HAYDEN

Inflation Reduction Act:

Revisiting Price Negotiation & its Anticipated Impact on the Biopharma Landscape

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Executive Summary

When the Inflation Reduction Act (IRA) was signed into law in August 2022, it was evident that the law ushered in significant changes to the Medicare program that would substantially change US healthcare market dynamics. Additional information released over the past 17 months has helped us to understand the likely impact of the IRA on the healthcare ecosystem. In addition to broader IRA market dynamics, this paper assesses the potential response from payers and manufacturers, particularly with regard to changes to plan design, formulary coverage, and rebating dynamics.

IRA Review & DNP Selected Drugs

The DNP requires the Secretary of Health and Human Services (HHS) to negotiate a price for a select number of drugs each year in Medicare, beginning with 10 drugs for 2026. HHS published the 10 drugs selected for the first cycle of negotiation as shown in Table 1.[i] HCG uses the terms "negotiate" or "negotiation," in this paper, as these are the terms used in the IRA and by the Centers for Medicare & Medicaid Services (CMS). However, HCG recognizes that the IRA process is distinct from what is commonly thought of as "negotiation," given the severe penalties for failing to engage with CMS. The impact of the DNP will grow significantly over time; the 100 Medicare drugs expected to be selected for DNP between 2026-2031 represent almost half of drug spending in Medicare in 2020.[ii]

Table 1: First 10 Selected Drugs for Negotiation

DNP Drugs	Indication(s)
Eliquis	Prevention and treatment of blood clots
Jardiance	Diabetes; Heart failure
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease
Januvia	Diabetes
Farxiga	Diabetes; Heart failure; Chronic kidney disease
Entresto	Heart failure
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis
Imbruvica	Blood cancers
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis
NovoLog/Fiasp	Diabetes

The redesign of the Part D standard benefit, the second key provision of focus for this paper, redistributes financial responsibility

across stakeholders in Part D and across the phases of the benefit. Redesign reduces costs in the catastrophic phase for beneficiaries and the government, caps beneficiary out-of-pocket costs at a maximum out of pocket limit and lowers the government's share of catastrophic costs, resulting in greater financial risk associated with beneficiary drug costs shifting to plans. To account for this increased liability, plans are likely to increase premiums, adjust Part D bids and seek greater control of covered drugs. Manufacturers' liabilities will shift to the initial and catastrophic phases of coverage for non-DNP brands through the new mandated manufacturer discounts, which in most cases will result in higher liabilities for manufacturers, as these amounts will be unbounded and paid on behalf of all Part D beneficiaries.[iii]

Since the IRA became law, additional guidance has been issued on how the law will be implemented.[iv] With this additional clarity, it is important to revisit how the DNP may impact competitive dynamics within classes where one or more drugs will be negotiated, as well as the overall market impact.

Impact of the DNP: Scenario 1 Overview & Outcomes

To assess the potential impact of the IRA on stakeholders we consider 1) the direct impact of the IRA on payers and manufacturers, 2) how payers and manufacturers are expected to respond to this direct impact, and 3) how market dynamics may evolve as a result. In Table 2, we consider the direct effects of the IRA on both payers and manufacturers. Payers are expected to face higher liability from the Part D redesign and will see the loss of rebate dollars from DNP drugs. Manufacturers will see higher liability from the Part D redesign, new payments under the Manufacturer Discount Program (MDP), and lower revenue from price setting.

Table 2: Overview of Stakeholder Impact Resulting from the IRA (Redesign & DNP)

	Payers	Manufacturers
1 Impact of Redesign & Negotiation	***Payers will:*** • Face higher liability as a result of redesign • See a loss of DNP-drug rebate dollars	***Manufacturers will:*** • Face higher liability as a result of redesign • See new payments under MDP • See lower revenue from price setting

To understand how payers and manufacturers may respond to these direct effects, we discuss the likely outcomes of an illustrative scenario exploring a competitive class with high rebating and clinical differentiation. Table 3 provides an overview of this scenario detailing list price assumptions, competitive dynamics, clinical differentiation considerations, and the expected Maximum Fair Price (MFP) for the DNP brand.

Table 3: Overview of Scenario 1 Class Dynamics

Scenario 1: Therapeutic Area with 1 DNP Drug	
Assumptions	1. **Class Dynamics:** Highly competitive, non-protected class 2. **List Price:** All competitive drugs have a WAC of $600-$800 per month 3. **Competition:** Today, the market is dominated by the DNP brand (50% Medicare market share). HCG assumes current payer rebates for all brands within the class are high, at 60-70% of WAC 4. **Differentiation:** While all drugs within the class have similar efficacy, the drugs do have important clinical and dosing differences 5. **Maximum Fair Price:** HCG assumes the maximum fair price (MFP) for Drug 1 will be 20% of list price[v]

In Scenario 1, payers will face increased liability due to the redesign of Medicare Part D and a loss of rebate dollars associated with the DNP drug. In response to these market headwinds, as shown in Table 4, we expect payers will look to offset increased liability by increasing premiums and adjusting Part D bids, as well as by seeking greater control of covered drugs in order to mitigate risk. Depending on if the payer is net cost focused or rebate revenue focused, offset lost rebate dollars. In response to higher liabilities and lower revenue, we expect manufacturers will look to balance investments across rebates offered and patient support services provided as they seek to maintain coverage and affordable access for patients.

Table 4: Overview of Stakeholder Reaction for Scenario 1

	Payers	Manufacturers
2 Stakeholder Reaction	• Payers will seek to offset liability, mitigate risk, and offset lost rebate dollars • Payers may raise premiums and adjust Part D bids • Payers may tightly control access to medicines (e.g., exclusions, UM and PA)	• Manufacturers will seek to balance investments to obtain coverage and affordable access for patients

The market dynamics that emerge as a result of these reactions, highlighted in Table 5, are complex. If a payer is net price focused, we expect they will seek to drive utilization through the DNP-drug given the net cost differential between the DNP-drug and the competitive class (80% DNP discount, 60-70% non-DNP discount). Unless non-DNP competitor drugs match the DNP drug's net price, we expect payers will require use of the DNP drug prior to utilization of a non-DNP drug or will implement formulary restrictions.

If a payer is rebate revenue focused, we expect they will seek to offset lost rebates by attempting to derive additional rebates from non-DNP brands. We expect that in an effort to increase rebates among non-DNP drugs, payers will increase utilization management, particularly outside of the protected classes where plans are only required to provide formulary access to a minimum of two drugs per class and must provide coverage to the DNP brands.

Table 5: Overview of Market Outcome for Scenario 1

	Payers	Manufacturers
3 Market Outcome due to Stakeholder Reaction	• If a ***payer is net price focused***, they will prefer the DNP drug and restrict Non-DNP drugs to secondary market access through additional utilization management • If a ***payer is rebate focused***, they will pick one preferred non-DNP drug (to drive the highest rebate), consider listing the DNP-drug as non-preferred, and restrict the remaining non-DNP drug(s)	• Manufacturers will need to assess investments in affordability across payment channels (i.e., rebates, support programs) to determine if further investment in Medicare discretionary rebates is possible • Given the increase in liability from the redesign, incremental rebates will be challenging for manufacturers

Payers may also implement restrictions on DNP drugs, however through additional guidance CMS stated that it "shares concerns" that Part D plans may implement utilization management on brands that are selected for negotiation.[vi] CMS has clarified that payers must include the

DNP-drug on formulary and must justify placing the DNP-drug on a higher tier and if it has more restrictive utilization management than its therapeutic alternative, making it less likely that payers will prefer a non-DNP drug over a DNP-drug.[vii]

Manufacturers with drugs competing in highly rebated classes, such as those in Scenario 1, already face high gross-to-net pressure. However, they will need to determine if additional rebates should be provided and to what extent, as they seek to compete with a DNP drug with guaranteed access. Non-DNP manufacturers that are able to offer greater rebates will be in an advantageous position entering the post-IRA negotiation landscape. Manufacturers that have offered higher rebates may lose preferred access if they do not have the capacity to increase their discretionary rebate offers further.

Through our first scenario we can see that regardless of payer motivations and manufacturer response, markets with a brand subject to negotiation can expect to see higher utilization management and more restricted access for competing therapeutic options.

Impact of the DNP: Alternative Scenarios

Two DNP drugs in the same class

Alternative scenarios introduce complexities to these market predictions. Based on the initial 10 drugs selected for negotiation, it is clear that DNP drugs will have to compete against other DNP drugs in the same class as early as 2026. Because negotiation processes are conducted independently for each selected drug, competing DNP brands will likely have different MFPs. It is possible that the DNP brand with the higher MFP will offer discretionary rebates on top of the negotiated price in order to remain competitive with the other DNP brand. As noted above, we expect DNP drugs to have substantial price reductions, which could make it challenging for non-DNP drugs to compete. In non-protected classes with multiple negotiated drugs, given CMS' formulary standards of a minimum of two drugs per class, payers may limit preferred coverage to the DNP-drugs only.

6PC, same class

In protected classes, plans are required to cover “all or substantially all” drugs within each class or category which may result in different coverage outcomes when a drug within a protected class is negotiated.[viii] While payers cannot leverage the threat of a formulary exclusion to manufacturers with drugs in protected classes, as we have increasingly observed payers can use formulary tools to manage utilization for those not on existing therapies, in accordance with CMS requirements.[ix,x] Given this we expect that if there are DNP medicines in a protected class, payers will manage access through formulary tiering and additional utilization management in an effort to extract additional rebates from manufacturers and/or drive utilization to the lower net price DNP products. Payers may even seek to increase levels of formulary management to a degree that approaches a formulary exclusion.

Implications

The IRA will significantly change the market access landscape. As additional drugs are selected for negotiation each year across a wider reach of therapeutic areas, traditional utilization management patterns across classes in Part D will substantially change. In the short term, manufacturers should expect to be asked to pay higher discretionary rebates as payers try to offset losses from increased liability and decreased rebates for DNP drugs. As manufacturers balance pressure for incremental rebates, they will likely face heightened financial pressure

forcing them to choose between valuing market access and pipeline reinvestment. Additionally, the rebate pressure and uncertainty around increased utilization management and other formulary restrictions is likely to impact incentives to invest in developing drugs for the Medicare population or markets with classes for which there may be a DNP drug (which over time will be most therapeutic classes).

Despite the June 2023 guidance[xi], there are areas where further clarification is needed. While manufacturers must submit data to help determine MFP, it remains unclear how those data will be used in MFP determination. We emphasize that increased visibility into the negotiation process and operations of the DNP will aid stakeholders in preparing for a post-IRA landscape.

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[i] HHS Selects the First Drugs for Medicare Drug Price Negotiation. 29 August 2023. https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html

[ii] Scott M, et al., Updated Reconciliation Package Changes Drugs Eligible for Negotiation. Avalere. August 2022. https://avalere.com/insights/updated-reconciliation-package-changes-drugs-eligible-for-negotiation.

[iii] In 2025, manufacturers will pay discounts under the MDP on all brand medicines and on behalf of all beneficiaries. In contrast, under the Coverage Gap discount program, manufacturers pay 70% of costs in the coverage gap only on behalf of non-LIS beneficiaries.

[iv] Medicare Drug Price Negotiation Program: Initial Memorandum. Center for Medicare, 15 March 2023, https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf; Medicare Drug Price Negotiation Program: Revised Guidance. Center for Medicare, 30 June 2023, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[v] Maximum Fair Price assumption is derived by assuming the DNP will result in a MFP that reduces the current net price by 50%. Note that The Congressional Budget Office (CBO) estimates that net prices for selected drugs will decrease by roughly 50 percent, on average, as a result of negotiation. 2023 CBO Report, February 2023, https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf. Therefore, assuming current rebating puts the current net price at 40% (60% discount) of list price, than cutting that in half would result in a net price that is 20% of list price.

[vi] Medicare Drug Price Negotiation Program: Revised Guidance. Center for Medicare, 30 June 2023, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[vii] Ibid.

[viii] The six protected classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, immunosuppressants. Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Section 30.2.5.

[ix] Access to covered Part D drugs, 42 C.F.R. § 423.120(b)(2)(vi)(C) (2023).

[x] Medicare Part D's Six Protected Classes Policy. Partnership for Part D Access. February 2021. http://www.partdpartnership.org/uploads/8/4/2/1/8421729/avalere_report_on_six_protected_classes_--_february_2021.pdf.

[xi] Medicare Drug Price Negotiation Program: Revised Guidance. Center for Medicare, 30 June 2023, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.