Inflation Reduction Act – How Will the First 10 Drugs Selected for Medicare Price Negotiations Impact US Commercial Payers?

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HPR6

Background

The US Inflation Reduction Act (IRA) was signed into law by President Joseph R. Biden on August 16, 2022. The IRA brings about several sweeping reforms with the aim to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government. One of the key provisions in the IRA is the requirement for the federal government to negotiate drug prices for some Medicare Part B and D drugs with the highest total spend.

On August 29, 2023, the Centers for Medicare & Medicaid Services (CMS) announced its first list of drugs that will be subject to price negotiation.[1] The list consists of 10 drugs that include anticoagulants, antidiabetic agents, and therapies for heart failure, autoimmune conditions, and B-cell cancers, which account for ~20% (nearly $50.5 billion) of total drug costs in the total Part D gross covered prescriptions between June 1, 2022 and May 31, 2023.[1] Negotiations will occur in 2024, with negotiated prices going into effect in 2026.[2] The negotiation process will consider the selected drug's clinical benefit, unmet need, impact on Medicare beneficiaries, and other aspects such as Research & Development costs.[3] With the ongoing price negotiation process and upcoming implementation of Medicare-negotiated prices for the first 10 drugs selected, commercial payers must consider how this will impact coverage, management, and contracting not only for those selected drugs, but also competitor drugs in the same therapeutic class or indication.

Objectives

- To gain insight into how US commercial payers will update the management and contracting of the first 10 drugs selected for Medicare price negotiation under the IRA.
- To understand how management and contracting may evolve with the continued implementation of price negotiations.

Methods

Formulary details including tier placement and restrictions by certain US health plans for the 10 drugs selected for Medicare price negotiations was obtained through Decision Resource Group's (DRG) Fingertip Formulary. Five 30-minute interviews were conducted over teleconference with US payers representing national and regional Managed Care Organizations (MCOs), Integrated Delivery Networks (IDNs), and Pharmacy Benefit Managers (PBMs) (**Table 1**). The payers represented more than 65 million commercial covered lives and eight million Medicare Advantage covered lives. Four of the five payers represented health plans with four formulary tiers, while the other payer was part of a five-tier plan.

The first discussion topic of the interviews was to gain feedback on current and anticipated future impact of the IRA on health plans in general, including management and contracting of certain therapies, and to understand any remaining uncertainties that may exist. The second discussion topic was around understanding current commercial and Medicare Advantage management of the 10 drugs selected for Medicare price negotiations and anticipated changes in terms of tier placement, restrictions, and contracting for the specific selected drugs as well as other competitor drugs that may not have been selected for price negotiation but are in the same therapeutic class or indication.

Table 1. Stakeholder Demographics

		National MCO #1	National MCO #2	Regional MCO	PBM	IDN
Position/Title		Pharmacy Director	Vice President, Pharmacy Policy and Strategy	Specialty and Pharmacy Contracts Manager	Vice President, Pharma Strategy and Contracting	Chief Medical Officer
Health Plan Formulary Type		4 tier	4 tier	5 tier	4 tier	4 tier
Covered Lives (in millions)	Commercial	1.4	13	1.1	50	0.17
	Medicare	0.2	2	0.1	6	0.08

Abbreviations: IDN = Integrated delivery network; MCO = Managed care organization; PBM = Pharmacy benefit manager

Results

Current Management of Selected Therapies

The 10 therapies selected for Medicare price negotiations under the IRA include Eliquis®, Jardiance®, Xarelto®, Januvia®, Farxiga®, Entresto®, Enbrel®, Imbruvica®, Stelara®, and insulin aspart brands Fiasp® and Novolog®. Many of these products are already preferred agents across varying plans, which indicates there is significant contracting and discounting in place. Certain products such as Enbrel®, Imbruvica®, and Stelara® are covered in Specialty tiers due to their monthly cost being higher than the specialty-tier cost threshold. Utilization management in the form of quantity limits, prior authorization, and step edits are employed across products. Several stakeholders noted that they do not cover Novolog® or Fiasp® and only allow competitor products due to contracts in place with the other insulin aspart manufacturers.

Table 2. Current Management of Selected Therapies

	National MCO #1	National MCO #2	Regional MCO	PBM	IDN
Apixaban (Eliquis)	T2 P QL	T2 P QL	T3	T2 P	T2 P QL
Empagliflozin (Jardiance)	T2 P PA ST	T2 P	T3	T2 P	T2 P QL ST
Rivaroxaban (Xarelto)	T2 P QL	T2 P QL	T3	T2 P	T2 P QL
Sitagliptin (Januvia)	T2 P PA ST	T2 P	T3	T2 P	T2 P QL ST
Dapagliflozin (Farxiga)	T3 NP	T2 P	T3	T2 P	T2 P QL ST
Sacubitril/ Valsartan (Entresto)	T2 P PA	T2 P	T3	T2 P	T2 P QL
Etanercept (Enbrel)	T4 S	T4 S	T4 S QL PA	T4 S ST	T4 S PA QL
Ibrutinib (Imbruvica)	T2 P PA	T4 S	T5 S NP PA	T4 S	T4 S PA QL
Ustekinumab (Stelara)	T2 P	T4 S PA	T4 S	T4 S ST	T4 S
Insulin Aspart (Fiasp/Novolog)	T3 NP	T3 NP	T4 S	NC	NC

Key: T2 – Tier 2 T3 – Tier 3 T4 – Tier 4 T5 – Tier 5 NC – Not Covered

Abbreviations: IDN = Integrated delivery network; MCO = Managed care organization; NP = Non-preferred; P = Preferred brand; PA = Prior authorization; PBM = Pharmacy benefit manager QL = Quantity limit; S = Specialty; ST = Step therapy

Anticipated Future Management of Selected Therapies

Payers were not aligned on their predictions in terms of impact of Medicare price negotiation on the future management and contracting of selected therapies (**Table 3**). The two national MCO representatives had starkly different perceptions. One national MCO representative was fairly aligned with the PBM representative, while the other national MCO representative was aligned with the regional MCO and IDN representatives.

National MCO #1 expected changes in terms of contracting among competitors. Notably, they anticipated Medicare price negotiations would be leveraged to obtain greater discounts for their commercial health plans—employer-sponsored and Medicare Advantage—for drugs in competitive disease areas such as Eliquis®, Jardiance®, Xarelto®, Januvia®, Farxiga®, and Entresto®. Moreover, they believed increased discounting based on Medicare price negotiations may help to improve the formulary tier for Enbrel® and insulin aspart.

The expectations from national MCO #2 and the regional MCO representative were fairly aligned. They did not anticipate changes for almost all selected drugs as they already have satisfactory contracts in place, were deemed efficacious and safe, had significant sales volumes, and were providing overall good value. Both representatives expected no changes for Imbruvica® as oncology products must be covered as a protected class and contracting is rare in this therapy area. Additional discounting was generally not expected to be significant enough to warrant a tier change, except for the insulin aspart products, where the regional MCO representative mentioned the IRA provision capping out-of-pocket spending of insulin could reopen contracting negotiations for preferred products.

The PBM representative predicted new negotiated prices would impact expected discounts for direct or indirect competitors of the selected drugs. They anticipated the lowest cost drugs with overlapping indications (e.g., Eliquis® and Xarelto®) would be leveraged by health plans to negotiate additional rebates from the more expensive competition. The PBM representative mentioned the possibility of introducing a step through a biosimilar of adalimumab for Enbrel® and Stelara® if discounts were not considered sufficient. No changes were expected for the insulin aspart products as those were deemed to already provide acceptable discounts.

The IDN representative expected minimal changes across selected therapies, except a potential decrease in restrictions on Imbruvica® with discounting based on price negotiations, given their plan covers it with a prior authorization and a step edit.

Table 3. Anticipated Impact on Selected Therapies in Terms of Tier Placement, Restrictions, and Contracting

	National MCO #1	National MCO #2	Regional MCO	PBM	IDN
Apixaban (Eliquis)	x			x	
Empagliflozin (Jardiance)	x			x	
Rivaroxaban (Xarelto)	x			x	
Sitagliptin (Januvia)	x			x	
Dapagliflozin (Farxiga)	x			x	
Sacubitril/ Valsartan (Entresto)	x			x	
Etanercept (Enbrel)	x			x	
Ibrutinib (Imbruvica)	x				x
Ustekinumab (Stelara)				x	x
Insulin Aspart (Fiasp/Novolog)	x		x		

Key: No significant impact x Impact on Tier placement, Restrictions, or Contracting

Abbreviations: IDN = Integrated delivery network; MCO = Managed care organization; PBM = Pharmacy benefit manager

Anticipated Impact on Competitor Therapies

The five payer representatives described multiple ways the IRA and Medicare price negotiations could impact other competitor drugs in the same therapeutic class or indication that were not selected for price negotiations.

Payer representatives described a class effect across drugs with the same indication or mechanism of action. Payers are likely to leverage discounts obtained from Medicare price negotiations to lower competitors' prices. Using insulin as an example, one payer representative expects an impact on contracting as payers would consider swapping preferred brands for those that are more heavily discounted. On the other hand, another payer representative thought insulin prices were already competitive and did not expect significant changes across these products.

It has also been noted that payers would avoid disrupting any existing advantageous contracts in place, especially if the therapy has multiple indications, has been proven safe and effective, or has important volume sales. As an example, one payer representative mentioned they had an outcome-based contract for Entresto® that showed a reduction in hospitalizations. Similarly, another payer representative expected no change within heart failure drugs given their perceived value. Furthermore, a few payer representatives expected no changes across the board for drugs such as Januvia®, where the sodium/glucose cotransport transporter 2 competition has low sales volume compared with their preferred branded product.

Payer representatives flagged that measures taken by Medicare price negotiations may take significant time to be implemented. By this time, several generics and biosimilars for the selected therapies are expected to launch. Those launches are poised to have a potentially greater impact on price than the price negotiations. Furthermore, payers may also consider using generics and biosimilars as step throughs depending on the outcome of the Medicare negotiations.

Other Considerations

Regarding predictions on anticipated or desired products to be selected for the next rounds of Medicare price negotiations, the interviewed payers considered glucagon-like peptide 1s (GLP-1s) to be the most likely target. There was no consensus on which GLP-1 should be selected; however, the selection of any GLP-1 would have price and contracting implications for the entire drug class. Payers also considered oral cancer agents, specifically ones indicated for prostate cancer, to be a high priority for future negotiations. The selection of additional cancer therapies for price negotiation could bring about a shift in the current payer management landscape where there is currently very little discounting expected for these treatments. However, if more cancer treatments are selected in future rounds of price negotiation, this expectation may change. Some other products and classes mentioned by payers included Janus kinase inhibitors, migraine medications, and immunologic treatments.

Moreso than the Medicare price negotiations, payers thought the introduction of biosimilars for several of these products would be a bigger disruption, putting downward pressure on the drug cost. The Medicare price negotiations and IRA provision to limit price increases to the rate of inflation will lead to pharmaceutical companies increasing their initial list price of most treatments.

Discussion

There are several key questions that persist as the initial Medicare price negotiations are underway. These will likely not be answered until the updated Medicare prices are published and implemented. One key uncertainty is whether the negotiated prices will be a significant change from the current cost to payers. Most of the selected drugs are already discounted quite heavily to health plans given their high utilization, and that is the reason many are already on a preferred brand tier. One payer mentioned that they are not convinced that CMS will get better rates through negotiations than what is already on the table for health plans. And with such high utilization, there may be a negative impact on members if health plans decide to change their current tier placement due to expectations for further increases in discounts, resulting in greater out-of-pocket costs or restrictions for members that are already using the treatment. However, it is anticipated that PBMs will be the most interested in leveraging the price negotiations to obtain increased discounts for health plans.

Another potential concern by payers is that manufacturers may look to reduce their commercial rebates and discounts to make up for the anticipated loss in profit from Medicare because of the negotiations. While payers do not anticipate that this will happen due to the negative impact it would have on product utilization, they do acknowledge it as a possibility. Given the manufacturers with products selected in this first round of negotiation all have large portfolios of branded agents, it is possible that the increased level of discounting for their selected product or products can be spread across their portfolio and will not cause a major impact overall. The issue may arise if or when a manufacturer with a small number of branded products is selected for price negotiations and health plans and PBMs are looking to negotiate greater discounts. In this case the manufacturer may have less ability or willingness to engage in these contracting discussions. Then it will depend on whether the product is difficult to restrict or remove from the formulary due to competition, utilization, efficacy, physician perception, or other considerations; in that case, the health plan may not implement restrictions. But if the product is considered replaceable, it may be pushed down in tier placement or potentially even removed from the formulary.

Overall, the commercial payers predicted an increase in discounts for therapies across the board as more products come up for price negotiations. This along with the IRA provision limiting price increases to the rate of inflation is anticipated to result in higher initial list prices of therapies at launch. As a result, there is potential for health plans to begin implementing more control and restrictions on their formularies or excluding products through greater utilization of closed formularies. For manufacturers to avoid these negative consequences and best position themselves for potential upcoming price negotiations, it will be more important than ever to generate strong supportive evidence and a highly impactful value story throughout the life cycle of the product.

Conclusions

- Many products selected for Medicare price negotiations are already preferred by commercial health plans due to existing discounts.
- PBMs and certain national health plans expect increased discounts based on Medicare price negotiations to maintain preferred status.
- Competitors to therapies that are subject to price negotiation, even if they were not themselves selected, will likely be expected to offer increased discounts to maintain their formulary status.
- In addition to greater discounting, health plans may implement more restrictive or even closed formularies to further limit available product options particularly in competitive therapeutic classes.

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