Payer Reactions and Perceptions: Impact of the first IRA Price Negotiation

As the maximum fair prices (MFPs) under the Inflation Reduction Act (IRA) set clearer benchmarks for drug costs, payers are rapidly adapting their strategies and expectations. These shifts, which include intensified rebate negotiations, tighter utilization management, and evolving product preferences, demand that manufacturers refine their pricing, value communication, and market access approaches. This document presents key payer insights and outlines how manufacturers can successfully navigate this evolving landscape.

How has the IRA affected pharmaceutical prices?

The IRA of 2022 is a US federal law designed to address inflation, reduce healthcare costs, promote clean energy, and improve tax fairness. In addition to extending access to health insurance through the Affordable Care Act (ACA), the IRA also mandates lower prescription drug costs by allowing Medicare to negotiate prices for some drugs that have high Medicare spending.

The US Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), announced the first 10 drugs covered under Medicare Part D that will undergo price negotiation. The HHS stated that these 10 drugs accounted for \$50.5 billion in total Part D covered prescription drug costs between June 1, 2022, and May 31, 2023, and that Medicare enrollees paid a total of \$3.4 billion in out-of-pocket costs for these drugs in 2022. The Maximum Fair Prices (MFPs) are now publicly available and described in the table below.

N°	Drug	WAC* for 2023	Maximum fair price* for 2026	Discount of MFP from 2023 WAC price
1	Eliquis (apixaban)	\$ 521	\$ 231	56%
2	Xarelto (rivaroxaban)	\$ 517	\$ 197	62%
3	Entresto (sacubitril/valsartan)	\$ 628	\$ 295	53%
4	Jardiance (empagliflozin)	\$ 573	\$ 197	66%
5	Januvia (sitagliptin)	\$ 527	\$ 113	79%
6	Farxiga (dapagliflozin)	\$ 556	\$ 179	68%
7	Fiasp/NovoLog (insulin aspart)	\$ 495	\$ 119	76%
8	Enbrel (etanercept)	\$ 7,106	\$ 2,355	67%
9	Stelara (ustekinumab)	\$ 13,836	\$ 4,695	66%
10	Imbruvica (ibrutinib)	\$ 14,934	\$ 9,319	38%
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First 10 drugs to receive maximum fair price

abbreviations: N, number; WAC, wholesale acquisition cost; MFP, maximum fair prices

Source: <u>https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf</u>

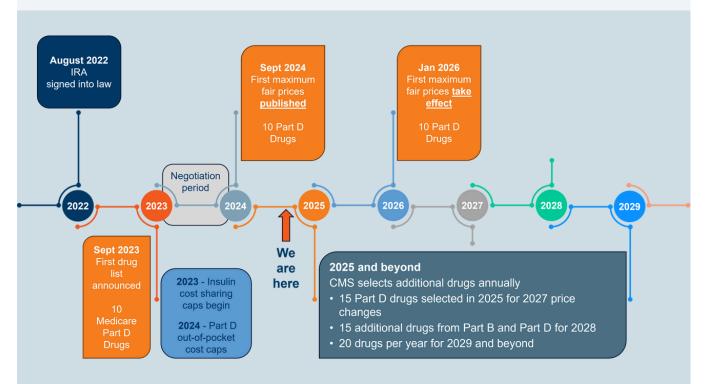
The Congressional Budget Office (CBO) estimates that the drug pricing provisions in the law will reduce the federal deficit by \$237 billion between 2022 and 2031.

The 10 drugs accounted for \$50.5 billion in total Part D annual drug spend

In 2025, another 15 drugs will be added to the negotiation process. The expectation is that more drugs will be included in subsequent years, including Medicare Part B drugs from 2028.

Medicare drug pricing establishes a public reference point, which puts pressure on manufacturers to lower prices for these drugs for non-Medicare Part D patients as well. This broader impact may influence commercial payer negotiations and overall market dynamics.

IRA timeline



How does the IRA impact commercial health plans?

Genesis Research Group recently invited payers to participate in an online, qualitative and semi-quantitative survey regarding the recent publication of MFPs under the IRA for 10 key pharmaceutical products. The payer sample consisted of 12 payers from national Managed Care Organizations (MCOs), Integrated Delivery Networks (IDNs), and Pharmacy Benefit Managers (PBMs).

The payer sample represented 96 million MCO/IDN lives and 115 million PBM lives. The goal was to understand how healthcare payers and provider networks view the MFPs for these 10 drugs and what broader effects these might have.

Data were collected with the tech enabled RPR[™] platform. RPR can be used to develop robust market access strategies and fit-for-purpose evidence-generation plans.

Drugs excluded from negotiation process

- Drugs with a generic or biosimilar
- Plasma-derived products
- Small molecule drugs <9 years from FDA-approval (<13 years for biological products)
- Orphan drugs if the orphan indication is the only FDAapproval
- Small biotech drugs

RPR allows manufacturers to engage with a global network of 3,500+ vetted stakeholders across 65+ countries to test market access and evidence strategies as they evolve.

What do US payers outside of Medicare think?

The payers in our sample generally view the published MFPs favorably and expect MFPs will reduce costs and improve patient access.

However, payers expressed neutral or mixed perceptions for certain drugs with existing price caps, upcoming loss of patent exclusivity, and/or unmet expectations for deeper discounts.

The majority of respondents plan to use MFPs as leverage in price negotiations with other manufacturers with products in the same class or indication to treat the same conditions. Payers plan to adopt multifaceted strategies to compensate for revenue loss, including reducing operational costs, negotiating rebates on other products, enhancing utilization management, increasing premiums, and diversifying offerings.

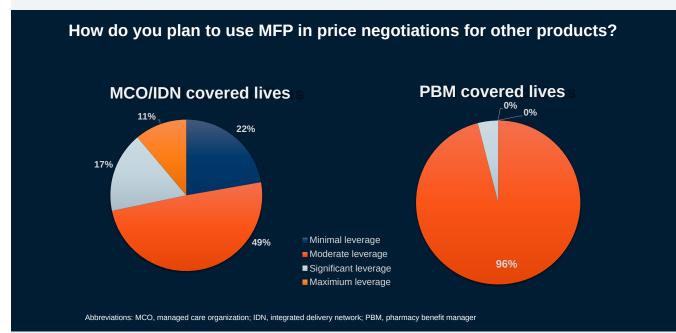
This indicates that payers view MFPs as new benchmarks that reset price expectations despite anticipating manufacturer pushback.

A majority of payers are planning to employ multiple utilization management (UM) strategies to steer utilization towards lower-cost MFP products while ensuring regulatory compliance. Multiple payers mentioned step therapy and preferred formulary placement as potential options.

MFPs are likely to serve as a benchmark for future negotiations, given the MFP is public pricing information and is likely to reshape price expectations for new brands that launch, especially those with similar mechanisms of action.

Fewer than half of all payers said they are likely to prefer MFP products. A preference for MFP products is primarily driven by potential cost savings, reduced patient copays, and improved adherence, ultimately enhancing patient outcomes. Several payers indicated they might prefer non-MFP products in situations where they offer significant clinical advantages or aggressive discounts to compete with the MFP products.

Most payers anticipate downstream effects in adjacent therapeutic areas, expecting increased pressure on manufacturers for rebates. However, opinions were split on the potential for negotiation on non-adjacent areas, reflecting uncertainty about broader MFP impacts. Additionally, payers differed on the timeline, with some anticipating early 2026 impacts and others expecting delay. Opinions were also split on the expected timing. While some payers thought that price pressures on non-adjacent therapies could happen in early 2026, others thought that the impact could take longer.



Payers also noted the importance of considering the overall value of a drug based on clinical outcomes/clinical differentiation, and not just net cost. Our findings suggest payers will want to balance preferred MFP and non-MFP products based on clinical factors.

What might this mean for manufacturers?

Manufacturers should strive to stay informed as changes to the CMS guidance as MFP implementation unfold. Preparing to adapt pricing and market access strategies in response to regulatory changes and support payers in compliance efforts will be critical to success.

- Demonstrating clinical superiority or **unique value** through effective value communication and evidence development becomes increasingly important, as payers weigh clinical outcomes alongside cost in their formulary decisions.
- Manufacturers may face more demands from payers for competitive pricing and higher rebates, as payers leverage MFPs in negotiations across therapeutic areas.
- Manufacturers need to plan to reassess rebate offerings, especially for non-MFP products, to maintain formulary placement and competitiveness against MFP-priced alternatives.
- Manufacturers should anticipate stricter UM measures, formulary changes, and adjusted cost-sharing, which could affect patient access and utilization rates.
- For MFP-products nearing loss of exclusivity, manufacturers need to proactively manage lifecycle strategies to retain market share amid payer shifts toward generics and alternatives.
- Manufacturers may need to prepare for increased rebate negotiations in adjacent therapeutic areas, as payers seek parity in formulary placement and cost savings beyond MFP products.

How can Genesis Research Group help manufacturers?

Genesis Research Group offers comprehensive support to help manufacturers understand the implications of MFPs and broader IRA policies through a powerful combination of RPR-powered payer insights, real-world data analytics, and research capabilities. Each product and therapeutic area faces distinct challenges and opportunities. Our tenured team of experts can help assess IRA impacts on your specific product and therapeutic area through direct engagement with our network of payers and stakeholders.

Through our agile engagement model, we deliver rigorous insights to inform pricing strategies, value communication approaches, and evidence generation plans that address both immediate MFP considerations and broader market dynamics.

Whether you need to understand payer perspectives on clinical differentiation, evaluate competitive pricing scenarios, or develop lifecycle management strategies, our team provides tailored solutions backed by robust research and analytics.

Examples of projects to the understand the impact of MFPs on your products value, pricing, and access strategy

- Payer research to understand how MFP implementation affects commercial pricing negotiations and alters competitive landscapes for MFP products
- Pricing research to identify the necessary rebate levels for non-MFP products to secure or retain preferred formulary status alongside MFP products; coupled with analytics to assess how different payer control levels and their ability to influence market share correlate with rebate expectations
- Payer research to identify opportunities for strengthening product differentiation via clinical evidence, value communication, and innovative contracting
- Data analytics to evaluate current utilization management and cost differential controls within therapy areas impacted by MFPs, predicting how MFP product performance may drive changes in payer strategies

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To explore detailed findings from our recent payer research on IRA impacts and learn more about how we can help address your product's specific needs, connect with one of our experts at <u>solutions@genesisrg.com</u>.

Meet the experts



Adam Weston Executive Director, Access and Pricing



Ki Park VP, Market Access Strategy and Analytics



Rui Ferreira Senior Consultant, Access and Pricing



Kuldeep Singh Executive Vice President, Client Strategy



Genesis Research Group empowers life science companies to innovate differently by fundamentally transforming the way they engage with research partners. Through the integration of robust stakeholder insights (RPR[™]), data-agnostic expertise, and a revolutionary engagement model, we deliver real-world evidence, HEOR, and market access solutions that enable our partners to anticipate and address the evolving needs of payers, regulators, and stakeholders

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