

Inflation Reduction Act Drug-Pricing Provisions: Financial Impact on Manufacturers



Introduction

[Earlier this year](#), we discussed how it is time for manufacturers to assess the financial impact that each drug-pricing provision in the Inflation Reduction Act (IRA) may have on their drug portfolios or upcoming product launches.¹ This included various approaches for how manufacturers could proactively evaluate the impact of the IRA's drug-pricing provisions to better inform business strategies, project their financial performance, and even mitigate financial consequences.

In this supplement, we evaluate scenarios within the drug-pricing provisions to demonstrate potential financial impact on manufacturers. First, we discuss the projected \$22 billion increase in Part D discounts that manufacturers will face in 2025 driven by the Part D benefit redesign. Second, we discuss the Medicare price negotiation and how its impact on best price can spill over to Medicaid and the 340B Drug Discount Program ("340B program"). Finally, we will discuss the Part B and Part D inflation rebates and how they could impact pricing strategies.

IRA DRUG-PRICING PROVISIONS - FINANCIAL IMPACT SCENARIOS

A. Medicare Part D Redesign

Overview

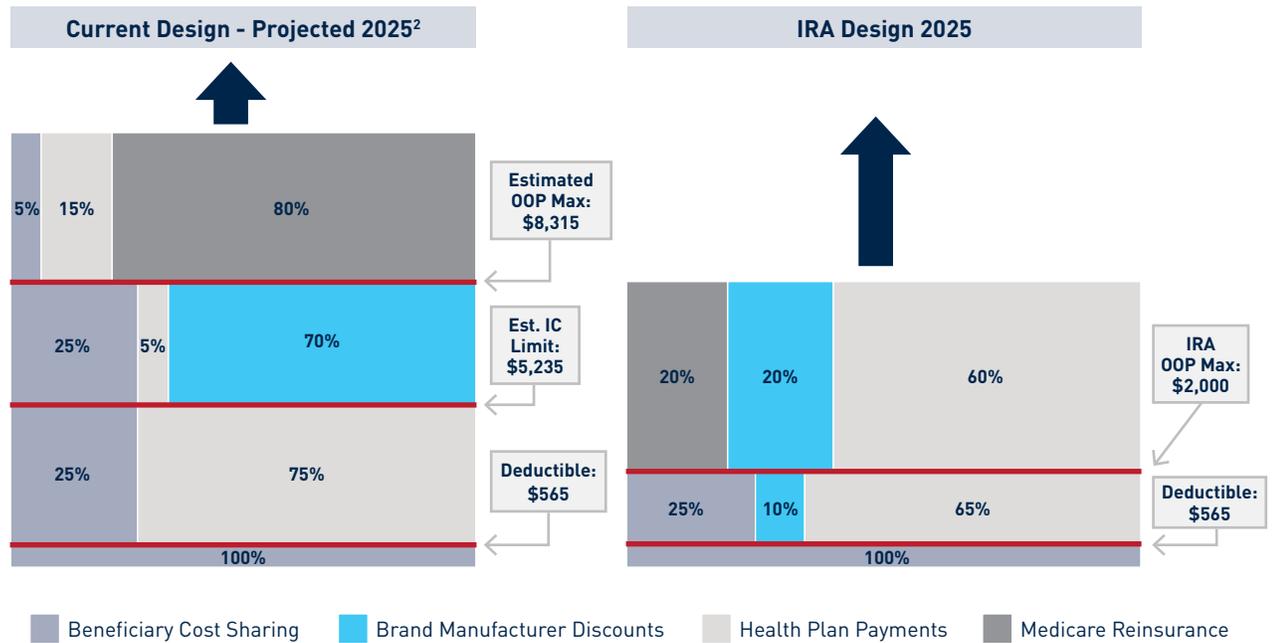
Under the IRA, the Medicare Part D benefit was redesigned, which will cause substantial but uneven financial impact on brand manufacturers. In 2025, the redesign will increase manufacturers' Part D discounts by a projected \$22 billion. More than ten manufacturers will face a projected increase in annual Part D discounts of at least \$500 million, and nearly one hundred manufacturers will face a projected increase of at least \$10 million.

The pre-IRA Medicare Part D benefit is defined by four phases: deductible, initial coverage, coverage gap ("donut hole"), and catastrophic. Under this design, manufacturers pay a 70 percent discount on branded prescription drug claims for beneficiaries that do not receive low-income subsidies (LIS) during the coverage gap and pay no discounts for claims dispensed to LIS beneficiaries.

¹ Ellie Blalock, Clay Willis, Austin Hay, and Josh Galuska, Inflation Reduction Act Drug-Pricing Provisions, BRG white paper (February 8, 2023). <https://www.thinkbrg.com/insights/publications/inflation-reduction-act-drug-pricing-provisions-financial-considerations/>

By 2025, the redesigned Part D benefit will eliminate the coverage gap, redefine manufacturer discounts in each phase of coverage, institute a \$2,000 out-of-pocket (OOP) cap, and require manufacturer discounts for both LIS and non-LIS beneficiaries. The IRA's changes to the Part D benefit design are depicted in Figure 1.

Figure 1. IRA Part D Benefit Design Changes for Brand Drugs (2025)



Note: Est. IC Limit is the estimated initial coverage limit (before beneficiary moves into the coverage gap). OOP is out of pocket.

Scenario

Understanding the financial impact of the redesign on a manufacturer's specific drug portfolio is challenging and requires an analysis of all Part D claims, not just those associated with a manufacturer's drugs. This data is often not accessible to manufacturers and many sources of similar data published by third parties do not represent a complete accounting of all Part D claims.

To evaluate the financial impact of the IRA Part D benefit redesign, we analyzed the 2020 Medicare Part D Drug Event data from the Centers for Medicare and Medicaid Services (CMS), which reflects 100 percent of Part D claims. We modeled manufacturer Part D discounts in 2025 under the pre-IRA benefit design as compared to under the IRA benefit redesign, thus estimating the change in manufacturer Part D discounts overall, by select therapeutic areas and by manufacturer.²

² BRG used CMS's Chronic Conditions Warehouse (CCW), which reflects 100 percent of Part D drug claims, to conduct this study. The latest available Part D Prescription Drug Event data from CMS relates to 2020 claims. To model the current Part D design at the time the IRA plan design changes will take effect in 2025, BRG inflated the 2020 drug costs by an annual growth rate of 8.65 percent, which represents the average growth in total Part D spend from 2017 to 2020. BRG also inflated the 2023 deductible, initial coverage limit, TrOOP, and coverage gap limits to estimate 2025 limits using an annual growth rate of 6 percent, which represents the average growth rate of these figures from 2020 to 2023. To model the IRA Part D design, BRG used the estimated 2025 drug spend, described above, and used the coverage and OOP limits set forth in the IRA for 2025. We did not consider the impact of other IRA provisions like the implementation of Part D inflationary rebates or Medicare's negotiation of drug prices on drug prices or beneficiary behavior.

Outcome

Manufacturer Part D discounts will increase under the IRA for three primary reasons. The first, and most significant, is the advent of manufacturer discounts for LIS beneficiaries. This impact is expected to account for \$19 billion of the \$22 billion in total projected increases in manufacturer Part D discounts in 2025. The second is the requirement of manufacturer Part D discounts in the initial and catastrophic phases of coverage which more than offset the eliminated 70 percent coverage gap discounts on non-LIS beneficiaries. This impact is expected to account for the remaining \$3 billion of projected increases in manufacturer Part D discounts in 2025. The third, which was not explicitly measured in this analysis but is discussed in the next section, involves likely changes in beneficiary adherence and increased prescription fills in the face of lower cost-sharing.

Figure 2 summarizes the projected impact that the IRA redesign will have on Part D discounts for select therapeutic areas.

Figure 2. IRA Impact on Part D Discounts for Select Therapeutic Areas

	IRA Impact on Manufacturer Part D Discounts		
	Projected Change (2025)	% Change	Percent of claims dispensed to LIS beneficiary
Antineoplastic Agents	6,364,069,477	798%	27%
Central Nervous System Agents	2,873,281,112	353%	50%
Hormones and Synthetic Substitutes	2,756,244,836	39%	38%
Anti-infective Agents	2,423,724,691	569%	34%
Respiratory Tract Agents	1,399,328,133	733%	41%
Gastrointestinal Drugs	637,103,789	136%	44%
Antitoxins, Immune Globulins, Toxoids, and Vaccines	507,346,759	400%	17%
Autonomic Drugs	433,232,917	38%	47%
Eye, Ear, Nose & Throat Preparations	290,228,336	49%	36%
Cardiovascular Drugs	52,622,839	6%	32%
Blood Formation, Coagulation & Thrombosis	-1,019,893,087	-23%	34%

As Figure 2 illustrates, the IRA has markedly different impacts across therapeutic areas. For example, the IRA is projected to increase manufacturer Part D discounts by nearly \$3 billion (353%) for CNS agents and only \$53 million (6%) for cardiovascular drugs. This is in contrast to blood formation, coagulation, and thrombosis drugs, where BRG projects the IRA will cause a decrease of \$1 billion (-23%) in Part D discounts.

The differences observed across therapeutic areas are caused by many nuanced factors, including the share of beneficiaries filling prescriptions who receive LIS, the cost of prescriptions, the number and cadence of prescriptions filled by a beneficiary, the brand/generic preferences and cost sensitivities of beneficiaries, and the characteristics of other drugs the beneficiaries take that impact the how quickly they progress through the phases of coverage. These factors vary by drug and drug therapy class, which is why it's critical that manufacturers understand the IRA's impact on their specific product portfolio.

The same uneven impacts are observed when looking at changes in Part D discounts for manufacturers' entire portfolios of branded drugs, rather than by therapeutic class. Many manufacturers are projected to face little to no changes in their Part D discounts, while other manufacturers are projected to pay more than \$1 billion in additional Part D discounts.

Figure 3. Projected Change of Part D Discounts by Manufacturer Across Portfolio

Projected Change: Part D Discounts in 2025	Number of Manufacturers ³
Increase of more than \$1 billion	5
Increase of \$100 million to \$1 billion	40
Increase of \$10 million to \$100 million	49
Increase of \$1 million to \$10 million	76
Increase of less than \$1 million	272
Decrease of less than \$1 million	40
Decrease of more than \$1 million	12

Manufacturer Considerations

In addition to the projected changes discussed above, the IRA's \$2,000 OOP cap and the ability for beneficiaries to smooth their OOP costs across the year are likely to impact adherence rates among Part D beneficiaries, could impact beneficiary preferences across brands, and may reduce financial incentives for beneficiaries to opt for lower-cost drugs. Changes in beneficiaries' behavior are likely to result in increased prescriptions filled and an increase in manufacturers' revenue through the Medicare Part D channel. In a 2020 study that BRG conducted of approximately 10,000 Medicare Part D beneficiaries, we found that alleviating beneficiaries' financial burdens resulted in beneficiaries being less likely to skip doses or split pills, delay starting a new medication, or postpone getting prescriptions filled.⁴

Further, as an illustration of how beneficiary OOP costs can impact prescription filling behavior, we observe differences across LIS and non-LIS beneficiaries within the cardiovascular drug and CNS agent therapeutic areas. LIS beneficiaries, which are subject to lower OOP costs, filled 34 percent more prescriptions for cardiovascular drugs and 104 percent more prescriptions for CNS agents than did non-LIS beneficiaries in 2020.⁵

The impact of the IRA's OOP provisions will likely be uneven across therapeutic areas and manufacturer drug portfolios. By carefully studying the countervailing forces—the downward pressure on revenue due to increased discounts and the upward pressure on revenue driven by increased prescriptions—manufacturers can inform future strategy and financial planning. Projecting the magnitude of these changes requires voluminous data, expertise, and economic modeling that may not be readily available to manufacturers internally. Economic modeling should be tailored to the specific beneficiary population that uses the manufacturer's prescriptions drugs, and should account for socioeconomic, medical, and other confounding beneficiary characteristics.

³ Labeler code and manufacturer information is sourced to the Elsevier Gold Standard Drug Database.

⁴ See Eva DuGoff and Aaron Vandervelde, Medicare Part D Benefit Design – Survey Results, prepared for PAN Foundation (July 31, 2020). <https://www.panfoundation.org/app/uploads/2020/09/BRG-Survey-Summary.pdf>

⁵ Many factors, including the differences in OOP costs, contribute to the difference in prescription-filling behavior across LIS and non-LIS beneficiaries. We do not project that the IRA's changes to the Part D benefit design will eliminate these differences.

B. Medicare Price Negotiation

Overview

Under the IRA, Medicare will directly negotiate a maximum fair price (MFP) for a subset of brand drugs without generic or biosimilar competition. In 2026, the first year of price negotiation, ten Part D drugs will be subject to negotiation. By 2030, eighty drugs will be subject to negotiation, including Part B drugs. Penalties for refusal to negotiate or for charging Medicare above the MFP are significant for manufacturers.

The MFP has a statutorily defined “ceiling” that varies depending on the life cycle and current pricing structure of the drug. Health and Human Services (HHS) may negotiate an MFP below the statutory ceiling price, but the MFP cannot exceed the ceiling. The ceiling is structured as the lesser of two prices:

1. *Discounted Nonfederal Average Manufacturer Price (Non-FAMP)*⁶
 - a. Non-FAMP is discounted as follows based on the life cycle of the drug:
 - i. “Short-monopoly” (less than twelve years from FDA approval): 25 percent
 - ii. “Extended-monopoly” (twelve to sixteen years from approval): 35 percent
 - iii. “Long-monopoly” (more than sixteen years from approval): 60 percent
2. *Average Net Price in Part D*
 - a. Average price, net of rebates negotiated by Part D plans or their pharmacy benefit managers (PBMs), for the most recent year for which data is available, weighted by enrollment in each plan.

Depending on the characteristics of a given drug, net revenue from the Medicare channel may be impacted by price negotiation. Additionally, the impact of the price negotiation may spill over into Medicaid and the 340B program, impacting net revenue for those channels.

The Medicaid program is entitled to a minimum rebate when a drug is dispensed to a Medicaid beneficiary. This rebate, known as the Unit Rebate Amount (URA), is calculated based on a formula that uses two statutorily defined prices called Average Manufacturer Price (AMP) and Best Price (BP). BP generally is the lowest commercial price and excludes prices offered to federal customers, though the MFP is explicitly included. This means that the MFP *could* increase the Medicaid URA for a negotiated drug, thereby decreasing net revenue through the Medicaid channel.

The 340B program allows certain types of hospitals and clinics (“covered entities”) to purchase drugs at a discounted price. This discounted price, known as the 340B ceiling price, is defined as the AMP minus the URA, as referenced above. If the MFP increases the URA, this will result in a lower 340B ceiling price, decreasing net revenue through the 340B channel.

To demonstrate the impact that price negotiation could have on net revenue through the Medicaid and 340B channels, we developed two scenarios modeling the MFP ceiling for hypothetical drugs.

⁶ Non-FAMP is the average price wholesalers pay manufacturers for drugs distributed to nonfederal purchasers.

Scenario 1: High Rebate, Short Monopoly

Our first scenario contemplates a drug that offers significant retrospective rebates to payers, including Part D and commercial plans. As of 2023, the product's list price is \$100 with an anticipated 5 percent price increase in each future year. We assume that the drug is selected for negotiation in 2026, at which point its list price will be \$116. The drug was initially approved by the FDA in 2016, making it a short-monopoly drug under the IRA. The table below lists the components of the MFP ceiling calculation for this drug, as of 2026.

Non-FAMP ^[1]	\$84
Applicable Discount	25%
<i>Discounted Non-FAMP</i>	\$63
<i>Average Part D Net Price</i> ^[2]	\$43
MFP Ceiling	\$43

^[1] 2021 Non-FAMP adjusted by inflation.

^[2] Weighted average net price as of the most recent available year.

Because this product is already significantly discounted to Part D plans (assumed 55 percent discount from list price) and is relatively early in its life cycle, the average Part D net price is the "lesser of" option and sets the MFP ceiling. If HHS does not negotiate an MFP below this ceiling, the impact to net prices in each channel is as follows:

	Without MFP	With MFP	Difference (%)
Medicare Net Price	\$52	\$43	-17%
Medicaid Net Price ^[3]	\$53	\$50	-6%
340B Ceiling Price	\$42	\$38	-10%

^[3] Reflects list price minus URA.

The most recent year of Part D net pricing data available to the CMS in 2024 (the year in which the initial MFP offer will be made) will be 2022 according to CMS initial guidance. As a result, by 2026, when the MFP is used for payment, this price will be four years old and will not reflect the annual 5 percent price increase that occurred in each intervening year. Absent MFP, this drug would have a net price in Medicare of \$52 in 2026.⁷ With the MFP, the net price is 13 percent lower at \$43.

Outcome

Because this drug carries significant rebates in the commercial market, its BP, even without the MFP (\$46), is low relative to its list price (\$116). The MFP sets a new, slightly lower best price at \$43. The reduction in BP brings the Medicaid net price down by 6 percent and the 340B ceiling price down by 10 percent. The impact on net revenue in the 340B and Medicaid channels is smaller compared to the impact in Medicare.

Scenario 2: Low Rebate, Long Monopoly

Our second scenario contemplates a drug that offers minimal retrospective rebates to payers. We assume a similar list price and price increase schedule as in Scenario 1. This drug was initially approved by the FDA in 2010, making it a long-monopoly drug under the IRA categorization. The table below lists the various components of the MFP ceiling calculation for this hypothetical drug, as of 2026.

Non-FAMP ^[4]	\$84
Applicable Discount	60%
<i>Discounted Non-FAMP</i>	\$34
<i>Average Part D Net Price</i> ^[5]	\$90
MFP Ceiling	\$34

^[4] 2021 non-FAMP adjusted by inflation.

^[5] Weighted average net price as of the most recent available year.

⁷ Assumes that Part D rebates as a percentage of list price would remain the same over time.

Because this product has minimal discounting to Part D plans (assumed 5 percent discount from list price) and is late in its life cycle, the discounted non-FAMP is the “lesser of” option and becomes the MFP ceiling. If HHS does not negotiate an MFP below this ceiling, the impact to net prices in each channel are as follows:

	Without MFP	With MFP	Difference (%)
Medicare Net Price	\$110	\$34	-69%
Medicaid Net Price ⁶	\$87	\$41	-53%
340B Ceiling Price	\$76	\$29	-62%

[6] Reflects list price minus URA.

Outcome

For this drug, the negative impact on net revenue is significant for all channels evaluated, ranging from a 53 percent decrease in the net Medicaid price to a 69 percent discount in the net Part D price. Because this drug does not carry significant discretionary payer rebates, the statutory discount associated with the MFP represents a significant change from the status quo that will require financial planning.

Manufacturer Considerations

Manufacturers should consider the following in preparing for price negotiation:

1. Examine their product portfolios to understand which drugs are eligible for price negotiation and likeliest to be selected due to projected volume of Medicare sales.
2. Estimate the likely MFP ceiling price for their drugs and compare to the net prices that would otherwise be offered in the market.
3. Calculate financial impact through Medicare channel by brand.
4. Calculate the impact on best price and the spillover financial impact through Medicaid and 340B channels.

C. Part B and Part D Inflation Rebates

Overview

The IRA requires manufacturers to pay inflation rebates for certain Part B and Part D drugs beginning in 2023. For those manufacturers that participate in the Medicaid Drug Rebate Program, the Part B and D inflation rebate will be similar in concept to the “additional rebate” portion of the Medicaid URA calculation, although the underlying inputs differ. Given that manufacturers have never before had to pay inflation rebates related to Part B or Part D and that CMS will be calculating the rebates due without an administrative review, it is imperative that manufacturers understand the financial impact inflation rebates may have on their current business as they evaluate future pricing strategies.

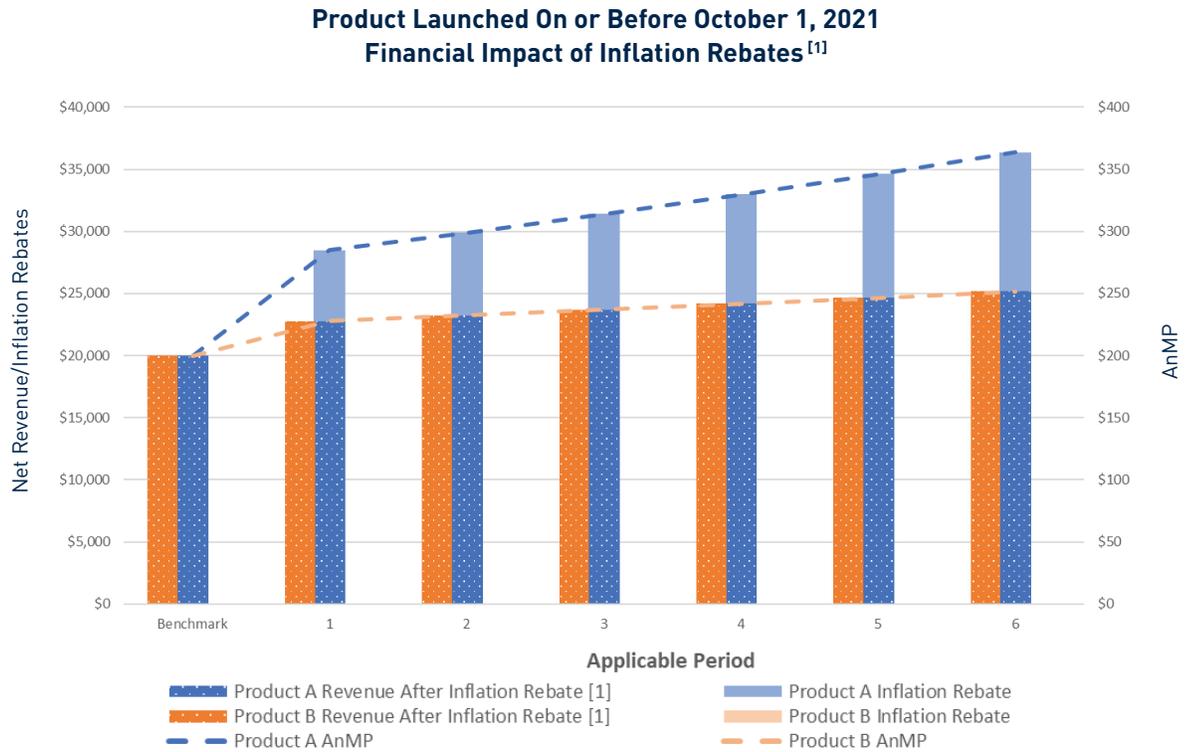
Below, we examine different price-change scenarios and evaluate the financial impact that common price-change patterns could have on Part D inflation rebates that would have to be paid by the manufacturer. These scenarios focus on Part D inflation rebates, but the concept is also applicable to Part B.

Scenario 1: Launched Products (on or before October 1, 2021)

Product A and Product B scenarios both have the same benchmark Annual Manufacturer Price (AnMP):

- Product A:** In the applicable Period 1, the AnMP is 25 percent higher than its inflation-adjusted payment amount. For each of the subsequent periods, the AnMP is 5 percent higher than the prior-period applicable AnMP.
- Product B:** In the applicable Period 1 and all subsequent periods, the AnMP increases at inflation and, therefore, is equal to each applicable period's inflation-adjusted payment amount per unit.

Figure 4. Product Launched on or before October 1, 2021; Financial Impact of Inflation Rebates



[1] For illustrative purposes only, as revenue after inflation rebates is calculated as utilization multiplied by AnMP minus inflation rebates. It is also assumed that AnMP and net revenue are a proxy ONLY to show impact of inflation rebates. The same Part D utilization (100 units) is assumed for both products.

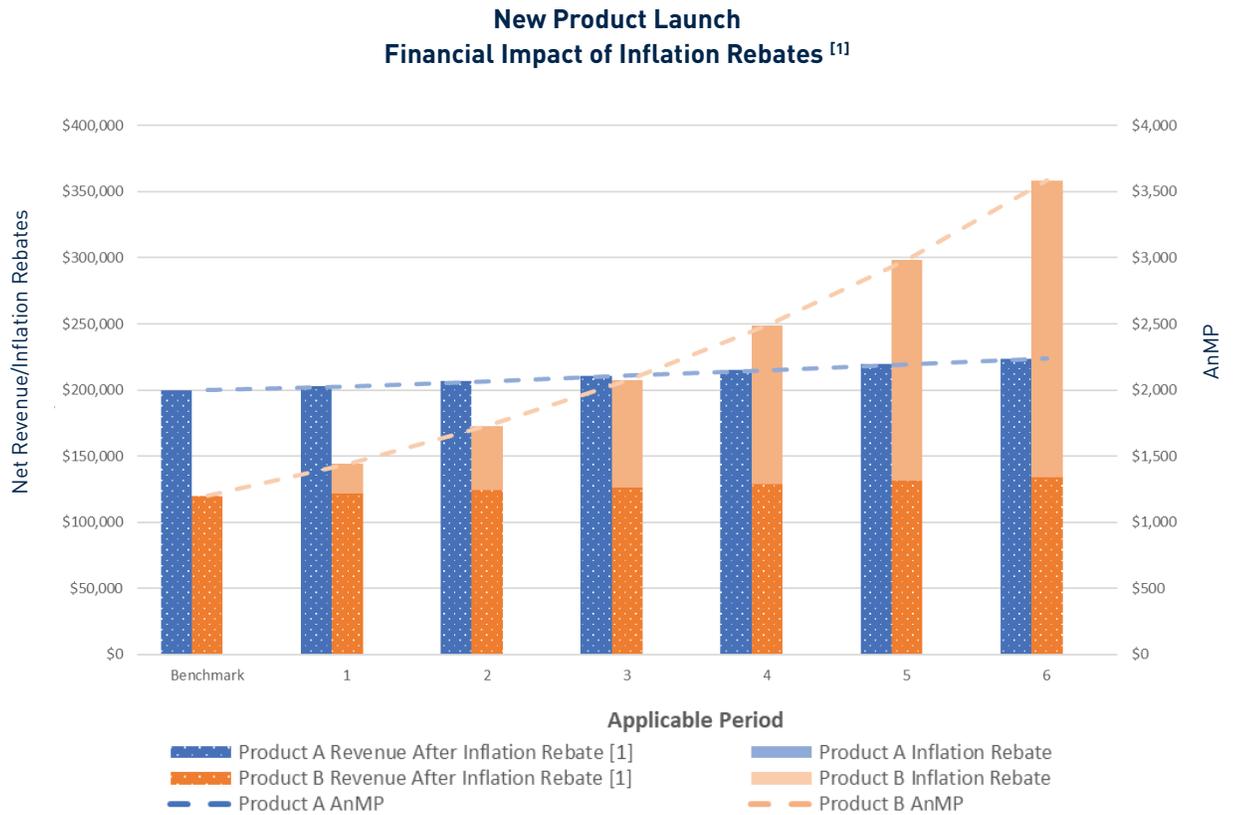
Outcome

Given its significant price increase in the first period, Product A triggers an inflation rebate payable to CMS. Inflation rebates then persist in subsequent periods even with smaller increases because Product A's cumulative price increases continue to outpace inflation. Product B, by contrast, did *not* trigger any inflation rebates because its AnMP increases at the same rate as inflation. The manufacturer of Product A would have a higher gross to net reduction given the additional liability from the inflation rebate payment.

Scenario 2: New Product Launch

- Product A** launched at a higher price than Product B but with subsequent price increases in each applicable period at the same rate as inflation.
- Product B** launched at a lower price than Product A but with subsequent price increases of 20 percent in each applicable period that outpace inflation.

Figure 5. New Product Launch; Financial Impact of Inflation Rebates



[1] For illustrative purposes only, as revenue after inflation rebates is calculated as utilization multiplied by AnMP minus inflation rebates. It is also assumed that AnMP and net revenue are a proxy ONLY to show impact of inflation rebates. The same Part D utilization (100 units) is assumed for both products.

Outcome

Product A, which launched at a higher price and then had limited price increases to the rate of inflation, did not trigger an inflation rebate. Product B, with its lower launch price and subsequent price increases that outpaced inflation, did trigger an inflation rebate. Because the price increase is cumulative, the rebate amount increased in each applicable period as Product B continued to take price increases above inflation.

Manufacturer Considerations

Manufacturers should consider the following in preparing for the impact of inflation rebates:

1. Examine product portfolios to understand which drugs could trigger Part B and Part D inflation rebates; and how utilization of such products may change over time, with a specific focus on growth drivers and new products coming to market.
2. For existing products, evaluate current and future price increases, relative to CPI-U expectations, and the impact those price increases would have on AnMP and Average Sales Price (ASP), which are used in the calculation of Part D and Part B inflation rebates.
3. Evaluate current and future commercial and retail discounting strategies that would impact the calculations of the AnMP and ASP.
4. For new products being launched, give careful consideration to launch price strategy (e.g., lower launch with higher-percentage increases versus higher launch with lower-percentage increases).

What to Do Next?

BRG professionals have helped lead manufacturers through the evaluation and assessment of potential financial impact associated with major drug-pricing provisions within the IRA. Proactively reviewing financial implications will allow manufacturers to make informed decisions that drive strategy and mitigate financial risk, which can be significant based on our experience. If you are interested in performing a financial evaluation around any or all the drug-pricing provisions, BRG can help.

Start the Conversation

Ellie Blalock

240.475.0697

eblalock@thinkbrg.com

Clay Willis

404.825.3319

cwillis@thinkbrg.com

Austin Hay

720.329.3667

ahay@thinkbrg.com

Susanna Leaf

240.476.2492

sleaf@thinkbrg.com

Josh Galuska

774.230.0062

jgaluska@thinkbrg.com



About BRG

Berkeley Research Group (BRG) is a global consulting firm that helps leading organizations advance in three key areas: disputes and investigations, corporate finance, and performance improvement and advisory. Headquartered in California with offices around the world, we are an integrated group of experts, industry leaders, academics, data scientists, and professionals working across borders and disciplines. We harness our collective expertise to deliver the inspired insights and practical strategies our clients need to stay ahead of what's next.

[THINKBRG.COM](https://www.thinkbrg.com)

Copyright ©2023 by Berkeley Research Group, LLC. Except as may be expressly provided elsewhere in this publication, permission is hereby granted to produce and distribute copies of individual works from this publication for non-profit educational purposes, provided that the author, source, and copyright notice are included on each copy. This permission is in addition to rights of reproduction granted under Sections 107, 108, and other provisions of the US Copyright Act and its amendments.

Disclaimer: The opinions expressed in this publication are those of the individual author(s) and do not represent the opinions of BRG or its other employees and affiliates. The information provided in the publication is not intended to and does not render legal, accounting, tax, or other professional advice or services, and no client relationship is established with BRG by making any information available in this publication, or from you transmitting an email or other message to us. None of the information contained herein should be used as a substitute for consultation with competent advisors.