

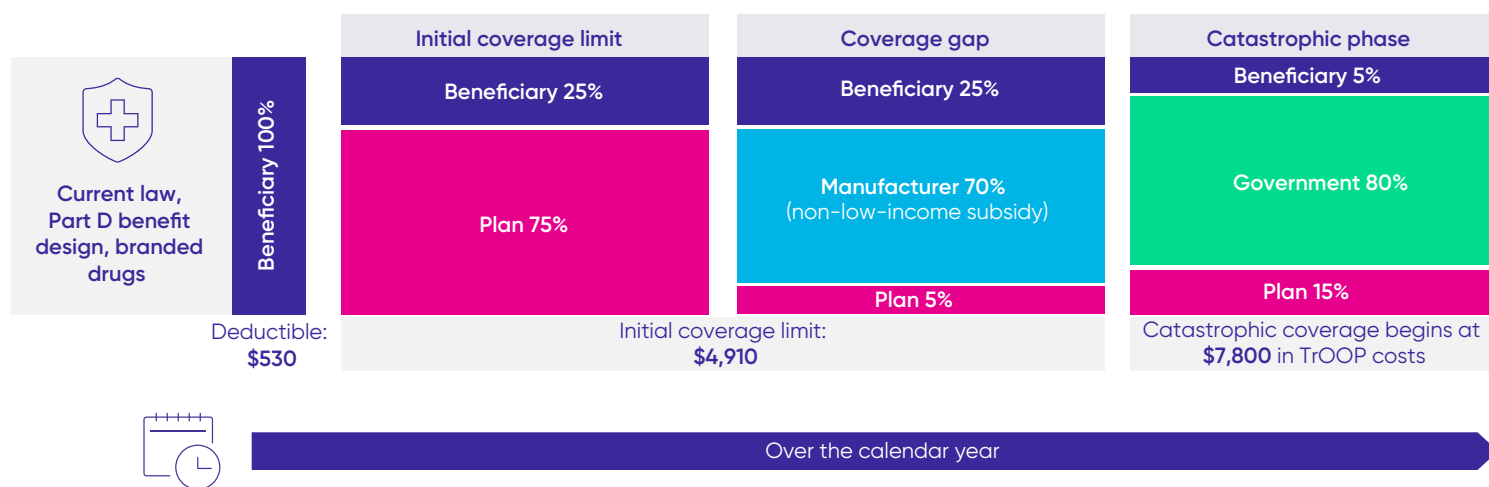
Ensuring the most vulnerable have access— Revisiting the Medicare Part D benefit

In many ways, the Medicare prescription drug benefit, Part D, is a successful demonstration of public-private partnership; however, beneficiaries are increasingly facing affordability challenges at the pharmacy because of the structure of the Part D benefit. Due to the way that Part D was set up, payers are prohibited from offering a plan design with an out-of-pocket (OOP) cap, a feature that exists in most Medicare Part B plans and nearly all commercial plans.

It is no surprise that higher OOP costs are associated with markedly higher rates of patients not initiating therapy, not adhering to a treatment regimen, or abandoning prescriptions at the pharmacy. For example, one study indicated that nearly half of patients with OOP costs above \$2,000 abandoned their oral anticancer prescription at the pharmacy. Higher OOP costs were also associated with increased rates of delayed initiation.¹

As seen in **Figure 1**, it is estimated that by 2024, beneficiaries would need to pay over \$3,000 in costs before they enter catastrophic coverage. Manufacturers would contribute over \$4,000 towards the true out-of-pocket (TrOOP) costs. Even after reaching the catastrophic phase, beneficiaries would still face a 5% coinsurance, which could be hundreds, if not thousands, of dollars a month for the rest of the year.²

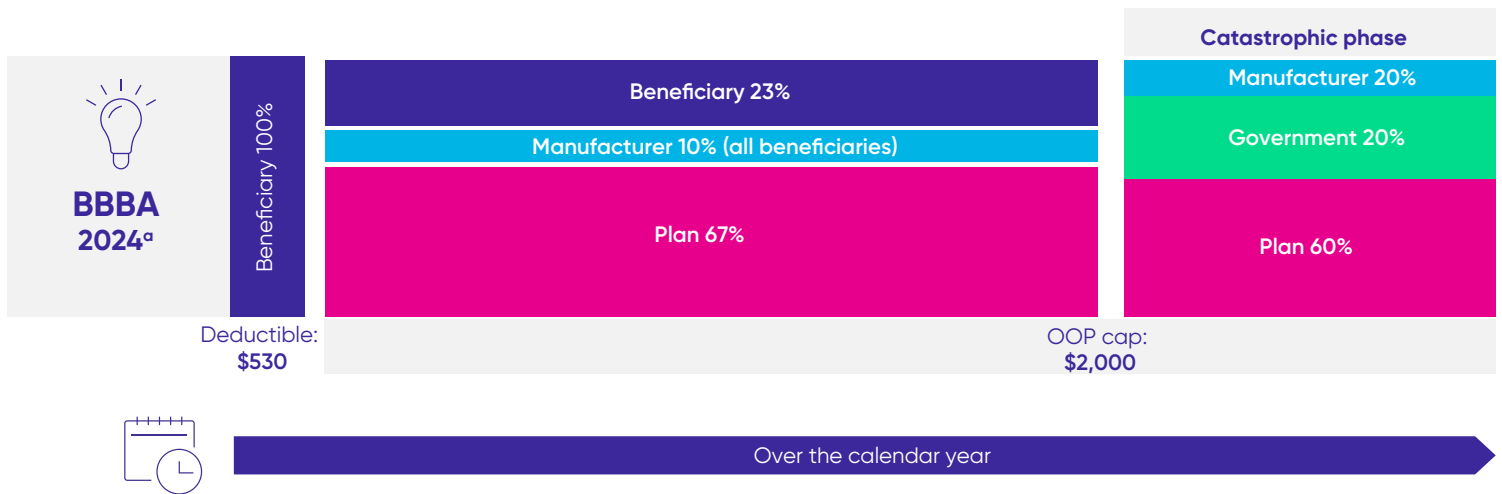
Figure 1. Current baseline for Medicare Part D (2024)



Whether as a scaled-down version of the Build Back Better Act (BBBA)³ or standalone legislation, there remains bipartisan interest in redesigning Part D. As seen in **Figure 2**, among the provisions under consideration is a \$2,000 annual OOP cap on spending for Part D beneficiaries. Ending the 5% catastrophic phase coinsurance would be significant to patients, particularly those taking orphan drugs.

Also under the BBBA, cost-sharing for nonsubsidized beneficiaries would drop from 25% to 23% during the initial coverage phase, and the manufacturer coverage discount program would be replaced by a 10% liability in the initial coverage phase and a 20% liability in the catastrophic phase.³ This liability would be phased-in for low-income subsidy beneficiary claims.

Figure 2. Proposed Part D benefit design for branded drugs under the BBBA (starting in 2024)



^aWhile some of the changes are phased-in over time, this figure illustrates the plan liability and manufacturer liability for low-income subsidy individuals when they are fully phased-in.

Illustrating the OOP cap for rare disease patients

An OOP cap will help millions of beneficiaries, whether directly through the cap or even just the security of knowing that there is a cap for the year. For patients, particularly those with rare diseases whose only treatment options are biologics that often come with higher costs, this change is a path to improved access.

These patients often face OOP costs in the thousands for their first fill of the year and then hundreds of dollars each month.

Using case studies of patients who suffer from pulmonary hypertension, primary biliary cholangitis, and cancer, Xcenda conducted an analysis of the difference in patient OOP if the Part D benefit were redesigned to cap beneficiary spending at \$2,000 per plan year (Figure 3).

Figure 3. Estimated total patient OOP costs per patient (2024)

	Fill 1		Fills 2+		Total annual OOP	
	Baseline	BBBA	Baseline	BBBA	Baseline	BBBA
<i>Pulmonary hypertension</i>	\$4,230	\$2,000	\$1,550	\$0	\$21,280	\$2,000
<i>Savings</i>		(\$2,230)		(\$1,550)		(\$19,280)
<i>Primary biliary cholangitis</i>	\$3,295	\$2,000	\$615	\$0	\$10,675	\$2,000
<i>Savings</i>		(\$1,295)		(\$615)		(\$8,675)
<i>Acute myeloid leukemia</i>	\$4,665	\$2,000	\$1,985	\$0	\$10,620 ^a	\$2,000
<i>Savings</i>		(\$2,665)		(\$1,985)		(\$8,620)

^aThe oncology patient is assumed to have 4 fills.

The analysis shows that a patient with pulmonary hypertension could save almost \$20,000 per year if a \$2,000 OOP cap were established. A patient taking a treatment for primary biliary cholangitis could save over \$8,000 per year. In this analysis, the total annual OOP cost per patient with acute myeloid leukemia would be reduced by just over \$8,600. For each of these prescriptions, patients would see a reduction in their OOP costs by over 400%.

Beyond the OOP cap, Congress should also consider passing a “smoothing” mechanism, that is, allowing beneficiaries to divide that OOP cap amount over the course of the plan year—rather than face high OOP costs in any given month. This would help to minimize the impact of costs faced by rare disease patients. For instance, if a rare disease patient faced the \$2,000 OOP cap in February, the patient may choose to smooth out the payments over the year and make 11 monthly payments of \$181. Most people budget on a monthly basis; therefore, a smoothing mechanism will allow them to spread out the costs evenly over the year.

A recent survey of Medicare beneficiaries indicated that OOP costs spread out over the year would make them 2 times more likely to start a new medication.⁴ Moreover, half of all Medicare beneficiaries live on incomes below \$29,650 per person, according to a 2019 analysis, with one in four beneficiaries having incomes below \$17,000.⁵

Rare and ultra-rare disease drugs are inherently more expensive because they reach fewer beneficiaries. But these drugs address critical unmet needs and should be encouraged, not decimated, by legislation. Many adult rare disease patients will endure years of misdiagnosis during their patient journey, only to find once they are properly diagnosed that the rare disease medication is out of reach because of the copayment in Medicare Part D. And the reality is that often there is still no treatment option, or only one treatment option, thus making a copayment for rare patients an unnecessary burden.

Conclusion

Despite having insurance through Part D, rare disease patients remain disproportionately vulnerable to high OOP liability. Given what we know about the connection between high OOP costs and medication initiation (much less medication adherence), it is impossible to ignore that many patients—including those who are very ill—are unable to follow the best course of treatment because they simply cannot afford it.^{6,7} This is particularly burdensome for rare disease patients, known to have high medical burdens for both services and treatments.⁸

Ensuring rare disease patients have access to prescribed treatments within the Part D benefit is essential to improving health outcomes. It is time to revisit the Part D benefit and make it equitable to the Part B benefit where patients have access to OOP caps. The idea that some patients may end up bankrupt because their Medicare prescription falls under Part D rather than the Part B outpatient benefit is maddening. Patients with rare diseases are fortunate if they have any available treatments much less having to worry about how and if they are covered by Medicare.

Lower patient cost-sharing through an OOP cap with a smoothing mechanism in Part D is likely to improve rare disease prescription abandonment rates, help with more appropriate utilization, and enhance access to rare disease products. Innovation can be a miracle but it shouldn't be out of reach for those who need it.

Methodology

- In order to gauge the impact of current law vs the BBBA on patient OOP spending, Xcenda examined specific brand drugs for example patients with various conditions
- Assumptions:
 - Premiums were not factored into OOP
 - Drug prices were obtained through Medicare.gov using the 2022 standard benefit design for standalone prescription drug plans in the example patient profile's geographic area
 - **Note:** The assumption in this analysis is that a patient would get the oncology treatment for 4 months; all other treatments assume 12 months/12 fills
- 2022 drug prices were increased by about 12.8% for brands and reduced by about 10.9% for generics per year, to estimate drug costs in 2024. This reflects an Xcenda estimation of drug price trends based on the Peterson-KFF Health System Tracker⁹
 - Parameters are considered fully phased-in by 2024 (ie, reinsurance liability represents parameters for 2024 and subsequent years)
 - Impacts of potential smoothing of patient cost-sharing throughout the year and other provisions of the legislation are not reflected in the profiles

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