100 (H.R.19);
  (2) Smoothing or spreading out of cost sharing, but only under certain circumstances (e.g., OOP exceeds a designated threshold) and in periodic installments over the remainder of the plan year.
- We have previously proposed that smoothing of annual OOP cost caps uniformly across the calendar year (i.e., monthly OOP cost caps) is a more effective solution (Doshi et al., *AJMC*, 2017).

OBJECTIVE

- To estimate OOP costs for specialty drugs required by non-LIS Part D beneficiaries under alternative policy scenarios (Table 1)
- To estimate specialty drug prescription abandonment rates and affordability associated with required OOP costs at the beginning of the year (i.e., in January) under alternative policy scenarios

METHODS

Data Source: Data were extracted from multiple sources including government websites for Part D parameters and proposed policies in Congressional bills, SSR Health database for drug list prices, Medicare Current Beneficiary Survey for estimating median monthly incomes for non-LIS, and published literature to estimate speciality drug abandonment rates (Doshi et al., 2017; Starner et al., 2014).

Study Population: Non-LIS Part D patients using the top 3 specialty drug classes, with findings illustrated with examples of one specialty drug for each class (Sprycel® for cancer [i.e., chronic myeloid leukemia], Aubagio® for multiple sclerosis, and Humira® for autoimmune conditions). These represent a range of list prices. OOP costs would be similar for other similarly priced specialty drugs.

Study Design and Analysis: We conducted three main analyses:

- Estimation of annual and monthly OOP costs for selected specialty drugs under 6 policy scenarios in 2020.
- Assessment of affordability of various policy scenarios, presenting OOP costs for the first prescription fill of the specialty drug in January as a percentage of the median monthly income, based on several income groups.
- Modeling of specialty drug prescription abandonment rates (% who abandon fill) associated with OOP costs in January under each policy scenario, based on estimates from the literature (doi: 10.1200/JCO.2017.74,5091; 10.1377/hlthaff.2014.0497).

RESULTS

Table 1. Alternative Part D cost-sharing policy scenarios evaluated in this study

Policy Scenario	Annual Part D OOP Cost Cap	OOP Cost Smoothing	Status
Scenario 1: Current Medicare Part D standard benefit	None	None	Status quo
Scenario 2: $3,100 Annual OOP Cap, without smoothing	$3,100	None	$3,100 cap proposed in H.R.19 (reintroduced 04/21)
Scenario 3: $2,000 Annual OOP Cap, without smoothing	$2,000	None	$2,000 cap proposed in H.R.3 (reintroduced 04/21)
Scenario 4: $3,100 Annual OOP Cap, with smoothing	$3,100	Spread out over 12 months	Smoothing concept introduced but inadequately addressed in proposed bills
Scenario 5: $2,000 Annual OOP Cap, with smoothing	$2,000	Spread out over 12 months	
Scenario 6: Income-Based Annual OOP Cap, with smoothing			Not introduced in any bill; proposed $500 level results in OOP costs <5% of relevant median income
(i) $500 (≤200% FPL)	$500	Spread out over 12 months	
(ii) $3,100 (>200% FPL)	$3,100		

Figure 1. Percentage of beneficiaries estimated to abandon filling their specialty drug prescription in January under alternative policy scenarios

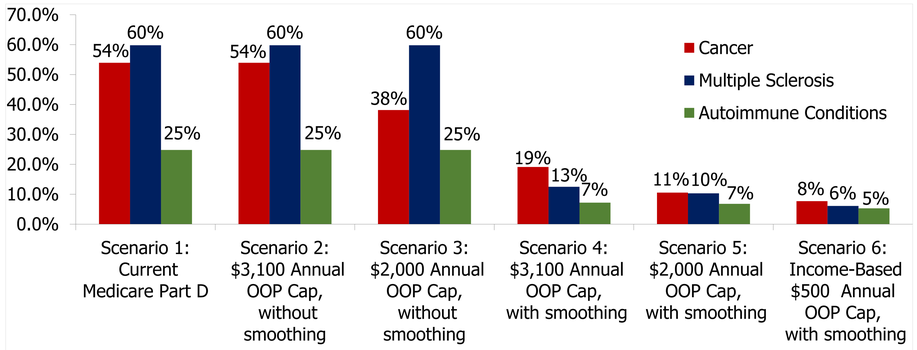

Table 2. Monthly out-of-pocket (OOP) costs and annual OOP costs for selected specialty drugs under alternative policy scenarios

Policy Scenario	Monthly Out-of-Pocket Cost for Specialty Drug													
	Cancer				Multiple Sclerosis (MS)					Autoimmune Conditions				
	Jan	Feb	Mar-Dec	Annual Total	Jan	Feb	Mar	Apr-Dec	Annual Total	Jan	Feb	Mar	Apr-Dec	Annual Total
Scenario 1: Current Medicare Part D standard benefit	$2,964	$694	$694	$10,602	$2,174	$835	$370	$370	$6,706	$1,727	$1,103	$280	$280	$5,632
Scenario 2: $3,100 Annual OOP Cap, without smoothing	$2,964	$136	$0	$3,100	$2,174	$835	$91	$0	$3,100	$1,727	$1,103	$270	$0	$3,100
Scenario 3: $2,000 Annual OOP Cap, without smoothing	$2,000	$0	$0	$2,000	$2,000	$0	$0	$0	$2,000	$1,727	$273	$0	$0	$2,000
Scenario 4: $3,100 Annual OOP Cap, with smoothing	$258	$258	$258	$3,100	$258	$258	$258	$258	$3,100	$258	$258	$258	$258	$3,100
Scenario 5: $2,000 Annual OOP Cap, with smoothing	$167	$167	$167	$2,000	$167	$167	$167	$167	$2,000	$167	$167	$167	$167	$2,000
Scenario 6: Income-Based Annual OOP Cap, with smoothing														
(i) $500 (≤200% FPL)	$42	$42	$42	$500	$42	$42	$42	$42	$500	$42	$42	$42	$42	$500
(ii) $3,100 (>200% FPL)	$258	$258	$258	$3,100	$258	$258	$258	$258	$3,100	$258	$258	$258	$258	$3,100

Note: Sum of monthly OOP costs may not match total annual OOP costs due to rounding.

Table 3. Monthly OOP costs for the first prescription fill of the specialty drug in January as a percentage of median monthly income under alternative policy scenarios

Policy Scenario	Monthly Out-of-Pocket Cost for Specialty Drug											
	Cancer				Multiple Sclerosis (MS)				Autoimmune Conditions			
		Percent of median monthly income				Percent of median monthly income				Percent of median monthly income		
	OOP cost in January	Non-LIS ≤ 200% FPL	Non-LIS 200%-400% FPL	Non-LIS >400% FPL	OOP cost in January	Non-LIS ≤ 200% FPL	Non-LIS 200%-400% FPL	Non-LIS >400% FPL	OOP cost in January	Non-LIS ≤200% FPL	Non-LIS 200%-400% FPL	Non-LIS >400% FPL
Scenario 1: Current Medicare Part D standard benefit	$2,964	166%	79%	35%	$2,174	121%	58%	26%	$1,727	96%	46%	20%
Scenario 2: $3,100 Annual OOP Cap, without smoothing	$2,964	166%	79%	35%	$2,174	121%	58%	26%	$1,727	96%	46%	20%
Scenario 3: $2,000 Annual OOP Cap, without smoothing	$2,000	112%	53%	24%	$2,000	112%	53%	24%	$1,727	96%	46%	20%
Scenario 4: $3,100 Annual OOP Cap, with smoothing	$258	14%	7%	3%	$258	14%	7%	3%	$258	14%	7%	3%
Scenario 5: $2,000 Annual OOP Cap, with smoothing	$167	9%	4%	2%	$167	9%	4%	2%	$167	9%	4%	2%
Scenario 6: Income-Based Annual OOP Cap, with smoothing												
(i) $500 (≤200% FPL)	$42	2%	na	na	$42	2%	na	na	$42	2%	na	na
(ii) $3,100 (>200% FPL)	$258	na	7%	3%	$258	na	7%	3%	$258	na	7%	3%

RESULTS

Scenario 1: The current Part D benefit results in substantial annual OOP cost burden especially earlier in the year (Table 2). Patients face specialty drug OOP costs of $2,964 for cancer, $2,174 for MS, and $1,727 for AI conditions in January alone, with associated abandonment rates of 54%, 60%, and 25%, respectively (Figure 1).

Scenarios 2 & 3: Applying annual OOP cost caps alone ($3,100 or $2,000) results in similarly high OOP costs and abandonment rates in January. For example, while the annual total OOP costs drop from $10,602 to $3,100 for cancer under Scenario 2, a patient would still face the same monthly specialty drug OOP cost of $2,964 in January. Similarly, January OOP costs for the specialty drug for autoimmune conditions stay the same at $1,727, even though annual total OOP costs drop from $5,632 in Scenario 1 to $3,100 under Scenario 2 and $2,000 under Scenario 3.

RESULTS (continued)

Scenarios 4 & 5: Smoothing of the annual OOP caps of $3,100 and $2,000 over 12 months resulted in consistent monthly OOP costs of $258 or $167, respectively, for all 3 drugs and was associated with lower abandonment rates (19% and 11% for cancer, 13% and 10% for MS, and 7% and 7% for autoimmune conditions).

Scenario 6: An income-based annual OOP cost cap of $500 with smoothing further lowered monthly OOP costs to $42 for the approximately 30% of non-LIS patients who have incomes ≤ 200% FPL and was associated with the lowest abandonment rates.

Affordability measures: As seen in Table 3, only policy scenarios with smoothing result in OOP costs in January that are affordable for non-LIS patients with incomes ≤ 200% FPL (Scenario 6) and non-LIS patients with incomes > 200% FPL (Scenarios 4, 5, and 6).

CONCLUSION

- The existing Part D benefit results in high OOP costs for specialty drugs, especially early in the year, that exceed median monthly income for some income groups and can lead to high rates of abandonment.
- An annual OOP cost cap alone fails to address the disproportionate distribution of the financial burden, with OOP costs still being heavily concentrated at the beginning of each year. Thus, it does not sufficiently alleviate OOP access barriers to prescribed drugs.
- Only conversion of the annual OOP caps into monthly caps via smoothing over 12 months alleviates affordability and access issues.

IMPLICATIONS FOR POLICY AND PRACTICE

- Our findings suggest that without monthly OOP cost caps, introduction of an annual OOP cap will not solve current affordability and access issues for all specialty drug users under Medicare Part D.
- Clauses permitting smoothing of cost sharing in recent Congressional bills are inadequate and apply only to certain enrollees and under certain circumstances. They do not translate into monthly OOP caps and only spread out costs for the remaining plan year (e.g., if high-cost first drug fill is in October, this OOP cost is spread over only 3 months).
- The most effective and equitable option would apply different annual cost caps based on income and smooth these costs over 12 months.

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