



Implications of the IRA's Maximum Fair Price (MFP) Negotiations: A Preliminary Analysis of Medicare Formulary Shifts

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MFP Formulary Impact Analysis

Background and Analysis Overview

Medicare Formulary Analysis Executive Summary

Objective: Outline how MFP-induced changes to pricing and rebate streams impact 2026 Medicare formularies, with a focus on the impact to MFP drugs, to understand initial implications and future MFP strategy

Key findings and implications:


- MFP discounts did not lead to large-scale coverage improvements for most drugs in the 2026 group of products
- Despite required coverage of MFP drugs, payers are willing to pick winners: Stelara and Enbrel disadvantaged to a biosimilar alternative; Jardiance behind step requirement for Farxiga (or its generic) at CVS
- However, multiple MFP drugs in the same class does not have to result in a winner, as demonstrated by parity coverage for Xarelto and Eliquis

Background on the IRA's MFP Negotiation Program

- The Inflation Reduction Act (IRA) was signed into law in August 2022, as an effort to reduce the federal government budget deficit including, but not limited to, efforts aimed at reducing in drug spend
- The IRA enables the Secretary of Health and Human Services (HHS) to negotiate a price for a select number of drugs each year for Medicare, beginning with 10 Part D drugs for 2026

Exhibit 1 below outlines the inclusion / exclusion criteria that are used to select the drugs that will be negotiated under this program

Drug Eligibility¹

-  To be considered for selection, must be a **single source drug**
-  At least **7 years since FDA approval** for small molecules, or **11 years since FDA licensure for biologics** and for which there is no generic or biosimilar competition
-  Ranked the 50 negotiation-eligible drugs according to **highest total gross covered prescription drug costs** under Medicare Part D

Exemption Policy²

-  "Low spend" drugs (**less than \$200 million of Medicare spending**)
-  **Orphan drugs**, defined as drugs with one designation and approval for a rare disease
-  **Plasma-derived biologic products** derived from human blood or plasma
-  The brand comprises 80% of the manufacturer's revenue in Medicare³ (exempt through 2028)

- In August 2023, the first 10 drugs were selected as part of the MFP program. As per the program roll-out plan, all are Part D (pharmacy benefit) drugs
- The discount rates (38%-79%) for these 10 Part D drugs was announced in August 2024 and will go into effect on January 1st, 2026. Additionally, MFP discounts coincide with the elimination of rebates on these MFP drugs
- **Supplementary Exhibits A & B** outline key details on these first 10 drugs in 2026, as well those selected as part of the 2027 class

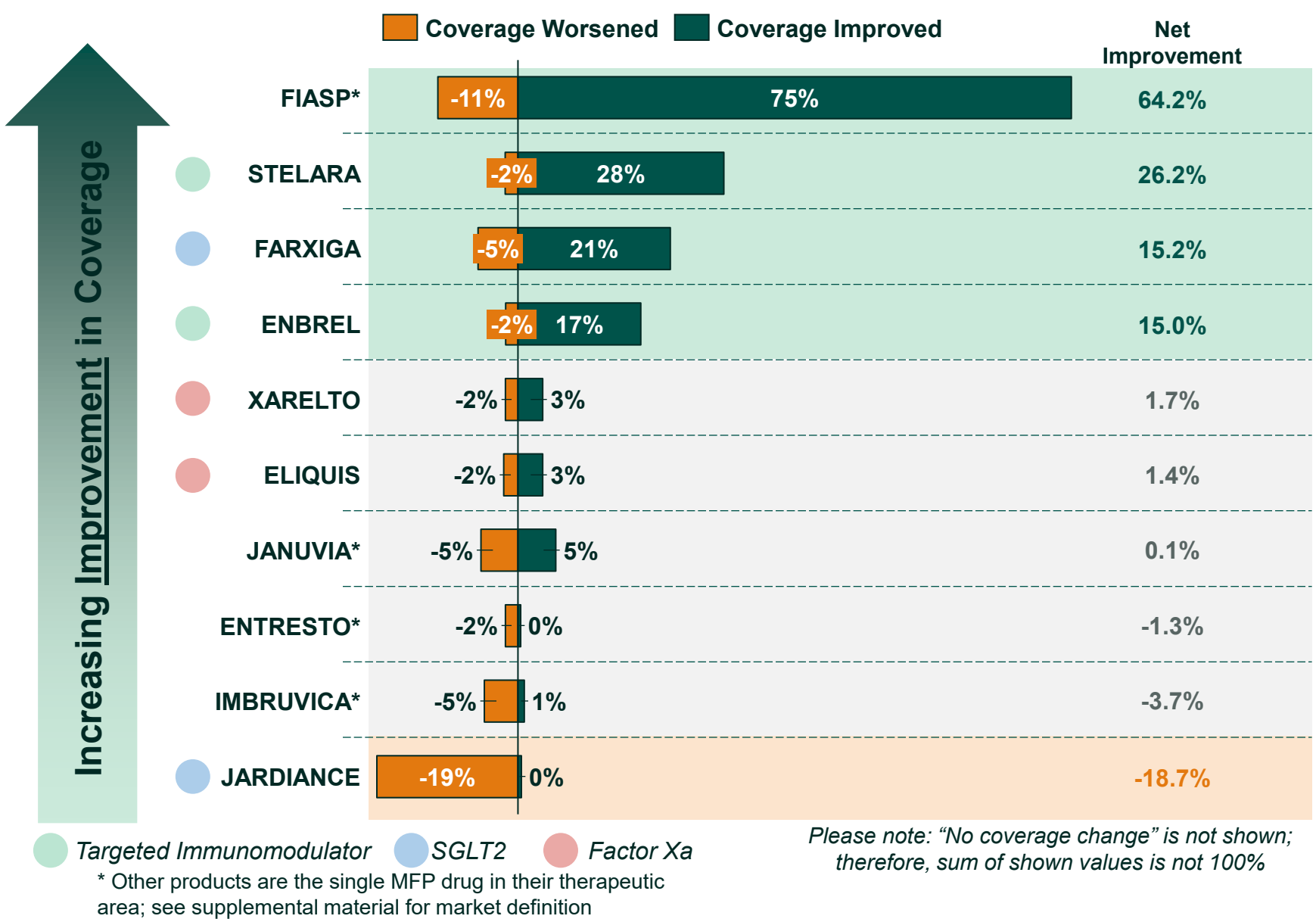
MFP Formulary Impact Analysis

MFP Drug Coverage Changes in 2026

First-Look View into MFP Drug Coverage Changes

- Weighted distributions of coverage changes between 2025 and 2026 were established based on enrolled lives and formulary changes:
- **No change** – No impact to formulary coverage, tier, or PA / ST status
- **Coverage Improved** – Move from not covered to covered, improved formulary tier (lower #), and/or elimination of PA / ST status¹
- **Coverage Worsened** – Opposite of ‘coverage improved’ [note: MFP drugs must be covered, per IRA requirement]

Exhibit 2: First-Look Formulary Coverage Trends Across 2026 MFP Drugs
(% of enrolled lives with coverage change)



Key Takeaways

- **4 of 10 MFP drugs see notable improvements**, with Fiasp, Stelara and Enbrel’s most common gains coming in the form of required coverage. Farxiga’s most common improvement is a shift from tier 4 to tier 3
- **5 of 10 MFP drugs remain nearly net neutral** (+/-4% of 2025 results)
- **Jardiance sees a notable worsening** in coverage moving into 2026, mostly driven by change of preferential status to parity coverage (Humana, Kaiser) or addition of ST restriction (CVS Caremark)

To understand the full impact, we must dive deeper and contextualize MFP drug coverage changes vs. the of their competitor set

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Defining the Competitor Market Basket

Objective: Given that impact to patients can be defined only partially by the **absolute** change (or lack thereof) in coverage tier and restrictions (*Exhibit 2*), the Hayden team evaluated further by defining access change **relative** to competitors to uncover preferences in formulary design

Exhibit 3: Defining MFP Drug Coverage Classifications within the Market Basket

- In order to understand the relative change in coverage across MFP drugs as compared to their competitive market basket, a coverage classification for each MFP drug in each of 2025 and 2026 was assigned
 - Supplementary Exhibit A details the market baskets assessed for each drug in the 2026 MFP class
- The YoY change in these coverage labels provides a deeper view into the full implications of the impact of MFP negotiations on formulary strategy

| Classification | Definition |
|-----------------------------|--|
| MFP drug picked for leader | The MFP drug has the best coverage in the market basket, and does not share this with others |
| MFP drug in preferred class | The MFP drug shares top coverage status with at least one other drug in the market basket |
| All at parity | At parity to competitors that are covered in the market basket |
| MFP drug non-preferred | There is at least one other competitor with a better coverage position than the MFP drug |
| MFP drug not covered | MFP drug is not covered on formulary |

To classify the YoY differences across 2026 MFP drugs' coverage classifications, results were grouped into 3 distinct buckets:

- Coverage Improved – 2026 classification **better** than 2025 classification
- Coverage Worsened – 2026 classification **worse** than 2025 classification
- Neutral – 2026 classification is equal to the 2025 classification



The next page outlines the distribution of the 10 2026 MFP drugs across these groupings

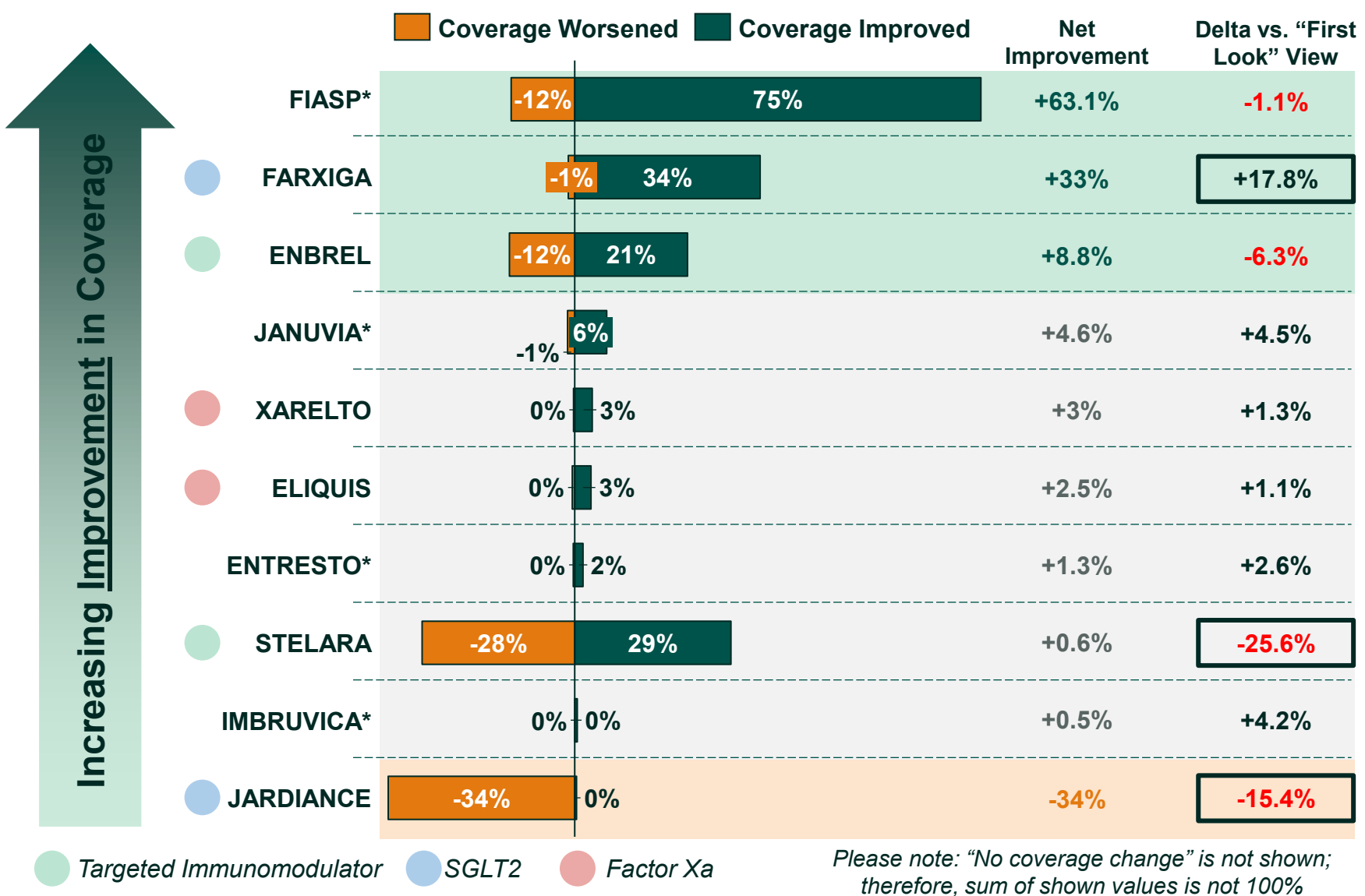
Note: Hayden assessed existence of published PA / ST requirements, not their extent of restrictiveness; Sources: Medicare Part D formulary data, published September 2025 (2025 coverage) and October 2025 (2026 coverage); Medicare enrolled lives based on data published October 2025; Hayden Research & Analysis (Q4 2025)

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Market Basket View of MFP Drug Changes

Considering relative coverage to competitor drugs unearths a fuller picture of the MFP impact, and notably different results for Stelara, Farxiga and Jardiance

Exhibit 4: Competitive Positioning Formulary Trends Across 2026 MFP Drugs (% of enrolled lives with coverage change)



Supplementary Exhibit C outlines the detailed year over year coverage classifications by product that inform this chart

Despite being MFP drugs, Stelara and Enbrel are both disadvantaged to biosimilars by many payers

- Stelara and Enbrel primarily remain T5 PA YoY; both gained access where previously not covered (Exhibit 2 and supplemental material for more detail)
- Both suffered a decline in competitive positioning, with biosimilar Yesintek often preferred (T3 PA) for its sub-MFP discount price point, resulting in Stelara and Enbrel as non-preferred for ~75% of lives in 2026

While most plans have Jardiance and Farxiga at parity, CVS has Jardiance disadvantaged to Farxiga

- 21% of lives see an improved tiering for Farxiga, shifting from T4 to T3 (Exhibit 2); these mostly improve competitive position to parity to Jardiance
- Simultaneously, Jardiance coverage worsens for 19% of lives (Exhibit 2), led by CVS adding a step requirement to try Farxiga or its generic, dapagliflozin; see supplemental material for detailed market shifts

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Conclusions, Questions & Areas to Watch

Key Analysis Learnings

MFP discounts do not lead to large-scale coverage improvements for most drugs in the 2026 class

- When formulary changes of competitors are considered, 6 of 10 MFP drugs have a net improvement across <5% of lives

Payers are **willing to pick biosimilar winners**, like Yesintek, a Stelara biosimilar, over MFP brands Stelara and Enbrel

- In this case, payers are likely preferring Yesintek for its sub-Stelara / Enbrel MFP discounted price point
- Continued evidence that payers are willing to prefer lower cost biosimilars may be critical to preserve future biosimilar investment

Payers are also **willing to pick winners amongst MFP brands**, such as Farxiga being advantaged over Jardiance at some CVS plans

Conversely, Eliquis and Xarelto remaining at near full parity demonstrates that **having 2 MFP drugs in a given class does not have to result in a winner**

Possible Future Questions to Explore

- How much of the competitive positioning changes noted were **driven by a select few payers vs. a broad set?** How consistent at the plan-level?
- How, if at all, do payer **enrollment distributions** (e.g., PDP vs. MAPD vs. EGWP vs. SNP / LIS lives) **correlate with formulary changes made?**
- What impact will MFP discounts and formulary changes have on **drug utilization and market share in 2026?**

Areas to Watch in 2026 and 2027

- **2026 MFP drugs taking WAC pricing decreases** as MFP discounts kick in that impact non-Medicare business (e.g., Fiasp, Farxiga, Jardiance, etc.)¹
- **GLP-1s:** Overlapping impact of 2027 MFP discounts and recent Most Favored Nation (MFN) deals resulting in price cuts
- **How MFP negotiations may evolve with greater oncology exposure** (Xtandi, Pomalyst, Ibrance and Calquence joining Imbruvica in 2027, and Part B drugs eligible for negotiation starting in 2028)
- **Expansion of classes with multiple MFP drugs** (Otezla joining Stelara / Enbrel; Calquence joining Imbruvica; Tradjenta joining Januvia, Trelegy and Breo Ellipta both negotiated for 2027)
 - 2026 learnings with Farxiga and Jardiance suggest that we should be on watch for payers taking this approach elsewhere with multiple MFP drugs

Access Forward

M

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Supplementary Exhibit A

Overview of 2026 MFP Drugs and Discount Levels

| Drug | MFP Discount (%) ¹ | Key Indications ¹ (non-exhaustive) | Modeled Competitors ² |
|-----------|-------------------------------|--|--|
| Januvia | 79% | Diabetes | Actos, Brynovin, Nesina, Onglyza, Tradjenta, Zituvio |
| Fiasp | 76% | Diabetes | Admelog, Apidra, Humalog, Kirsty, Lyumjev, Merilog, Novolog |
| Farxiga | 68% | Diabetes; Heart failure; Chronic kidney disease | Brenzavvy, Dapagliflozin, Inpefa, Invokana, Jardiance, Steglatro |
| Enbrel | 67% | Rheumatoid arthritis, Psoriasis, Psoriatic arthritis | Abrilada, Actemra, Amjevita, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Imuldosa, Inflectra, Orencia, Otezla, Otulfi, Pyzchiva, Remicade, Rinvoq, Rituxan, Selarsdi, Simlandi, Simponi, Skyrizi, Sotyktu, Stelara, Steqeyma, Taltz, Tremfya, Wezlana, Xeljanz, Yesintek, Yuflyma, Yusimry |
| Jardiance | 66% | Diabetes; Heart failure; Chronic kidney disease | Brenzavvy, Dapagliflozin, Farxiga, Inpefa, Invokana, Steglatro |
| Stelara | 66% | Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis | Abrilada, Amjevita, Cimzia, Cosentyx, Cyltezo, Enbrel, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Imuldosa, Inflectra, Omvoh, Otezla, Otulfi, Pyzchiva, Remicade, Rinvoq, Selarsdi, Simlandi, Simponi, Skyrizi, Sotyktu, Steqeyma, Taltz, Tremfya, Wezlana, Yesintek, Xeljanz, Yuflyma, Yusimry |
| Xarelto | 62% | Prevention & treatment of blood clots; Reduction of risk for coronary or peripheral artery disease | Eliquis, Pradaxa, Savaysa |
| Eliquis | 56% | Prevention and treatment of blood clots | Pradaxa, Savaysa, Xarelto |
| Entresto | 53% | Heart failure | Bidil, Corlanor |
| Imbruvica | 28% | Blood cancers | Brukinsa, Calquence, Jakafi, Jaypirca |

MFP Formulary Impact Analysis

Supplementary Exhibit B

Overview of 2027 MFP Drugs and Discount Levels

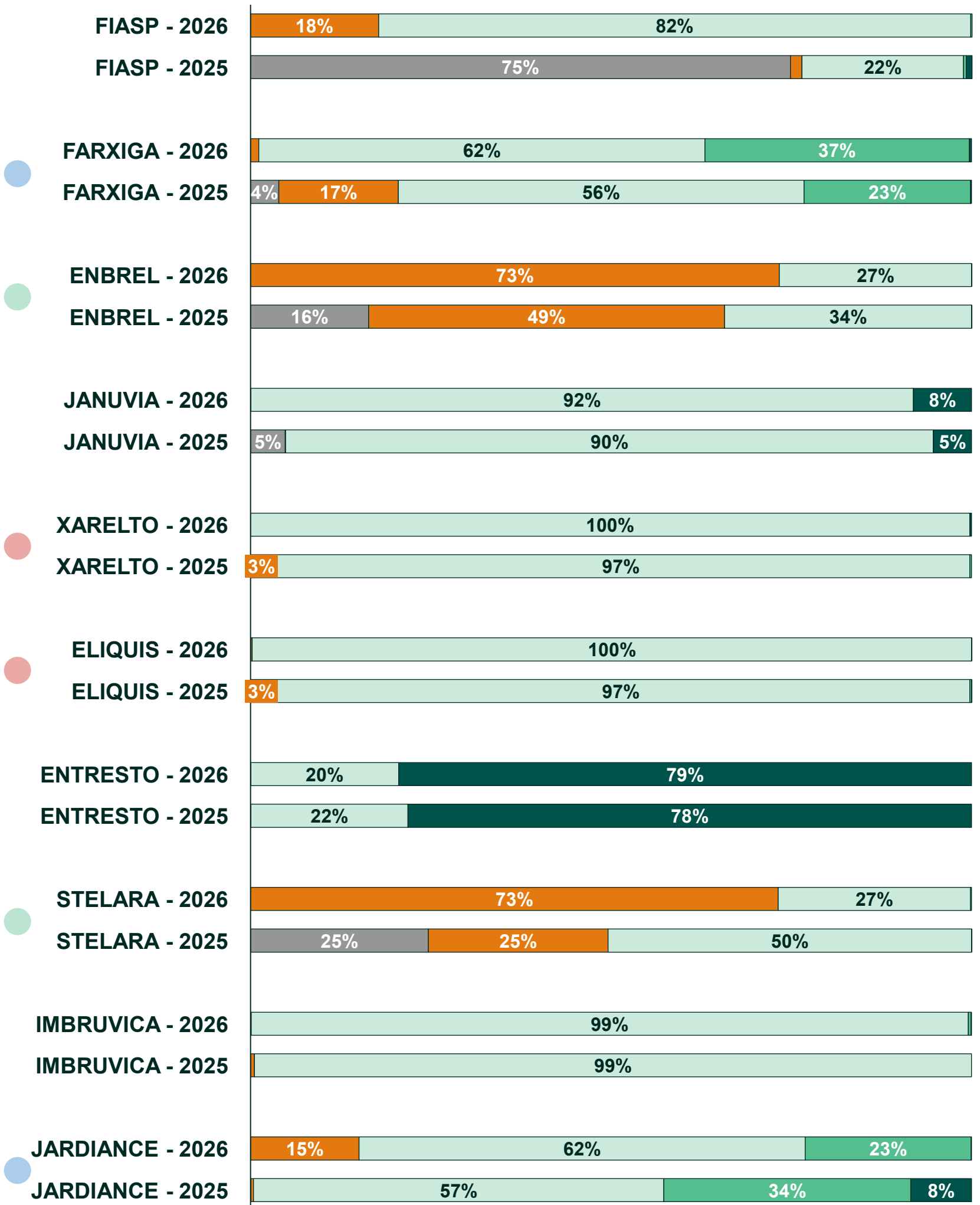
| Drug | MFP Discount (%) ¹ | Key Indications ¹ (<i>non-exhaustive</i>) | Competitor Overlap with 2026 / 2027 MFP Drugs |
|---------------------------------|-------------------------------|--|--|
| Ozempic; Rybelsus; Wegovy | 71% | Type 2 diabetes; Type 2 diabetes and cardiovascular disease; Obesity/overweight and cardiovascular disease | <i>None</i> |
| Trelegy Ellipta | 73% | Asthma; Chronic obstructive pulmonary disease | Breo Ellipta (2027) |
| Xtandi | 48% | Prostate Cancer | <i>None</i> |
| Pomalyst | 60% | Kaposi sarcoma; Multiple myeloma | <i>None</i> |
| Ofev | 50% | Idiopathic pulmonary fibrosis | <i>None</i> |
| Ibrance | 50% | Breast Cancer | <i>None</i> |
| Linzess | 75% | Chronic idiopathic constipation; Irritable bowel syndrome with constipation | <i>None</i> |
| Calquence | 40% | Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma | Imbruvica (2026) |
| Austedo; Austedo XR | 38% | Chorea in Huntington's disease; Tardive dyskinesia | <i>None</i> |
| Breo Ellipta | 83% | Asthma; Chronic obstructive pulmonary disease | Trelegy Ellipta (2027) |
| Xifaxan | 63% | Hepatic encephalopathy; Irritable bowel syndrome with diarrhea | <i>None</i> |
| Vraylar | 44% | Bipolar I disorder; Major depressive disorder; Schizophrenia | <i>None</i> |
| Tradjenta | 84% | Type 2 diabetes | Januvia (2026) |
| Janumet; Janumet XR | 85% | Type 2 diabetes | <i>None</i> |
| Otezla | 65% | Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis | Stelara & Enbrel (2026) |

MFP Formulary Impact Analysis

Supplementary Exhibit C

Results for 2026 MFP Drugs

Detailed Year over Year Changes to Relative Competitive Positioning (Percent of Enrolled Lives)



Legend

- MFP not covered
- All at parity
- MFP picked for leader
- MFP drug non-preferred
- MFP in preferred class

● Targeted Immunomodulator ● SGLT2 ● Factor Xa

* Other products are the single MFP drug in their therapeutic area; see Supplementary Exhibit A

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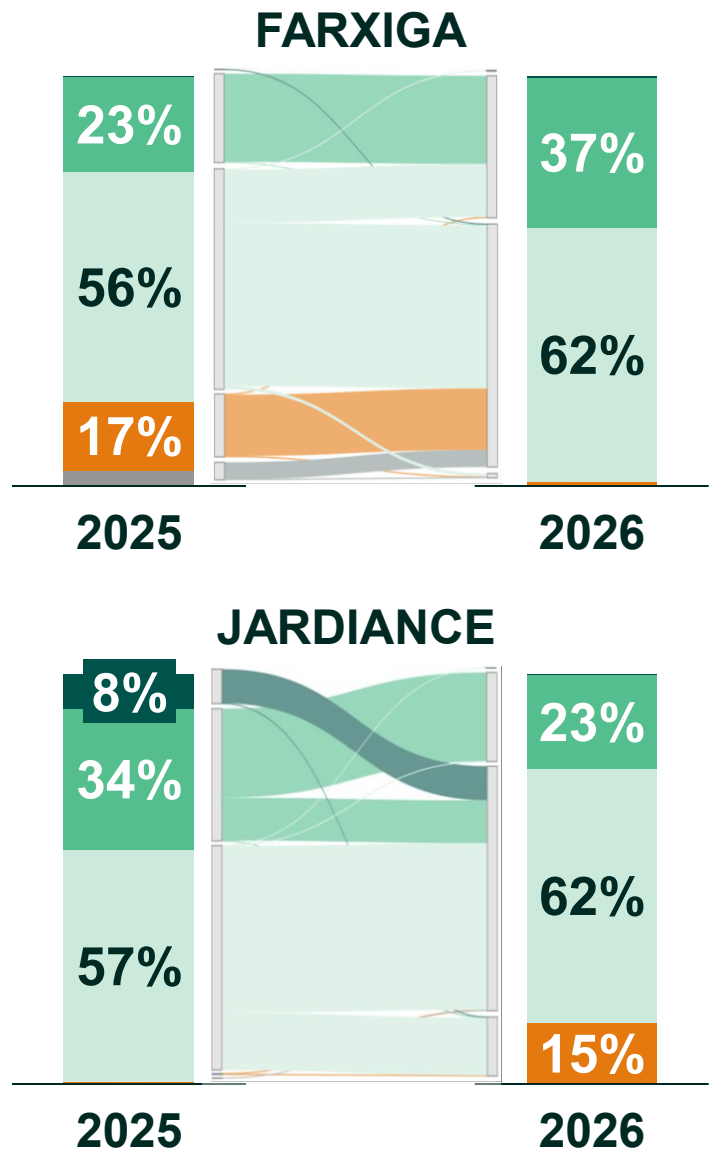
MFP Formulary Impact Analysis

Supplementary Exhibit D

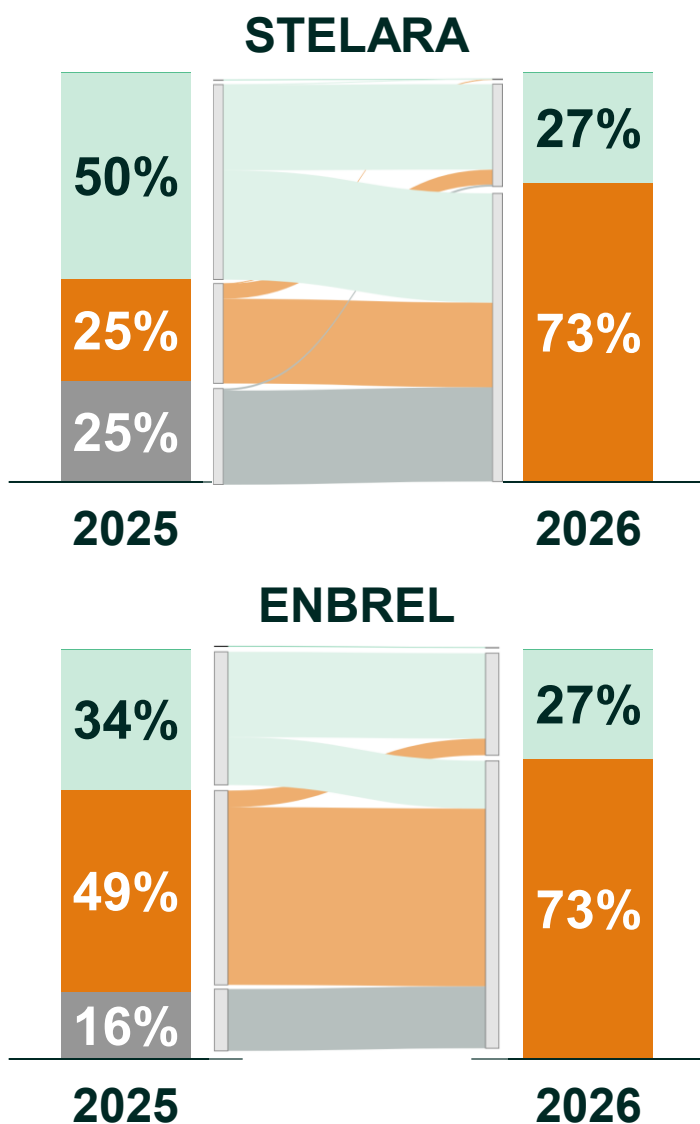
Year over Year Coverage Changes by Enrolled Lives, for Select Markets

SGLT2 Market

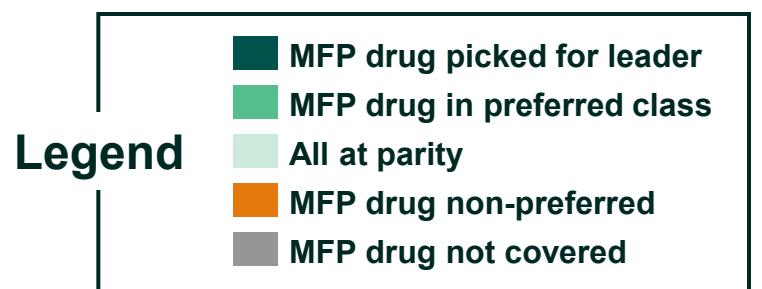
- FARXIGA gains ground at the expense of JARDIANCE in the SGLT2 race
- Market basket includes Invokana, which has coverage at some payers but did not change access for most payers (if it was covered in 2025)
- Among payers who implemented a change in SGLT2 access:
 - Humana: All at parity in 2026, moving from 2025 coverage of Jardiance preferred and Farxiga non-preferred
 - CVS Caremark: parity in 2025; Jardiance has ST added in 2026, thus moving it to non-preferred tier and making Farxiga a preferred product. ST requirement is to try dapagliflozin (branded or generic Farxiga)
 - Kaiser: Jardiance loses solo coverage status; Farxiga moves from Not Covered to All at Parity



Autoimmune market



- STELARA & ENBREL have similar trajectories in the transition from 2025 to 2026 and MFP status:
 - 2025 access mix predominantly includes parity, non-preferred tier, or not covered
 - 2026 positioning is more homogenous, with most payers placing the MFP drugs in non-preferred tier or at market parity
- In 2026, the preferred competitor is often a biosimilar, typically Yesintek (Biocon Biologics) or – less commonly – Selarsdi (Alvotech)



MFP Formulary Impact Analysis

Supplementary Exhibit E



Overview of Evaluation Methodology

Snapshots of Formulary, Plan, and Mapping Files

| contract_id | plan_id | formulary_id | contract_name | segment_id | premium | deductible | plan_name |
|-----------------|--------------|---------------------------------|--------------------------|------------------------|-----------------|------------|------------|
| S5820 | 034 | 00026000 | UNITEDHEALTHCARE | 0 | 0 | 615 | AARP Medic |
| contract_number | plan_id | plan_type | parent_organization | eghp_flag | snp_flag | | |
| S5820 | 034 | Medicare Prescription Drug Plan | UnitedHealth Group, Inc. | 0 | 0 | | |
| contract_year | formulary_id | ndc | tier_level_value | prior_authorization_yn | step_therapy_yn | | |
| 2026 | 00026000 | 00006503001 | 3 | Y | N | | |
| 2026 | 00026000 | 00006508501 | 5 | Y | N | | |
| 2026 | 00026000 | 00006508601 | 5 | Y | N | | |
| 2026 | 00026000 | 00006508701 | 5 | Y | N | | |

Raw Data from CMS

Preparation and Analysis Methods



Zoom in

Isolate NDCs of interest based on market basket for each MFP drug



Find the signal among the noise

- Convert highly granular data by NDC (National Drug Code) into aggregated coverage status by brand for each plan
- Identify brands with no coverage based on absence from the data



Measure the impact

Connect across data sets to improve reporting

- Weight plans by enrolled lives to highlight patient experience associated with coverage details and changes
- Include contract details (parent organization, plan information, PDP vs MAPD, and more) to enable deep dives into underlying trends



Study the details

Condense data into a concise access summary for each MFP drug to enable scoring and reporting

Coverage for Mock Organization ABC Plan 001: SGLT2 Market

| | 2025 | 2026 |
|---------------------------------|--|---|
| Coverage | <ul style="list-style-type: none"> • Tier 3: Farxiga, Jardiance | <ul style="list-style-type: none"> • Tier 3: Farxiga, dapagliflozin • Tier 3 ST: Jardiance |
| Relative Access for MFP Drug(s) | <ul style="list-style-type: none"> • Farxiga: All at parity • Jardiance: All at parity | <ul style="list-style-type: none"> • Farxiga: MFP drug in preferred class • Jardiance: MFP drug non-preferred |
| Year over Year Comparison | <ul style="list-style-type: none"> • Farxiga: <ul style="list-style-type: none"> • No change in actual formulary coverage • Better relative access positioning • Jardiance <ul style="list-style-type: none"> • Worse actual access (step restriction added) • Worse relative access positioning | |

Summary and Scoring

Key Sources

- Medicare Part D formulary data, published September 2025 (2025 coverage) and October 2025 (2026 coverage)
- Medicare enrolled lives based on data published October 2025