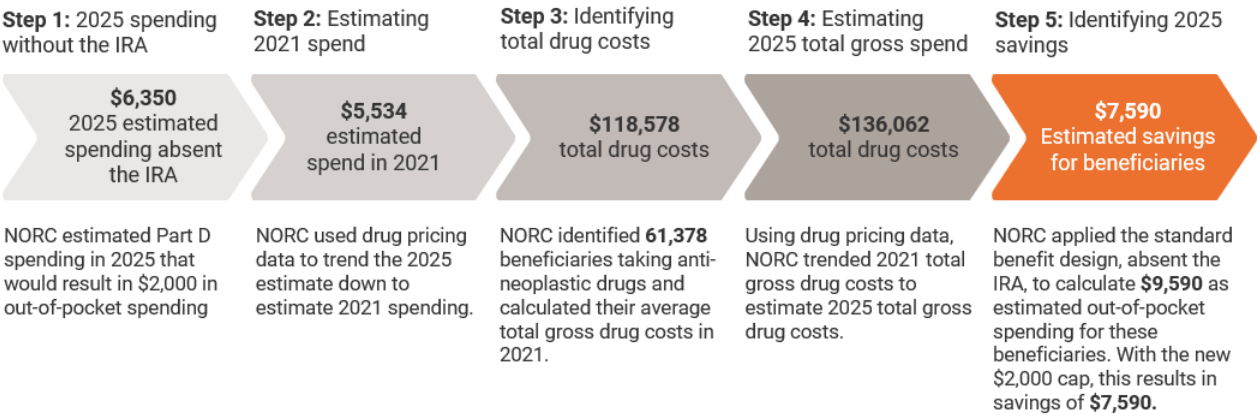
NORC at the University of Chicago

# Methodology for Part D IRA Analysis

Using the 2021 Prescription Drug Event (PDE) claims file, which represents 100% of Medicare beneficiaries with Part D coverage, NORC estimated the number of beneficiaries taking anti-neoplastic drugs at any point in the year (see Appendix for full list of NDCs). NORC excluded beneficiaries who received any low-income subsidy (LIS), since these beneficiaries face no or limited cost-sharing for their prescriptions. NORC also limited the analysis to beneficiaries enrolled in standalone prescription drug plans (PDPs), to those continuously enrolled in a PDP during the calendar year, and to those in non-employer plans[1]. Using these criteria attempts to limit the analysis to Medicare beneficiaries with basic Part D coverage.[2] The IRA legislative text suggests the cap will be based on the defined standard benefit coverage, not what an actual beneficiary pays – meaning for beneficiaries with enhanced coverage, they may hit the cap at less than $2,000 in out-of-pocket costs.

Upon applying the criteria, NORC initially identified 61,968 beneficiaries in 2021 with at least one claim for an anti-neoplastic drug prescription. These beneficiaries had an average of $117,474 in total gross drug costs and $8,074 in out-of-pocket spending across all their Part D prescriptions, not just for the specified anti-neoplastic NDCs.

To simulate the impact of the Inflation Reduction Act (IRA) out-of-pocket maximum beginning in 2025, NORC took the following high-level steps, which are described in detail below:




[1] In total, NORC identified 246,771 beneficiaries in MA-PDs and PDPs with at least one claim for any anti-neoplastic drug in 2021. Of those, 140,937 were enrolled in PDPs, and 106,424 were non-LIS PDP enrollees. NORC further limited the population to those with continuous full-year enrollment (89,431), and the those not enrolled in employer group plans, to arrive at the population estimate of 61,968.

[2] As of 2018, KFF estimated that almost half (46%) of plans offer basic Part D benefits – though no plans offer the defined standard benefit, while 54% offer enhanced benefits. See: https://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit

**Step 1: 2025 Spending Without the IRA**

NORC estimated that under the 2025 Part D benefit parameters[3] not reflecting the legislative changes under the IRA, $2,000 in beneficiary out-of-pocket spending is associated with approximately $6,350 in total covered Part D spending.

**Step 2: Estimating 2021 Spend**

NORC consulted several sources to generate an assumption about drug price growth between 2021 and 2025, including the IQVIA Institute "The Use of Medicines in the U.S. 2022" and the Vizient Winter 2023 "Pharmacy Market Outlook".[4] IQVIA projected a 5-year WAC CAGR between 2 and 5%, while Vizient projects overall 3.7% drug price inflation growth from 2023-2024.

NORC used an average annual growth rate of 3.5% annually, which represents the midpoint of the IQVIA estimates and is close Vizient's estimate. This estimate is also somewhat higher than CBO's projections of the growth in the consumer price index (CPI-U)[5], which will limit brand drug price growth under the IRA, however, it is not considered here because our goal is to simulate costs prior to IRA implementation.

Trending $6,350 in 2025 down to 2021 by an average annual rate of 3.5% results in $5,534 in 2021.

**Step 3: Identifying Total Drug Costs for Affected Beneficiaries**

As described above, NORC identified 61,968 beneficiaries with at least one Part D claim for an anti-neoplastic drug. Most of these beneficiaries had annual gross drug costs that exceeded $5,534. Excluding those whose costs were below $5,534, we found **61,378** beneficiaries (i.e. about 600 beneficiaries had gross costs below $5,534), whose average gross drug costs were $118,570. The distribution of their costs is outlined below in Table 1.

Of these beneficiaries, 42 percent (26,838) were female, and 10.5 percent (6,442) were non-white. The mean age was 75.42 years, and the median age was 75.00 years.

**Step 4: Estimating 2025 Total Gross Spend**

Next, we took the average drug costs from step 3 ($118,570) and trended forward to 2025, using the same growth rate assumptions from Step 2. This results in an average of $132,062 in 2025.

**Step 5: Identifying 2025 Savings**

[3] 2022 Medicare Trustees' Report, Table V.E.2 – SMI Cost-Sharing and Premium Amounts. https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf#page=204

[4] IQVIA Institute Report: "The Use of Medicines in the U.S. 2022". https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022, Vizient Winter 2023 Pharmacy Market Outlook. https://newsroom.vizientinc.com/en-US/releases/releases-drug-inflation-rate-continues-upward-trend-at-378-vizient-pharmacy-market-outlook

[5] The May 2022 CBO Economic Projections project CPI-U growth of 3.1% in 2023, 2.4% in 2024, and 2.3% in 2025. https://www.cbo.gov/data/budget-economic-data#4

Finally, we estimated beneficiary out-of-pocket costs in 2025 absent the IRA by applying the standard benefit design to a total gross cost of $136,062.

This resulted in estimated beneficiary out-of-pocket spending of $9,590, as shown below in Table 1:

**Table 1: Part D Standard Benefit (2025, No IRA)**

| | | Beneficiary | Plan / CMS | Manufacturer |
|---|---|---|---|---|
| Catastrophic | 5% Beneficiary<br>15% Plan<br>80% CMS | $6,211 | $118,015 | -- |
| Coverage Gap | 25% Beneficiary<br>5% Plan<br>70% Manufacturer | $1,685 | $320 | $4,720 |
| Initial Coverage Phase | 25% Beneficiary<br>75% Plan | $1,139 | $3,416 | -- |
| Deductible | 100% Beneficiary | $555 | -- | -- |

The difference between $9,590 and $2,000 -- **$7,590** --- represents beneficiary savings resulting from the introduction of an OOP cap under the IRA.

**Sensitivity Analysis**

The calculations above are based on average spending for a beneficiary in the sample identified. However, the average costs from 2021 mask substantial variation in total gross drug costs across beneficiaries, with beneficiaries in the 1st percentile of spending estimated to save $1,315, up to beneficiaries in the 99th percentile estimated to save $19,296, summarized below in Table 2:

**Table 2: Beneficiaries with Gross Drug Costs >$5,534 in 2021**

| | Total Gross Drug Costs in 2021 | Estimated Savings in 2025 |
|---|---|---|
| 1st Percentile | $9,203 | $1,315 |
| 25th Percentile | $59,694 | $3,772 |
| 50th Percentile | $126,006 | $7,087 |
| 75th Percentile | $199,059 | $10,740 |
| 99th Percentile | $322,590 | $19,296 |

**Drug Specific Analysis**

NORC repeated the analysis described above for beneficiaries taking certain anti-neoplastic drugs. This analysis differs slightly from the bulk of the analysis described above because total

drug costs are limited to spending on just the drug in question, not all drugs for the specified beneficiary.

Our analysis finds that across 7 brand anti-neoplastic drugs, many beneficiaries will experience savings from the IRA OOP cap based on their spending for that drug alone, demonstrated below in Table 3:

**Table 3: Beneficiaries Taking 7 Brand Anti-Neoplastic Drugs**

| Drug | Number of Beneficiaries | Estimated Savings in 2025 |
|---|---|---|
| Ibrance® | 3,612 | $6,084 |
| Imbruvica® | 4,252 | $7,431 |
| Jakafi® | 4,041 | $8,445 |
| Pomalyst® | 3,179 | $8,635 |
| Revlimid® | 13,760 | $8,989 |
| Sprycel® | 840 | $5,538 |
| Xtandi® | 7,345 | $5,878 |

*Limitations*

This analysis is limited to the impact of a single provision in the Inflation Reduction Act – the Part D out-of-pocket cap, and does not attempt to quantify the impact of other provisions such as inflation rebates or Medicare drug price negotiation, or the interaction of these provisions with the OOP cap. It relies on assumptions about growth rates in drug prices from sources that were produced either before the IRA was enacted or do not appear to incorporate the impact of the legislation on projections.

In addition, it is noteworthy that under the Part D program, anti-neoplastics are considered a "protected class", one six classes of drugs in which plans are required to cover all or substantially all drugs. This requirement may reduce plans' ability to successfully negotiate discounts or rebates from drug manufacturers, meaning that prices for drugs in this class (and therefore beneficiary savings from the IRA) may be higher than for other types of drugs.[6] Our analysis assumes no changes to this policy or plans' incentives.

Additionally, our analysis does not assume any changes to the mix of brand or generic drugs available to Part D beneficiaries. It is possible between now and 2025, newly available generic drugs will come to market, potentially changing both the pricing of existing drugs, and the range of options available to beneficiaries.

Finally, our application of the standard benefit design on beneficiary drug costs assumes that all drugs are brand and subject to the manufacturer discount in the coverage gap, whereas in reality, beneficiaries may take a mix of brand and generic drugs.

[6] See https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf and https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy