



The Effect of Medicare's Drug Price Negotiation Program on Out-of-Pocket Spending

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Overview of the Drug Price Negotiation Program

The Drug Price Negotiation Program (DPNP) authorizes the Centers for Medicare & Medicaid Services (CMS) to negotiate the prices of the 10 single source, brand-name, Part D-covered drugs with the highest total expenditures as of September 1, 2023, with the negotiated prices—also referred to as maximum fair prices—taking effect in 2026. In subsequent years, the number of drugs subject to negotiation will grow and include Part B-covered drugs.

In selecting drugs to negotiate, CMS may consider only those approved at least 7 years (for small-molecule drugs) or 11 years (for biologics) before the date of publication of the list of selected drugs. Some drugs are excluded from eligibility for the negotiation process, such as orphan drugs and certain small biotech drugs.

The DPNP also specifies the ceiling price that a drug's negotiated price may not exceed. The ceiling price is the lower of (1) the enrollment-weighted average negotiated price across all Part D drug plans (the plan average method) or (2) a pre-specified percentage of the non-federal average manufacturer price (non-FAMP) that varies based on the time elapsed since the Food and Drug Administration (FDA) approved the drug (the non-FAMP method).

The Inflation Reduction Act specifies additional changes that will affect Part D out-of-pocket spending, including a cap on annual out-of-pocket spending (initially set at \$2,000) and a requirement that manufacturers pay rebates to Medicare when they raise prices faster than inflation.

Medicare Part D provides prescription drug coverage for [more than 50 million](#) Medicare beneficiaries who choose to enroll. In recent years, the price of brand-name prescription drugs under Part D has increased dramatically, rising [more than 10% per year](#) from 2009 to 2018, and the average net cost of brand-name drugs is [higher for Medicare D plans](#) than for other federal payers. In response, Congress authorized the Medicare Drug Price Negotiation Program (DPNP) as part of the 2022 Inflation Reduction Act, giving CMS authority to negotiate the prices of drugs with the highest Medicare expenditures and specifying a formula for the maximum ceiling price that the negotiated price cannot exceed.

To understand how the DPNP could affect the out-of-pocket spending of different groups of Medicare Part D enrollees, Mathematica simulated the DPNP process to estimate what ceiling prices and out-of-pocket spending on the 10 highest-expenditure drugs would have been in 2021, the most recent year for which complete Part D data were available.

In addition to sharp decreases in the prices of those drugs, we identified meaningfully different reductions in out-of-pocket spending by race and ethnicity and other beneficiary characteristics, with American Indian/Alaska Native enrollees realizing the greatest savings from DPNP policies and non-Hispanic Blacks and disabled enrollees the least.

The 10 selected drugs accounted for 13% of Part D spending

As illustrated in Table 1, the 10 negotiation-eligible drugs with the highest expenditures accounted for a significant share of Part D spending, with Januvia accounting for the most spending—about 2%—of any eligible Part D drug.

This finding aligns roughly with a previous [analysis](#) showing that the top 10 drugs (before adjusting for rebates and without regard to their eligibility for negotiation) accounted for 22% of Part D spending and the top 50 drugs constituted nearly 50% of all spending.

The top 10 list will change

[The list of selected drugs](#) announced by the U.S. Department of Health and Human Services on September 1, 2023, includes only three that made our 2021 list—Januvia, Novolog, and Enbrel—suggesting the set of drugs with the highest expenditures can change markedly from year to year. Three other drugs on the 2023 list—Eliquis, Imbruvica, and Xarelto—received FDA approval too recently to qualify for the 2021 list, whereas the remaining four drugs on the 2023 list—Farxiga, Entresto, Stelara, and Jardiance—did not meet the spending criteria for 2021. ▲

Prices of selected drugs in 2021 would have declined at least 63%, on average, at the point of sale

In line with prior studies estimating declines of [66%](#), we estimated substantial price reductions after applying ceiling prices to the selected drugs, as indicated in Table 2. Among the 10 drugs, none would have experienced a point-of-sale price reduction of less than 50%. These estimates are conservative in the sense that actual, negotiated prices for these drugs cannot be higher than the ceiling price but might be lower, potentially resulting in even larger price drops.

Table 1. Drugs that would have been selected for Medicare price negotiation for 2021

Drug name	FDA approval date	Total spending (\$)	% of Part D spending
Januvia	10/16/2006	3,228,599,250	1.95
Humira*	12/31/2002	3,168,341,703	1.91
Novolog	6/7/2000	2,407,271,150	1.45
Levemir	6/16/2005	2,122,100,688	1.28
Humalog	6/14/1996	1,912,834,076	1.15
Enbrel	11/2/1998	1,904,688,466	1.15
Symbicort*	7/1/2006	1,751,036,418	1.06
Victoza	1/25/2010	1,675,287,761	1.01
Invega Sustenna	7/31/2009	1,365,992,995	0.82
Restasis*	10/10/2003	1,300,359,841	0.78
All top-10 drugs		20,836,512,348	12.56

Note: Total spending indicates gross drug cost and does not reflect rebates or other price concessions.

* Generic or biosimilar versions of these drugs were not on the market until after the start of 2021. None of the drugs would have qualified for the Biosimilar Delay provision in the DPNP at the time of their selection.

Table 2. Simulated change in prices for drugs selected for negotiation for 2021

Average change	-63%
Minimum change	-50%
Median change	-62%
Maximum change	-76%
Number of drugs with ceiling price based on the “plan average method”	3
Number of drugs with ceiling price based on the “non-FAMP method”	7

Note: Changes in price reflect the difference between a given drug’s retail price in the 2021 prescription drug event data (prior to any rebates) and estimated ceiling price. Accounting for rebates after the point of sale, we estimate price decreases would have ranged from 16% to 75%, with a mean of 45%. The plan average method is the enrollment-weighted average negotiated price across all Part D drug plans; the non-FAMP method applies a pre-specified percentage of the non-federal average manufacturer price that varies based on the time elapsed since the Food and Drug Administration approved the drug.

Out-of-pocket spending would have fallen 23% due to the DPNP, with variation across groups

If there had been no other changes to the Part D benefit, median Part D out-of-pocket spending on all Part D drugs would have declined by 23% under the DPNP in 2021, from \$1,250 per enrollee to \$967 (Figure 1).

Median savings would vary across different demographic groups. Asian/Pacific Islanders would experience the largest percentage decrease in out-of-pocket spending (25%), whereas American Indians/Alaska Natives would see the largest dollar decrease per enrollee (\$523), corresponding to a 24% decrease relative to the 2021 baseline. Non-Hispanic Blacks, by contrast, would have the smallest decrease in spending, whether measured in dollar or percentage terms.

Reductions in out-of-pocket spending also would be lower for enrollees who are disabled (19%) than for enrollees who qualified for Medicare due to their age (24%) or end-stage renal disease (ESRD) only (24%). Finally, out-of-pocket spending reductions would be slightly higher for men than for women (24 versus 22%) (data not shown).

Capping out-of-pocket spending would have resulted in additional savings, on average

Although the findings in Figure 1 illustrate how out-of-pocket spending would have changed if the rest of the Part D program had remained unchanged, the Inflation Reduction Act also imposes a cap on enrollees' out-of-pocket spending, initially set at \$2,000, starting in 2025. Because median baseline spending for all groups was well below \$2,000, the \$2,000 spending cap would not affect the changes in median spending shown in Figure 1.

However, a spending cap will reduce average spending after price negotiation and relative to baseline because enrollees who otherwise would have spent more than \$2,000 out of pocket will now have their spending capped. With the application of this cap, average Part D out-of-pocket spending on all Part D drugs would have declined by 33% in 2021 (Figure 2).

As with the uncapped median analysis in Figure 1, American Indians/Alaska Natives would see the largest dollar decrease in average out-of-pocket spending per enrollee (\$817), corresponding to a 37% decrease relative to the 2021 baseline, echoing [other authors' findings](#). Non-Hispanic Blacks and disabled enrollees would continue to realize smaller savings of 32% and 30%, respectively, relative to baseline.

Figure 1. Estimated median out-of-pocket spending

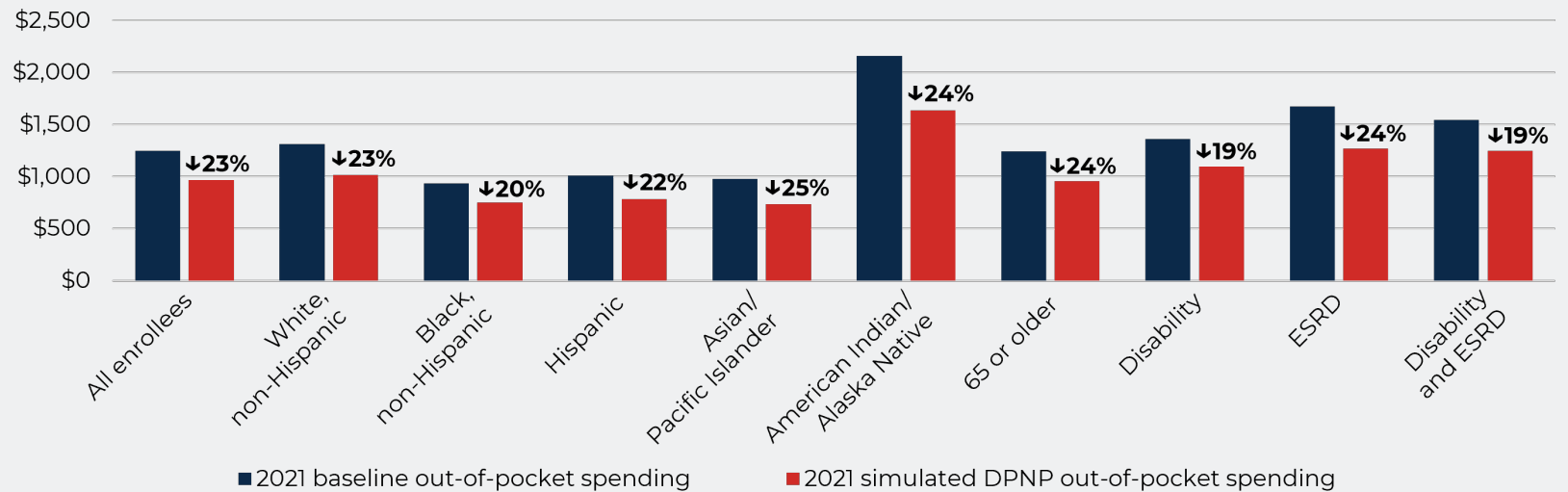
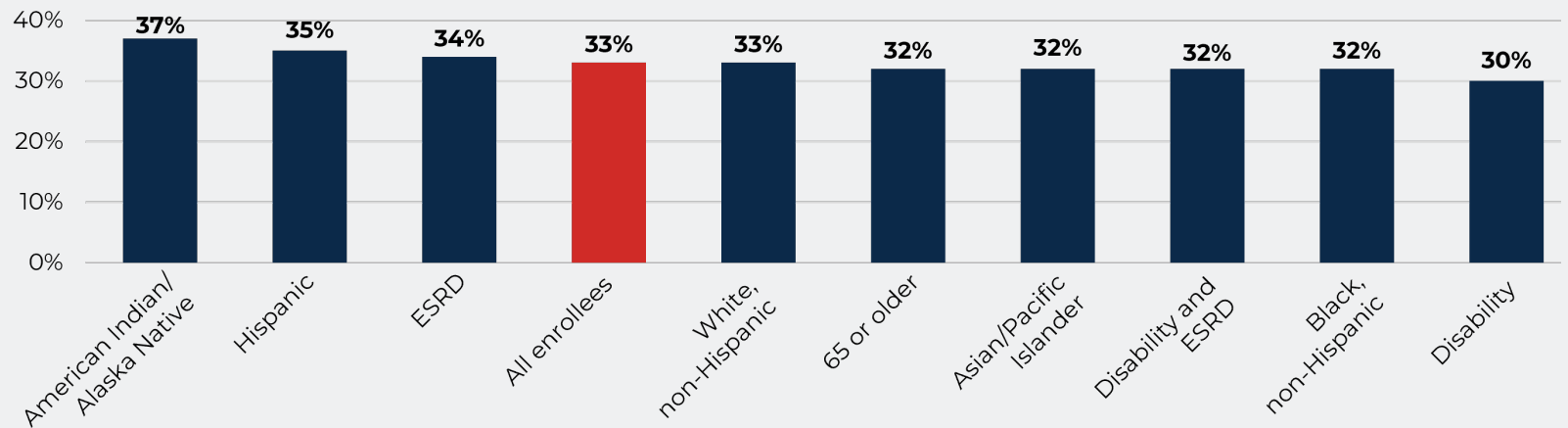


Figure 2. Estimated reduction in average out-of-pocket spending when spending is capped



Note: Enrollees included are those who used at least one of the 10 drugs selected for negotiation and who are not receiving the Low-Income Subsidy. Out-of-pocket spending includes spending on all Part D drugs and is not limited to those with negotiated prices. 65 or older refers to enrollees originally entitled to Medicare due to their age, whereas Disability and ESRD refers to enrollees originally entitled to Medicare because they are disabled or have ESRD, respectively.

The road ahead

We estimate that drug price negotiation will lead to sizable reductions in Part D enrollees' out-of-pocket spending for all groups considered, with some groups benefiting significantly more than others. Those who are American Indian/Alaska Native, are male, or originally qualified for Medicare due to ESRD will see the largest percentage reductions in out-of-pocket spending, whereas those who are non-Hispanic Black or disabled will see the lowest reductions. Given the [established reality](#) of health care disparities more broadly, it will be important as we move forward to understand why these differences exist.

For example, to the extent some groups are [disproportionately impacted by specific conditions](#) not treated by the drugs selected for negotiation, those groups will benefit less from the selected drugs' lower prices.

Yet we also know that even when focusing on individuals with the same condition—[rheumatoid arthritis](#) is but one example—use of medication to treat the condition varies across racial groups. When this occurs, disparities in savings from lower prices can reflect, at least in part, disparities in treatment of the underlying condition.

Whether and how CMS can address these observed differences in savings will depend on the causes of those dissimilarities. In some ways, CMS's ability to target disparities explicitly is limited in the DPNP. For example, the Inflation Reduction Act does not grant CMS the authority to select drugs for negotiation based on observed disparities. On the other hand, CMS can incorporate equity considerations into its assessments of relative value and its determinations of preliminary prices as part of the negotiation process and [plans to do exactly that](#).

A broader equity issue could emerge from the impact on plan premiums, particularly for selected drugs whose prices fall the least under the DPNP: If the move to lower list prices via negotiation leads to lower rebates to plans after the point of sale, premiums for the plan's participants could rise for plans that had previously used those rebates to lower premiums. Essentially, this would represent a shift of financial burden from enrollees using one or more of the selected drugs to all plan participants. Such a change could impact especially those enrollees who have incomes that are low but not low enough to qualify for the Low-Income Subsidy.

Determining the validity of competing hypotheses to explain why we observe the disparities we do or simulating the impact of lower negotiated prices on premiums is beyond the scope of this study, as is prescribing remedies. However, as CMS strives to advance equity as an integral part of its [strategic plan](#), we believe continued attention to understanding and addressing the causes and implications of these differences is warranted as CMS moves through its inaugural Medicare drug price negotiation process.

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Methods

This analysis used a variety of data sources, including 2021 Medicare Part D drug event, plan characteristics, and other data from the CMS Chronic Conditions Data Warehouse. We supplemented these data with 2016–2018 First Databank files to identify drug unit prices for our ceiling price calculations. We also relied on various FDA data sets to determine dates of drug approval and the applicability of exclusions and exceptions.

To identify the set of selected drugs for 2021, the Inflation Reduction Act requires us to rank expenditure data from a 12-month period preceding the publication of the selected drug list, for which we used calendar year 2018 data available from CMS's Medicare Part D Spending by Drug database as a proxy. In determining the final list of selected drugs, we were unable to apply the small biotech exception, as we lacked the required manufacturer-submitted data.

In calculating ceiling prices using the two different methods specified in the Inflation Reduction Act, we relied on assumptions from the literature when we did not have all the data necessary. For the plan average method, we used 2018 wholesale acquisition cost (WAC) unit prices as a basis for our calculations. We used [estimates from the Congressional Budget Office](#) and [Government Accountability Office](#) to adjust WAC unit prices to account for (1) typical Part D retail prices by specialty type and (2) rebates provided by manufacturers after point of sale based on drug class.

For the non-FAMP method, we used 2018 WAC unit prices to estimate the non-FAMP prices for each selected drug based on [estimates from the Congressional Budget Office](#). We also used 2016 WAC unit prices and adjusted them for inflation using the Consumer Price Index for All Urban Consumers from September 1, 2016, to September 1, 2018. We used the lower of those two values to estimate the ceiling prices based on the time elapsed since FDA approval of the drug. (The ceiling is 75% of the non-FAMP unit price for drugs approved within 16 years of the drug selection date and 40% of the non-FAMP unit price for drugs approved more than 16 years from that date.)

In calculating out-of-pocket spending, we excluded Part D beneficiaries receiving the Low-Income Subsidy in 2021 because drug price changes are less likely to affect their out-of-pocket spending. We also examined the out-of-pocket spending impact of price changes at the National Drug Code (NDC)-11 level rather than first combining a drug's NDC-9-level prices calibrated to a 30-day supply, as CMS has indicated it will do in its [revised guidance](#). Our out-of-pocket spending estimates include out-of-pocket spending paid directly by beneficiaries as well as certain third-party payments made on the enrollees' behalf. We used information from the prescription drug event data and plan characteristics files to identify and validate payment algorithms used by the plan for each claim to simulate out-of-pocket spending under the DPNP. When we were unable to identify the algorithm, we applied the Defined Standard Part D benefit structure.

We estimated changes in out-of-pocket spending by assuming drug utilization remained unchanged at lower negotiated prices. If utilization would have increased in response to lower prices, this would limit the savings in out-of-pocket spending and to Medicare. On the other hand, substituting negotiated prices for our estimated ceiling prices would result in higher savings than we measured in this analysis. ▲