FIXING MEDICARE PART D:

How a Patient-First Approach to Out-of-Pocket Costs Will Bring Treatments Within Reach

LEUKEMIA & LYMPHOMA SOCIETY®

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About The Leukemia & Lymphoma Society

The Leukemia & Lymphoma Society® (LLS) is a global leader in the fight against cancer. The LLS mission: cure leukemia, lymphoma, multiple myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world, provides free information and support services, and is the voice for all blood cancer patients seeking access to quality, affordable, coordinated care.

Founded in 1949 and headquartered in Rye Brook, NY, LLS has regional offices throughout the United States and Canada. To learn more, visit www.LLS.org. Patients should contact the LLS Information Resource Center at (800) 955-4572, Monday through Friday, 9 a.m. to 9 p.m., ET.

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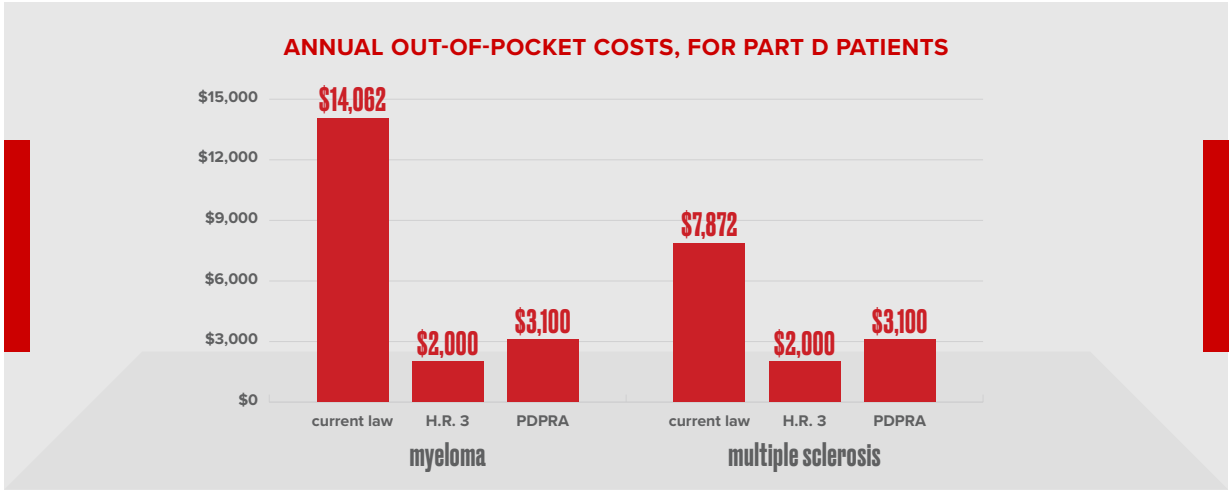
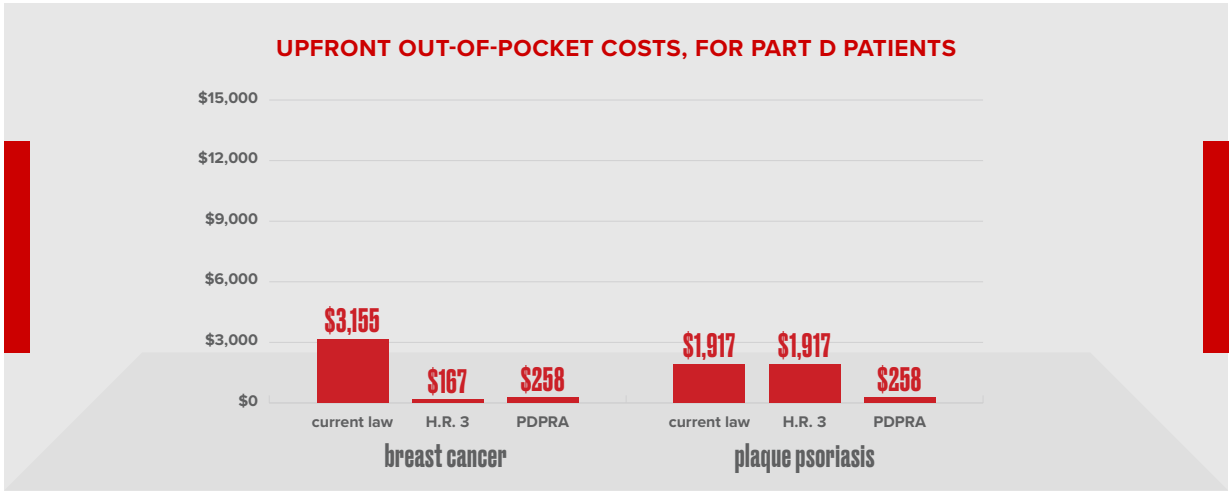
Summary

High upfront, out-of-pocket costs threaten Medicare enrollees who rely on specialty drugs to maintain their health and live productive lives. The 117th Congress has an opportunity to make a transformative change to protect Medicare Part D patients' from exorbitant out-of-pocket costs.

Part D enrollees often face extraordinary out-of-pocket costs when they seek to fill prescriptions for costly medications, such as those used to treat chronic and life-threatening conditions. Each year, more Medicare enrollees encounter these extreme costs. Congress has responded to this crisis with proposals that would redesign the Part D benefit, including the addition of new protections limiting out-of-pocket costs for enrollees.

In this study, The Leukemia & Lymphoma Society finds that an annual cap of patients' out-of-pocket costs, paired with an inclusive smoothing policy that spreads patients costs over the calendar year, would dramatically reduce out-of-pocket spending for Medicare patients with chronic conditions. By modeling out-of-pocket costs for patients with a variety of chronic conditions, we find that proposals considered in the previous 116th Congress could save many Medicare patients more than $10,000 per year and reduce some enrollees' upfront out-of-pocket costs from more than $4,000 to as little as $167.





Background

In recent years, high-cost, self-administered prescription drug therapies have become standard-of-care treatments for many chronic and life-threatening conditions, including cancer, multiple sclerosis, HIV, hepatitis C, and autoimmune diseases like arthritis. Patients with Medicare rely on their Medicare Part D prescription drug benefit to pay for these therapies. Part D enrollee cost sharing is calculated based on a complex benefit design with various coverage phases, typically incorporating the list price of the underlying drug.

Today, many serious, chronic conditions such as blood cancers can be managed if patients have access to oral medication they take daily, for years at a time. In many cases, these specialty drugs have high list prices. The increasing use of high-cost, self-administered prescription drugs in disease treatment—combined with the complex Part D benefit design—has led to a significant increase in Medicare enrollees who enter the highest level of Part D cost-sharing (known as the "catastrophic phase") without qualifying for low-income subsidy (LIS) program support.[1] In fact, in 2019, 1.5 million non-LIS enrollees reached the catastrophic phase. More than 480,000 of these enrollees reached the catastrophic phase due the out-of-pocket costs of a single prescription fill, up from 33,000 in 2010.[2]

The dramatic increase in patients facing $3,000 or more in out-of-pocket costs for a single prescription fill is incredibly concerning, considering research demonstrating that many Medicare patients facing high costs are forced to leave their prescription at the pharmacy counter. Forty-two percent of Medicare enrollees abandoned their cancer treatment when they're required to spend more than $2,000 out-of-pocket for a single prescription.[3] Given the vast number of patients who reach the catastrophic benefit, there are potentially hundreds of thousands of enrollees who are unable to afford catastrophic out-of-pocket costs and forced to abandon treatment altogether.

The growing number of enrollees entering the catastrophic phase, and the rising out-of-pocket costs facing by these enrollees, has prompted policymakers to consider solutions to improve the Part D benefit for patients. These solutions vary in scope but have uniformly included an annual limit on Part D enrollee out-of-pocket costs.[4]

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1 A minority of Part D enrollees—with incomes that qualify for the Low-Income Subsidy (LIS) Program—have an adjusted benefit design that dramatically lowers their out-of-pocket costs. Since these costs are low enough to not be prohibitive for most enrollees, this report focuses on costs encountered by enrollees who are not LIS-eligible.

2 MedPAC. (2021). Report to the Congress: Medicare Payment Policy, March 2021.

3 Doshi, J. et al. (2018). Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology 36, no. 5*.

4 An annual out-of-pocket cap was included as a core component of Medicare Part D redesign frameworks proposed by House Democrats (H.R. 3); the Senate Finance Committee then-Chair Chuck Grassley and then-Ranking Member Ron Wyden (the Prescription Drug Pricing Reduction and Health and Human Services Improvements Act, PDPRA); House Republicans (H.R. 19), the Trump Administration, and MedPAC, among others.

An annual out-of-pocket cap would protect enrollees from extraordinarily high costs during the plan year. Yet, an annual cap alone cannot solve a related problem: the extraordinary upfront cost-sharing enrollees face during a single month. Thus, policymakers in the 116th Congress incorporated a new reform in their Part D reform proposals: an out-of-pocket "smoothing" policy that would operate in tandem with an annual cap to help reduce the upfront costs an enrollee would need to pay at one time with the first prescription fill of their plan year. The proposed smoothing policy would effectively spread out-of-pocket costs across a longer period to ease the upfront cost burden to enrollees.

Given increases in drug list prices and cost-sharing for those in Part D, these reforms appear to have the potential to greatly benefit enrollees who are currently unable to afford lifesaving or life-sustaining medications. Given policymakers' Part D cap and smoothing policies differed in important ways, the effect of each of these policy options on patients' out-of-pocket costs requires analysis. This report clarifies the impact of those reform proposals on patients with chronic and life-threatening conditions.

Methodology

Part D reform proposals during the 116th Congress sought to change Part D elements, including adjustments to the coverage gap and catastrophic liabilities, adding an out-of-pocket cap, and smoothing high, upfront out-of-pocket costs. To determine how non-LIS enrollees taking drugs in a variety of therapeutic areas would be affected by various Part D redesign proposals, annual out-of-pocket costs were calculated for 10 hypothetical patients with various clinical conditions (Appendix A) on a month-by-month basis across three potential Part D policies (Appendix B).[5] This analysis assumes all legislation goes into effect in plan year 2022. We modeled only the out-of-pocket impact of the proposed Part D redesigns and smoothing policies and did not model any other policies included in the proposed legislation. Additionally, the model assumed standard benefit design, 2020 negotiated prices, prescription drug initiation in January, and 12 months of therapy over the course of the year (unless clinical guidelines recommended treatment for less than 12 months).

5 This analysis modeled beneficiaries annual and monthly OOP costs for potential policies, assuming that the beneficiaries in each profile presented with no significant comorbidities, tolerated the medication regimen with no toxicity, saw no progression in disease, and had no adjuvant therapies. The analysis randomly assigned each enrollee profile to one of the top 2020 plans by enrollment. Prescription drug data was gathered from Medicare Plan Finder using zip code 21215. The profiles reflect dosing recommendations in Micromedex.

Results and Discussion

The analysis of enrollee out-of-pocket costs from Part D policy reforms shows that Medicare beneficiaries relying on costly prescription therapies would benefit significantly from an out-of-pocket cap paired with a smoothing policy with inclusive eligibility criteria. The financial impacts of various approaches to the 10 patients modeled in this study indicate that Congress can maximize the financial benefit to enrollees of a Part D redesign framework with three key policies working in tandem:

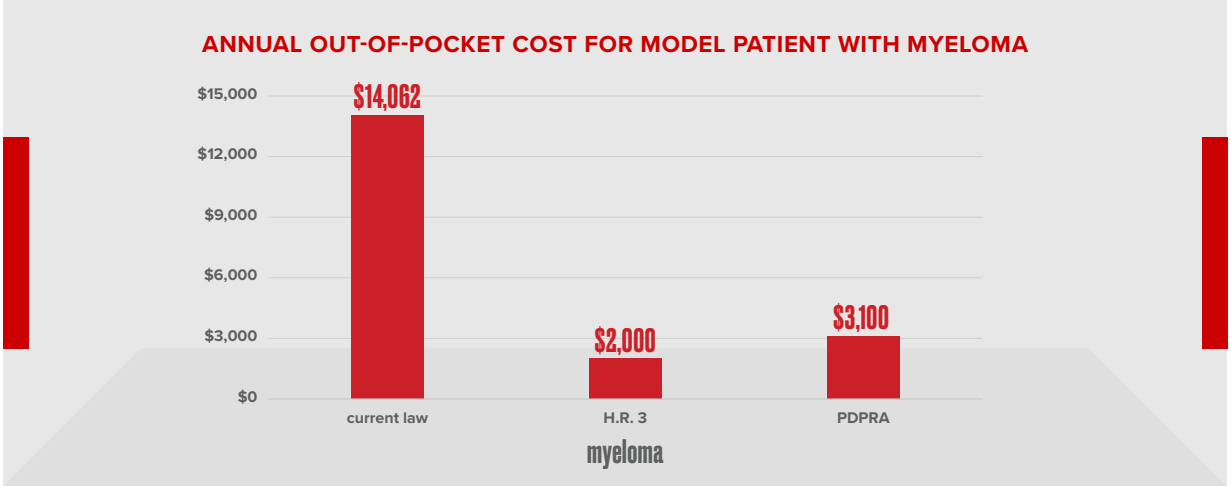
(1) a low annual out-of-pocket cap,

(2) a smoothing policy to prevent high upfront costs, and

(3) an inclusive eligibility trigger for smoothing protection.

An annual out-of-pocket cap

An annual out-of-pocket cap would improve drug affordability for patients by decreasing the total annual out-of-pocket costs paid by beneficiaries taking high-cost drugs. Although monthly out-of-pocket costs for beneficiaries with different conditions vary widely, the out-of-pocket cap provisions advanced in the 116th Congress[6] would provide a critical financial protection for all enrollees—significantly reducing the total amount beneficiaries would spend during the coverage year compared to current law. Such savings can reach $10,000 annually, depending on drug costs and the specific Part D reform policy, with the most significant savings associated with the lowest out-of-pocket cap thresholds. For example, a hypothetical enrollee with the blood cancer multiple myeloma modeled in this analysis would save $12,062 annually under the cap included in H.R. 3 compared to current law.



6 H.R.3 included an annual out-of-pocket cap set at $2,000 for Plan Year 2022, while H.R.19 and PDPRA included a $3,100 cap.

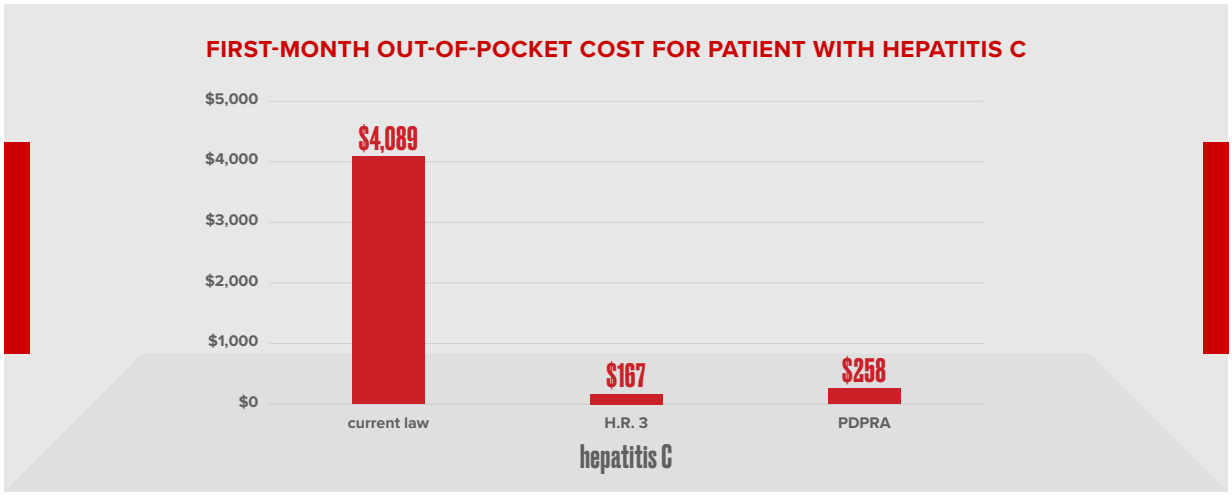
A smoothing policy

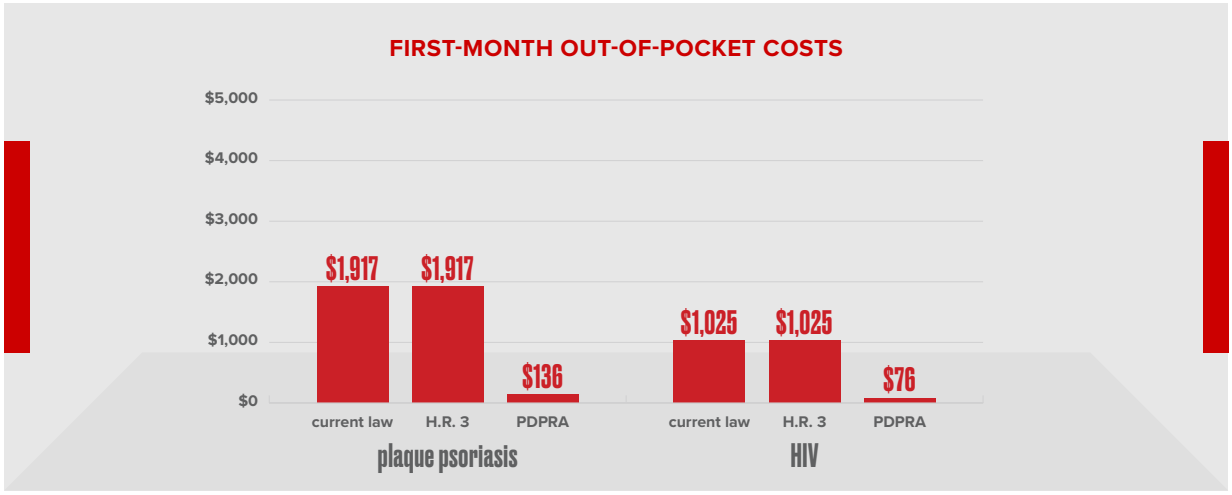
Given that most enrollees considered in this analysis hit the modeled out-of-pocket limits within the first few months of coverage, a smoothing policy is also an important mechanism to ensure *monthly* drug costs are affordable for patients with chronic or life-threatening conditions. Smoothing out-of-pocket costs throughout the coverage year would also prevent the up-front financial shock beneficiaries may experience when taking high-cost drugs. For example, under the policy included in the DPRA, the hypothetical enrollee with hepatitis C would have the same full-year financial liability, but the financial responsibility in January would be reduced from $4,089 in out-of-pocket costs to only $258. Though the smoothing policy would not change the enrollee's total annual out-of-pocket costs, these results demonstrate the extent to which such a policy would redistribute the up-front, high out-of-pocket burden over a longer period of time, such as the remainder of the coverage year.

An inclusive eligibility trigger for smoothing

The number of patients who could benefit from a smoothing policy depends on the threshold that triggers smoothing. While H.R. 3 would have required an enrollee to encounter the amount of the entire annual cap ($2,000) in upfront cost-sharing to be eligible for smoothing, the PDPRA would have made eligible any enrollee encountering costs of more than 1/12th the annual cap ($258) in a single month.

Under proposals like H.R. 3 with restrictive smoothing eligibility criteria, patients who face extraordinary upfront out-of-pocket costs under current law would continue to face those upfront costs. For example, modeled patients with plaque psoriasis or HIV would face $1,917 and $1,025 in upfront out-of-pocket costs, respectively, under H.R. 3—unchanged from the upfront costs they face under current law. Meanwhile, under the more inclusive eligibility trigger in the PDPRA, the same patients would have their upfront costs reduced to $136, for plaque psoriasis, and $76, for HIV.





Conclusion

Based on the results seen from this analysis (Appendix C), future Part D redesign policies should include *both* an out-of-pocket cap and a smoothing policy with an eligibility trigger low enough to prevent enrollees from encountering prohibitive upfront out-of-pocket costs. These policies, when implemented together, would significantly improve drug affordability and access by limiting total annual out-of-pocket costs while removing significant financial burdens many beneficiaries face in the beginning of the year. The combination of these policies would establish a transformative patient protection for Medicare enrollees and break down barriers that, today, too often stand between patients and the care they need. LLS calls on Congress to enact these critical policies as soon as possible.

> “Part D redesign policies should include *both* an out-of-pocket cap and a smoothing policy with an eligibility trigger low enough to prevent enrollees from encountering prohibitive upfront out-of-pocket costs.”

Appendix A. Clinical profiles of hypothetical patients

Utilization Schedule			
Patient	**Drug**	**Per Unit Cost**	**Dosing**
Patient 1: Chronic Myelogenous Leukemia (CML)	Sprycel 100 mg tablet	$499.48	100 mg once daily x 12 months
Patient 2: Chronic Lymphoid Leukemia (CLL)	Venclexta 100 mg tablet	$110.72	400 mg once daily x 12 months
Patient 3: Multiple Myeloma (MM)	Revlimid 25 mg capsule & dexamethasone 40 mg tablet	$801.66/$6.50	25 mg once daily x 21 days, then no doses x 7 days (total of 28 days) x 13 cycles over 12 months (dexamethasone 4x per cycle)
Patient 4: Chronic Lymphoid Leukemia (CLL)	Imbruvica 420 mg tablet	$496.95	420 mg once daily x 12 months
Patient 5: Multiple Sclerosis	Tecfidera 240 mg capsule	$148.72	240 mg twice daily x 12 months
Patient 6: Breast Cancer	Verzenio 200 mg tablet	$234.04	200 mg twice daily x 12 months
Patient 7: Non Small Cell Lung Cancer (NSCLC)	Mekinist 2 mg tablet & Tafinlar 75 mg capsule	$418.54/$96.76	2 mg once daily (with Tafinlar 150mg once daily) x 12 months
Patient 8: Plaque Psoriasis	Humira 40 mg (0.8 ml) Kit Box of 1 pen kit is sold in pack of 2	$5,735.19	40 mg subcutaneous injection every other week x 12 months (26 doses in total)
Patient 9: Human Immunodeficiency Virus (HIV)	Dovato 50 mg-300 mg tablet	$86.98	1 tablet (50/300) once daily x 12 months
Patient 10: Hepatitis C Virus (HCV)	Harvoni 90 mg–400 mg tablet & ribavirin 200mg capsules	$1172.34/$0.81	1 tablet (90/400) once daily (with ribavirin 200 mg 4x daily) x 12 weeks

Appendix B. Modeled policy scenarios

Part D Reform Policy	Liabilities in the Coverage Gap (for Branded Products)	OOP Cap	Smoothing Policy
Current Law as of 2022	• 5% plan • 70% manufacturer • 25% enrollee	• None	None
H.R. 3 (as passed by the House of Representatives)	• 65% plan • 10% manufacturer • 25% enrollee	• $2,000	Applies to drugs in which one fill produces out-of-pocket costs of $2,000 or more
PDPRA (as released in December 2019)	• 73% plan • 7% manufacturer • 20% enrollee	• $3,100	Applies to all incurred costs (no minimum amount) up to the out-of-pocket cap divided by the remaining months in the plan year

Appendix C. Monthly cost sharing for modeled patients under each policy scenario

1. Chronic Myelogenous Leukemia w/ Sprycel

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$3,203	$760	$760	$760	$760	$760	$760	$760	$760	$760	$760	$760	**$11,559**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**

2. Chronic Lymphoid Leukemia w/ Venclexta

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$3,117	$674	$674	$674	$674	$674	$674	$674	$674	$674	$674	$674	**$10,526**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$257	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**

3. Multiple Myeloma w/ Revlimid

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$3,412	$968	$968	$968	$968	$968	$968	$968	$968	$968	$968	$968	**$14,062**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**

4. Chronic Lymphoid Leukemia w/ Imbruvica

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$3,199	$756	$756	$756	$756	$756	$756	$756	$756	$756	$756	$756	**$11,513**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**

5. Multiple Sclerosis w/ Tecfidera

Patient OOP Spending

	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$2,626	$723	$452	$452	$452	$452	$452	$452	$452	$452	$452	$452	**$7,872**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$183	$265	$265	$265	$265	$265	$265	$265	$265	$265	$265	$265	**$3,100**

6. Breast Cancer w/ Verzenio

Patient OOP Spending

	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$3,155	$712	$712	$712	$712	$712	$712	$712	$712	$712	$712	$712	**$10,986**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**

7. Non Small Cell Lung Cancer w/ Meknist and Tafinlar

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$3,374	$931	$931	$931	$931	$931	$931	$931	$931	$931	$931	$931	**$13,614**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**

8. Plaque Psoriasis w/ Humira

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$1,917	$1,148	$311	$311	$311	$311	$311	$311	$311	$311	$311	$311	**$6,171**
Policy Scenario 2 H.R.3 (House-passed version)	$1,917	$83	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$136	$249	$272	$272	$272	$272	$272	$272	$272	$272	$272	$272	**$3,100**

9. HIV w/ Dovato

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$1,025	$661	$661	$625	$132	$132	$132	$132	$132	$132	$132	$132	**$4,031**
Policy Scenario 2 H.R.3 (House-passed version)	$1,025	$661	$313	$0	$0	$0	$0	$0	$0	$0	$0	$0	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$76	$125	$177	$236	$302	$312	$312	$312	$312	$312	$312	$312	**$3,100**

10. HCV w/ Harvoni

Patient OOP Spending	January	February	March	April	May	June	July	August	September	October	November	December	Totals
Policy Scenario 1 Current Law (2022)	$4,089	$1,646	$1,646	$0	$0	$0	$0	$0	$0	$0	$0	$0	**$7,381**
Policy Scenario 2 H.R.3 (House-passed version)	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	$167	**$2,000**
Policy Scenario 3 PDPRA (Dec 2019)	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	$258	**$3,100**