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IRA Drug Price Negotiations:

Key Competitive Considerations for Innovators

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WHITE PAPER

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Introduction

The Drug Pricing Provisions outlined within the Inflation Reduction Act (IRA) represent a seismic shift in pharmaceutical policy from CMS and HHS. These provisions alone have been estimated to reduce the federal deficit by $237B over 10 years,[1] but have already affected pipeline prioritization, commercial life cycle management, and M&A activity among leading manufacturers[3] – over half a dozen of whom have ongoing litigation to block certain provisions' implementation.[4]

Two of the three high-impact provisions – inflation-based rebate requirements in Medicare Parts B and D, and a redesign of statutory cost-sharing obligations in Part D – require complex modeling evaluations but can generally be addressed by manufacturers when pricing their products at launch.[3] However, the third provision, Drug Price Negotiation, represents a decades-long effort for policy-makers to curtail Medicare spending, but comes with a nearly 200-page revised guidance[2] rife with ambiguity. Within the document, CMS fails to clearly define key phrases such as "most clinically comparable" (2026 cycle) / "clinically comparable" (2027 cycle) when discussing therapeutic alternatives to the selected drugs and leaves the starting point for an initial offer open to a broad set of qualitative adjustments (Box 1).[2] These limitations create open questions for pharma/biotech executives as they prepare for potential future negotiations:

- What position may our selected drug be in relative to key competitors following negotiations (advantaged, parity, disadvantaged) from a drug pricing perspective?
- Will private payers leverage drug price negotiations for their own future contracting?
- What steps should manufacturers take to prepare their inline products for potential negotiations?

With AbbVie recording a $2.1B impairment charge on Imbruvica,[5] clear understanding of the anticipated impact of negotiated pricing on manufacturer revenues is desired by the industry, and has led to extensive prognostication regarding anticipated parameters and outcomes.[6] The outcomes of the current negotiations, which have been ongoing since February[7] and are scheduled to be made public in September,[1] should provide valuable data points for manufacturers whose products are selected in future years. With this white paper, our goal is to help manufacturers think through recent updates and competitive strategies to prepare for potential future negotiations. In particular, the four considerations that follow highlight the interconnectivity of policy and industry market events and should be kept in mind as innovative manufacturers continue to review their inline and pipeline products.

Box 1: CMS Guideline-Recommended Methodology for Developing an Initial Offer.[2]

1) Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication: CMS to use prescribing information approved by FDA but may consider off-label use based on nationally-recognized, evidence-based guidelines and CMS-approved Part D compendia. CMS to also consider similar data from the manufacturer, FDA, common classification systems, CMS compendia, guidelines, and literature reviews to identify therapeutic alternatives.

CMS defines "therapeutic alternative" as one or more products that are clinically comparable to the drug, may be brand/biologic or generic/biosimilar, and may be on- or off-label to treat a given indication. CMS will begin by identifying therapeutic alternatives within the same class as the drug before considering those in other classes, but in cases where there are many potential therapeutic alternatives, CMS may focus on the subset that are "most clinically comparable" (2026 cycle) / "clinically comparable" (2027 cycle).

CMS may consult with FDA, clinicians, patients, patient organizations, and/or academic experts to ensure that appropriate therapeutic alternatives are identified.

2) Developing a Starting Point for the Initial Offer: CMS to consider the range of Part D net prices and/or ASPs (for a 30-day equivalent supply) of the therapeutic alternatives to the drug as the starting point, or (2027 cycle) the MFP for any selected Part D drug from the 2026 cycle, if applicable and the lower price. If there are no therapeutic alternatives, then CMS will consider the FSS or "Big Four" agency prices for the starting point. If these values are greater than the statutory ceiling price, then CMS will use the statutory ceiling price as the starting point for the initial offer.

3) Adjusting (Qualitatively) Based on Clinical Benefit: CMS to lead a literature review and integrate data from the public and from manufacturers on the drug and its therapeutic alternatives (if they exist), including but not limited to clinical, utilization, outcomes, access, equity, and experience data, as well as perspectives from clinicians, patients, patient organizations, and/or FDA – and consider whether the drug fills an unmet medical need or represents a therapeutic advance.

4) Adjusting (Qualitatively) Based on Consideration of Manufacturer-Specific Data: Manufacturers may report (1) R&D costs and cost recovery to date, (2) current unit production and distribution costs, (3) prior federal financial support for discovery/development, (4) pending or approved patents, exclusivities, and applications and approvals, and (5) market data (e.g., Commercial vs Medicare net prices) and revenue and sales volume data for the drug in the US for CMS consideration.

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Consideration #1: Increased Channel-Specific Management and Utilization of Negotiated Products

Triangle Insights has previously discussed indirect impacts of price negotiations on manufacturers, suggesting that negotiated drugs may place downward pricing pressure on competitors in the same market basket in both Commercial and Medicare channels.[3] However, the nature of the price differences and the overlap with other drug pricing provisions and policy updates is expected to create channel-specific challenges in contracting, management, and utilization. To understand these challenges, the following circumstances should be kept top of mind:

- The outcome of price negotiations with CMS (i.e., the MFP) is, in its simplest form, a list price reduction down in the range the net price(s) of the most clinically comparable therapeutic alternatives[2]
  - *This reduction is only applicable to Medicare (not Commercial) channel lives*
- Updates by CMS this year[14] to the allocation of direct and indirect remuneration (DIR) between payers and Medicare reinsurance may continue to incentivize high-list/high-rebate drug pricing, (as market access opinion leaders have previously noted)[15]
  - *Negotiated drugs may be in a disadvantaged position at baseline vs their competitors*
- Lower patient out-of-pocket cost, a common incentive to drive utilization of low-list/low-rebate drugs, is less able to incentivize their use due to Part D Redesign (i.e., the $2,000 annual cap)[1]
  - *Stakeholders have less incentive to use negotiated drugs over other competitors*

With these circumstances in mind, it becomes clear that a "tale of two channels" may emerge for negotiated products, where – absent additional contracting beyond the MFP – Medicare coverage and restrictions begin to diverge from those in the Commercial channel. With payers potentially incentivized to favor high-rebate competitors, and patients no longer incentivized to push for low-list price alternatives, it may be important for innovators to take a channel-specific approach to pricing and contracting following CMS price negotiations in their respective market baskets.

Key Takeaway: Manufacturers Should Increasingly Contract in a Channel-Specific Manner for Products Directly or Indirectly Affected by CMS Negotiated Pricing.

Consideration #2: Changing Biosimilar Market Dynamics Increase Channel-Specific Pressure on Negotiated Products

For highly-rebated, pharmacy benefit selected drugs such as Enbrel, the circumstances described in Consideration #1 may become all too real, as its key competitor, Humira, will likely be considered a most clinically comparable therapeutic alternative during the negotiation process.[11] Based on the timing of adalimumab biosimilar entry and competitive rebate responses for Humira (from ~40% in 4Q'22 to ~65% in 1Q'23) and Enbrel (from ~50% in 4Q'22 to ~75% in 1Q'23) suggested by certain analysts,[13] the MFP for Enbrel may represent a substantial reduction in effective list price in the Medicare channel, but may still be less of a discount than the biosimilar-competitive rebating for Humira. However, the circumstances become even more challenging for Enbrel when considering the rapid price erosion in the adalimumab market over the past year (80-85% reductions in list price).[12] Volume erosion has finally begun to emerge, with Cordavis' private-label adalimumab achieving nearly ~15% share in its first month (Figure 1)[21] since CVS removed brand Humira from its key formularies,[17] and other innovators beginning to join the private-label trend.[16] Therefore, following CMS price negotiations, Enbrel may find it challenging to drive new volume under either high-rebate (i.e., vs Humira brand; AbbVie has its own co-branded contract with Cordavis[21] and anticipates limited loss of volume in 2024[18]) or low-list (i.e., vs adalimumab biosimilars[12]) pricing strategies. With the channel-specific challenges from Consideration #1 combining with the market dynamics described above, innovators should be careful to evaluate how their products may compete following CMS price negotiations in evolving markets.

Key Takeaway: Manufacturers Should Prepare for Biosimilar Erosion and Evaluate the Ability for Negotiated Products to Compete.

Consideration #3: Payers Gain Valuable Pricing Benchmarks from CMS (and Potentially at the State Level) Regardless of Generic Entry for Selected Drugs

Relative surprises among the selected drugs were Farxiga and Stelara, two drugs for which generic entry is anticipated as early as 2025,[8,9] ahead of implementation of negotiated prices in 2026. Importantly, HHS has clarified their approach to Stelara in particular, suggesting that should a biosimilar ustekinumab launch in 2025, "Stelara will be deselected, and negotiated prices will

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never take effect."[10] Whether or not their negotiated prices (to be released in September 2024) take effect, they may still provide payers with important perspectives on the qualitative value (see Box 1) that CMS feels these drugs provide. As private payers in the US have struggled to implement true HTA-like evaluation processes in their coverage and management decision-making, this type of price-vs-value benchmarking may begin to build a foundation for acceptable approaches in the private market moving forward.

Such benchmarking extends down to the state level as well, with Colorado leading the way among approximately 17 other US states in developing legislation, pursuing affordability reviews, or establishing upper payment limits for drugs they consider to be unaffordable.[19] Moving forward, federal and state-level pricing determinations may become a foundational component of private payers' access and contracting decision-making, and innovators may need to increasingly and effectively convey value (e.g., in the case of CMS) and patient affordability (e.g., in the case of Colorado) in order to maintain robust access.

Key Takeaway: Manufacturers Should Prepare for Increasingly Value-Based Discussions with Private Payers as Federal and State-Level Price Benchmarking Begins to Take Hold.

Consideration #4: Robust Product Value Propositions May Add Protection Against Negotiated Pricing in the Near-Term

Though IRA is fundamentally a pricing policy, at its core it is a thorough evaluation of a product's value proposition (Box 1), weighing the clinical benefits and drawbacks of selected drugs against their most clinically comparable therapeutic alternatives.[2] Nowhere among the 10 selected drugs by CMS are the value propositions more dichotomous than between Januvia and Jardiance (we exclude Farxiga from the comparison herein based on the generic entry uncertainty described above). Compared to inexpensive and highly-utilized second-line generics in type 2 diabetes (e.g., sulfonylureas), it may be challenging for DPP-4 inhibitors like Januvia to show differentiable value to CMS negotiators, particularly when the class is considered less effective than sulfonylureas in glycemic management based on ADA guidelines (Figure 2).[20] By contrast, extensive clinical development and indication expansion over the years for key SGLT-2 inhibitors such as Jardiance have prepared it to potentially withstand competitor- and indication-specific challenges to its value proposition. While the specifics of CMS negotiations are still to be disclosed, innovators (particularly those with next-generation GLP-1 agonists in their portfolios) would do well to prepare broad-based and differentiated value propositions for their products to increase their ability to withstand future CMS negotiations.

Key Takeaway: Manufacturers Should Develop Broad-Based and Differentiated Value Propositions to Limit the Potential Impact of Price Negotiation.

Conclusions

While negotiated pricing for selected drugs represents a foundational achievement for CMS in seeking to curtail Medicare spending, innovators must remain conscious of the competitive considerations outlined above and their impact on contracting and portfolio strategy development. Together with the other drug pricing provisions, negotiated pricing is positioned over the next decade to have a negative effect on profitability unless careful attention is paid to adequately pricing novel assets at launch based on a robust value proposition. Together with the indirect impacts outlined previously by Triangle Insights,[3] IRA as a whole represents a multifaceted pricing and contracting challenge not just for the drugs selected for negotiation, but for competitors within the same market basket as well as products at risk for future selection by CMS.

Contact Triangle Insights to learn more about how we can support you in navigating an ever-evolving pricing and access landscape and refining your portfolio and pipeline strategies to flexibly respond to the evolving landscape.

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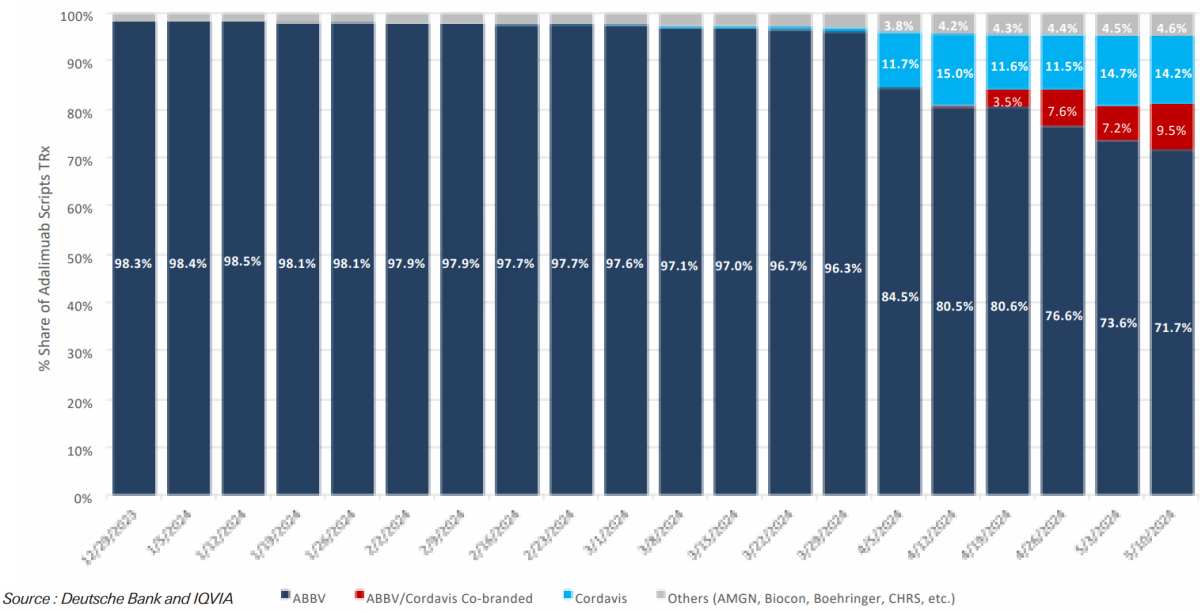
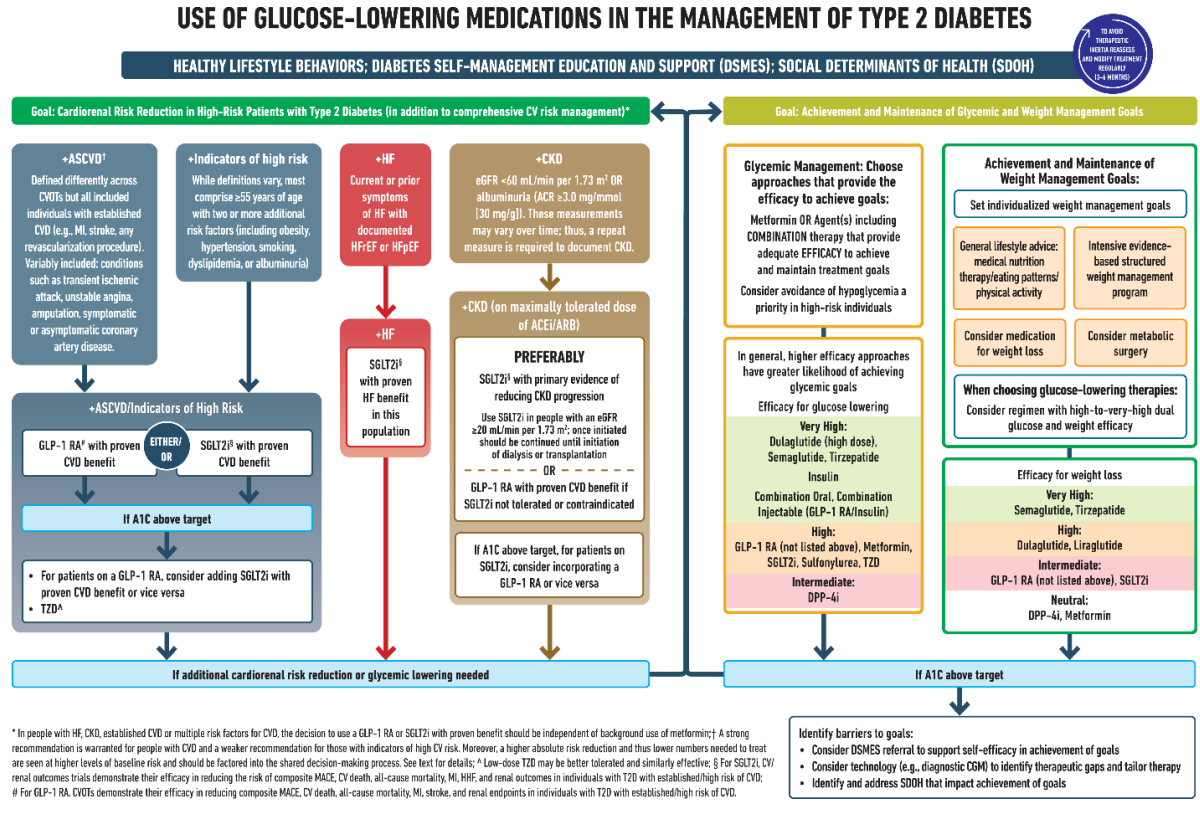
Figure 1: Humira (Adalimumab) TRx Market Share Breakdown (through mid-May 2024)



Source : Deutsche Bank and IQVIA

Figure 2: American Diabetes Association Type 2 Diabetes Treatment Guidelines (2023)



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