



What is New This Year, and How Will the IRA Continue to Affect Patient Access

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a medical knowledge group company

Magnolia Market Access: Today's Speakers



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Agenda

2024

- CMS releases negotiation summaries
- Part D spend shows impact of IRA

2025

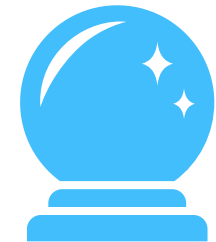
- PDP formulary impact of IRA
- Part D \$2000 Max. OOP takes effect
- IPAY27 drugs identified
- Manufacturer lawsuits
- New Administration

2026-27

- IPAY26 takes effect
- IPAY28 & IPAY29 drugs identified
- Legislative or regulatory changes?
- New patient protections?

Crystal Ball

- Universal healthcare?
- Medicare for all?
- EU-style access changes?



December 2024: CMS Release of IPAY26 Negotiation Details

Process and Outcome of Negotiations

CMS and manufacturer “reached agreement” on MFP for **5/10** drugs
- for **4/5** CMS accepted a revised manufacturer counteroffer following negotiation discussions

For the remaining 5 drugs, CMS sent a final written offer and manufacturers accepted by the deadlines

Discounts off list price range from 38% to 79%

Immediate Impact of Negotiations

Patients expected to save \$1.5B in 2026, with total savings of \$6B if in effect in 2023

News outlets reporting:

- Prices as “not so bad”,
- “Still more than 2 times higher than other countries”, with a 30-day supply of nine of the 10 drugs costing \$17,581 for Medicare in 2026, compared with \$6,725 in Sweden this year

Patients expected to save \$1.5B in 2026, Manufacturer Jan. 1 price increases not notably different than previous 5 years total savings of \$6B if in effect in 2023

January 2025: IPAY 2027 Drug List

Drug Name	Commonly Treated Conditions	Total Part D Gross Covered Prescription Drug Costs from 11/23-10/24 (rounded)	Number of Medicare Part D Enrollees Who Used the Drug from November 2023 - October 2024
Ozempic; Rybelsus; Wegovy	Type 2 diabetes; Type 2 diabetes and cardiovascular disease; Obesity/overweight and cardiovascular disease	\$14.4B	2,287,000
Trelegy Ellipta	Asthma; Chronic obstructive pulmonary disease	\$5.1B	1,252,000
Xtandi	Prostate cancer	\$3.2B	35,000
Pomalyst	Kaposi sarcoma; Multiple myeloma	\$2.1B	14,000
Ibrance	Breast cancer	\$2B	16,000
Ofev	Idiopathic pulmonary fibrosis	\$2B	24,000
Linzess	Chronic idiopathic constipation; Irritable bowel syndrome with constipation	\$2B	627,000
Calquence	Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma	\$1.6B	15,000
Austedo; Austedo XR	Chorea in Huntington's disease; Tardive dyskinesia	\$1.5B	26,000
Breo Ellipta	Asthma; Chronic obstructive pulmonary disease	\$1.4B	634,000
Tradjenta	Type 2 diabetes	\$1.1B	278,000
Xifaxan	Hepatic encephalopathy; Irritable bowel syndrome with diarrhea	\$1.1B	104,000
Vraylar	Bipolar I disorder; Major depressive disorder; Schizophrenia	\$1.1B	116,000
Janumet; Janumet XR	Type 2 diabetes	\$1.1B	243,000
Otezla	Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis	\$1B	31,000

2025: Navigating IRA Drug Price Negotiation: 5 Compass Points for Success

Therapeutic Alternatives

What will CMS choose as your TA and what do you want it to be?

Evidence Diversity

Do you currently have compelling evidence in Medicare populations?

Human Resources Planning

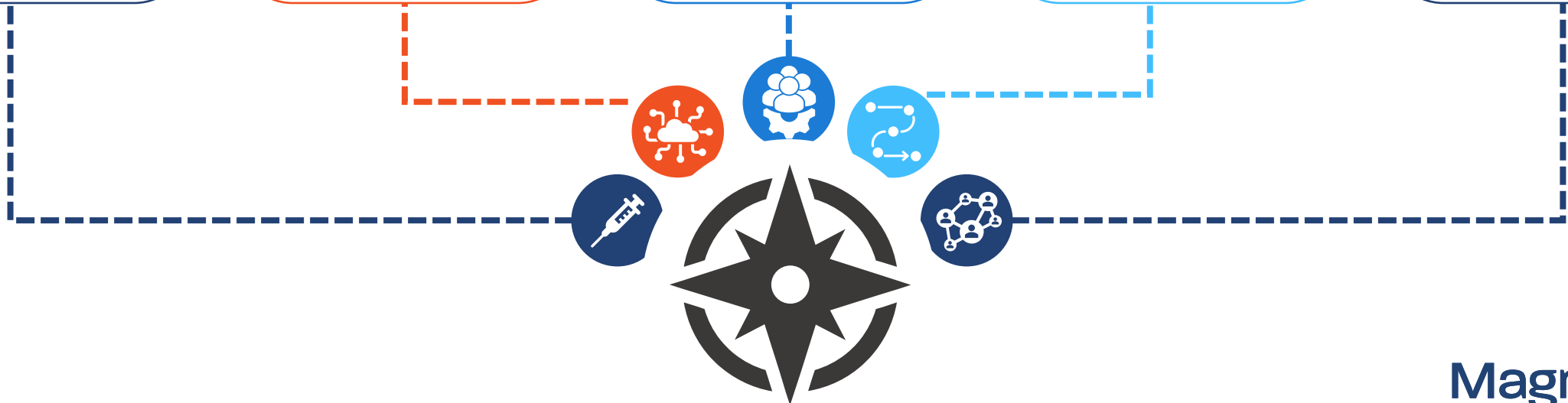
Has your organization implemented the right cross-functional team for optimized effort from submission through negotiation?

End-to-End Strategic & Tactical Alignment

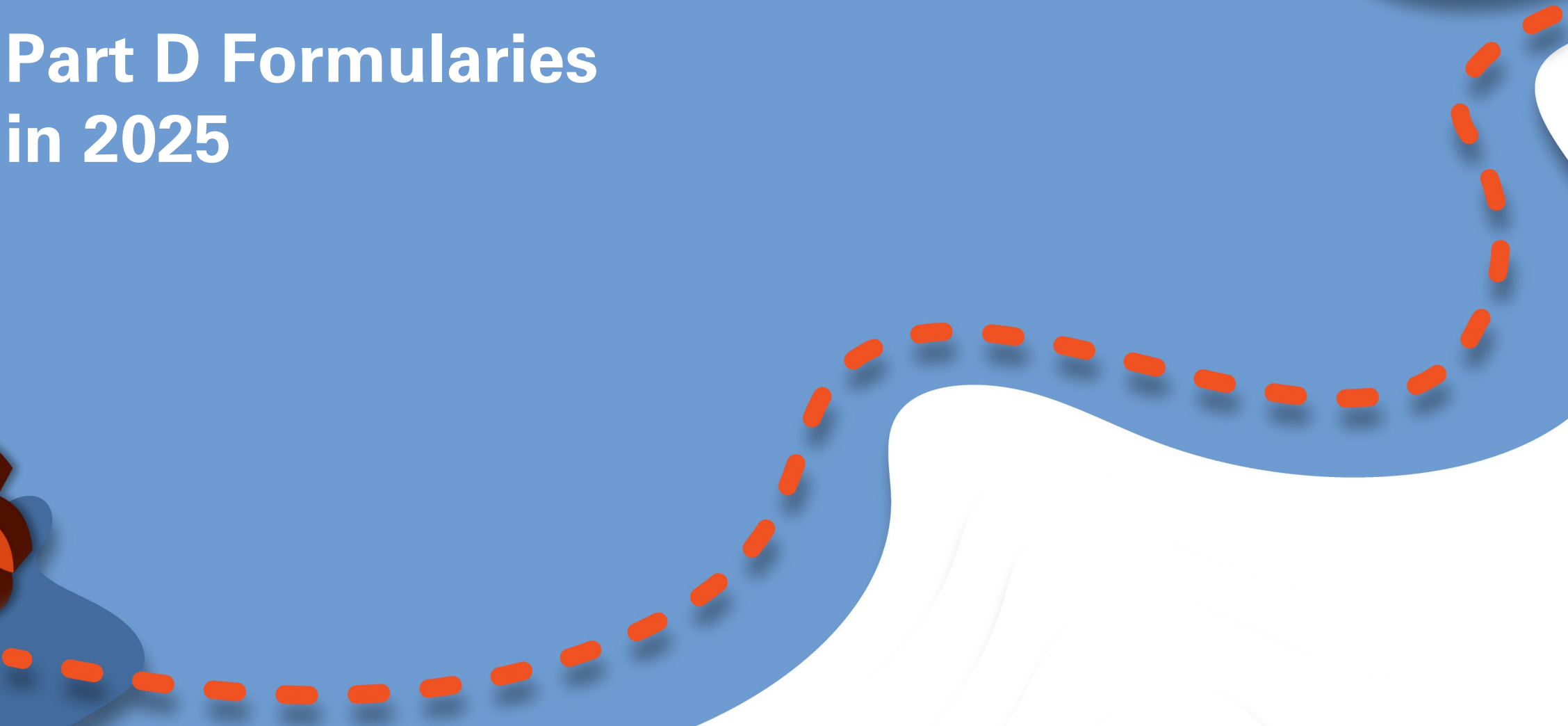
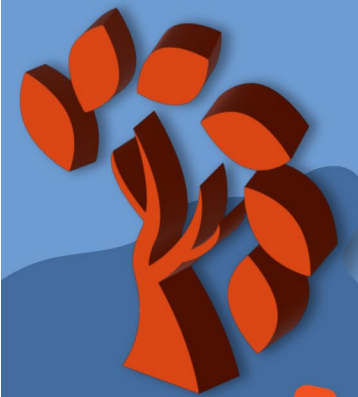
Does your organization have a clear roadmap to get from CMS drug selection announcement all the way through MFP publication?

Comprehensive Ecosystem Strategy

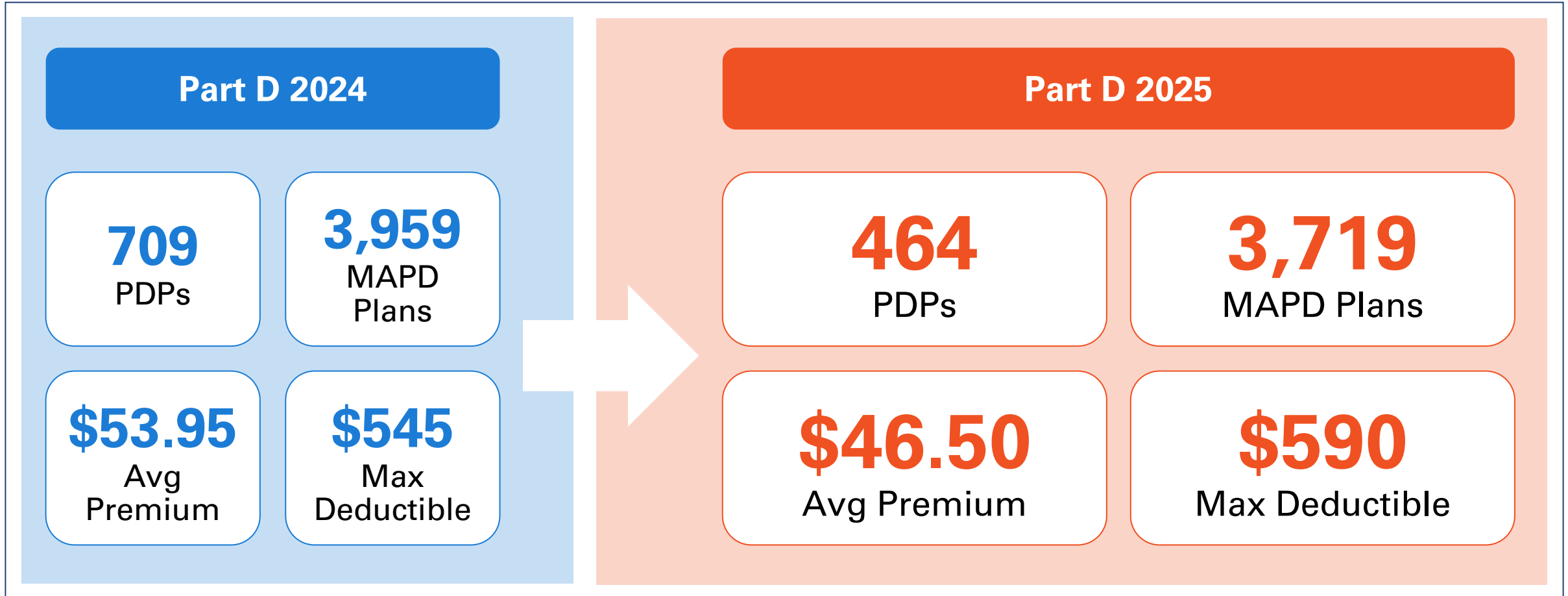
Have you considered your engagement and management plan for marketplace stakeholders (e.g., payers, advocacy orgs, industry groups, etc.)?



Part D Formularies in 2025



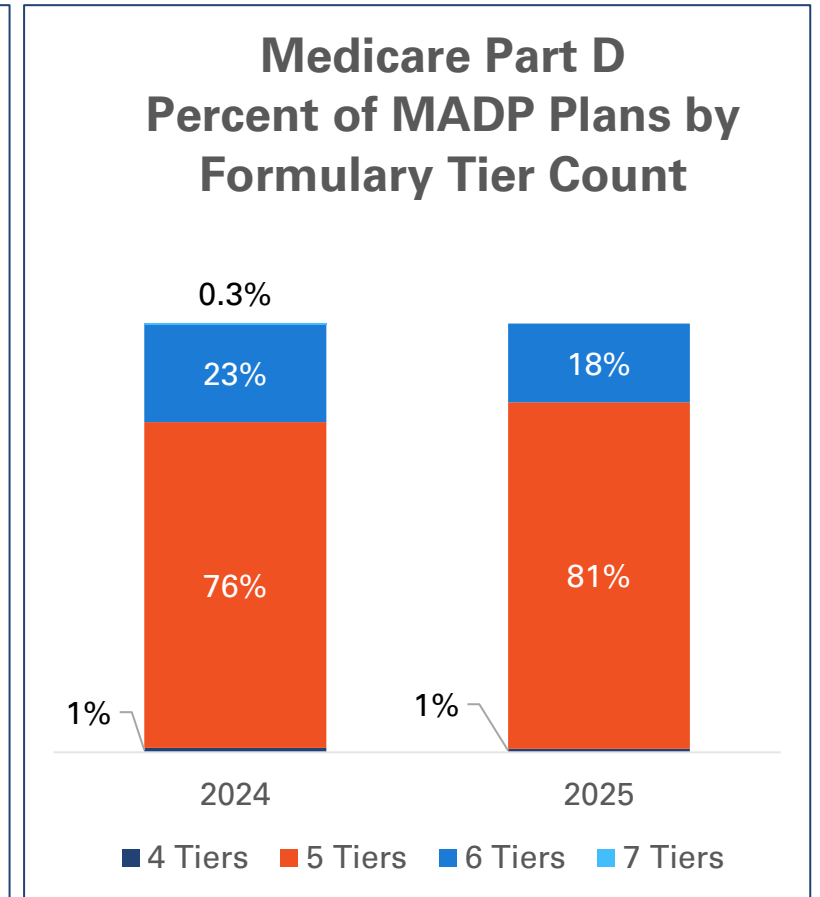
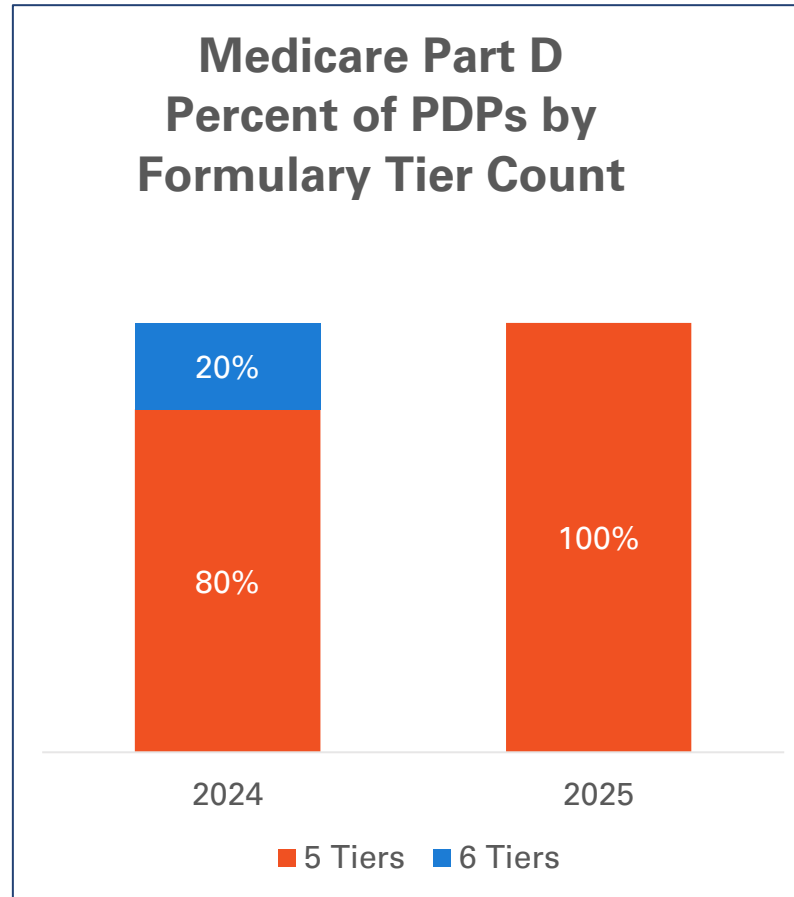
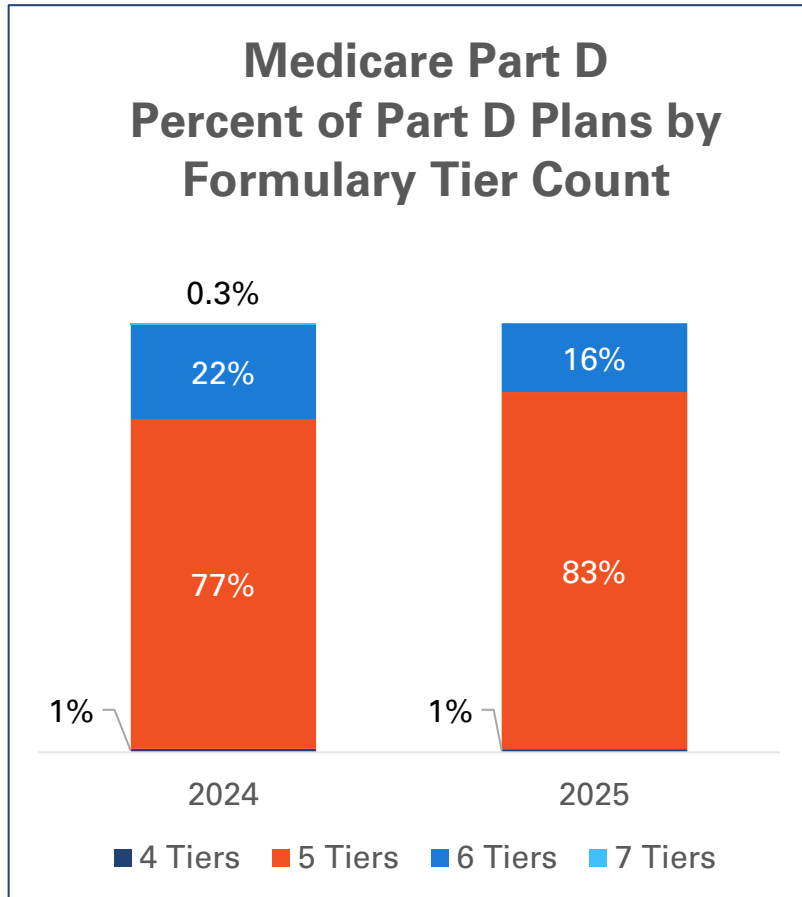
2025: What is Changing with Part D Formularies?



Medicare Landscape Files. 2024-2025. <https://www.cms.gov/medicare/coverage/prescription-drug-coverage>.

Medicare Advantage and Medicare Prescription Drug Programs Fact Sheet. 2025. <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-medicare-prescription-drug-programs-remain-stable-cms-implements-improvements>

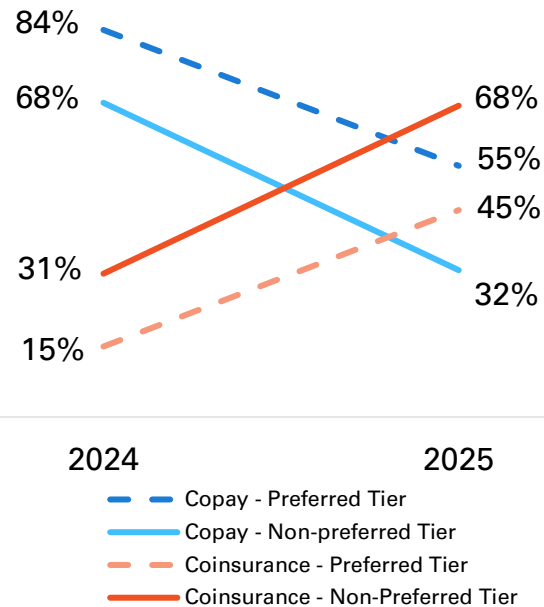
There was an Overall Increase in Plans Moving from a 6-tier to 5-tier Formulary; Plans Removed an “Other” Tier in These Instances



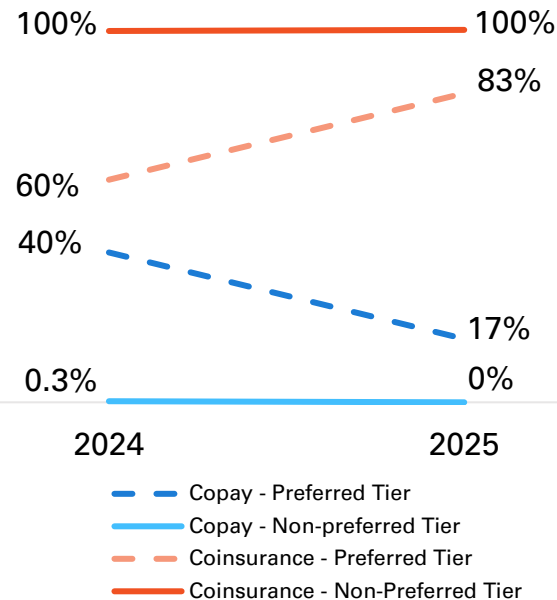
NOTE: This analysis and all other this point forward excludes PACE, Special Needs Plans, Part B Only Plans, and Employer sponsored plans
 “Other” tier includes Other Drug, Non-Medicare Rx/OTC Drugs, Select Care Drugs, Non-Medicare Rx Drugs, Non-Medicare OTC Drugs, Vaccines, Select Diabetic Drugs, Supplemental Drugs, and \$0 Drugs
 Medicare Monthly Prescription Drug Plan Formulary and Pharmacy Network Information. CY 2024 and CY 2025. <https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/monthly-prescription-drug-plan-formulary-and-pharmacy-network-information>

There was a Significant Shift from Copay to Coinsurance in Part D Preferred and Non-preference Drug Tiers

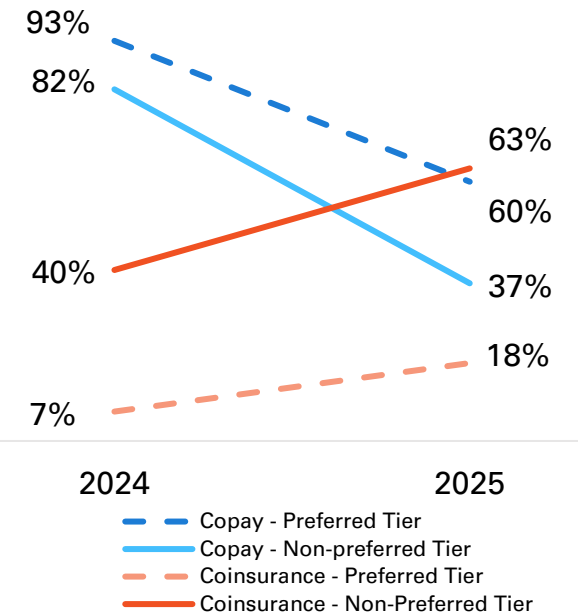
Medicare Part D Percent of Part D Plans by Cost Share Type



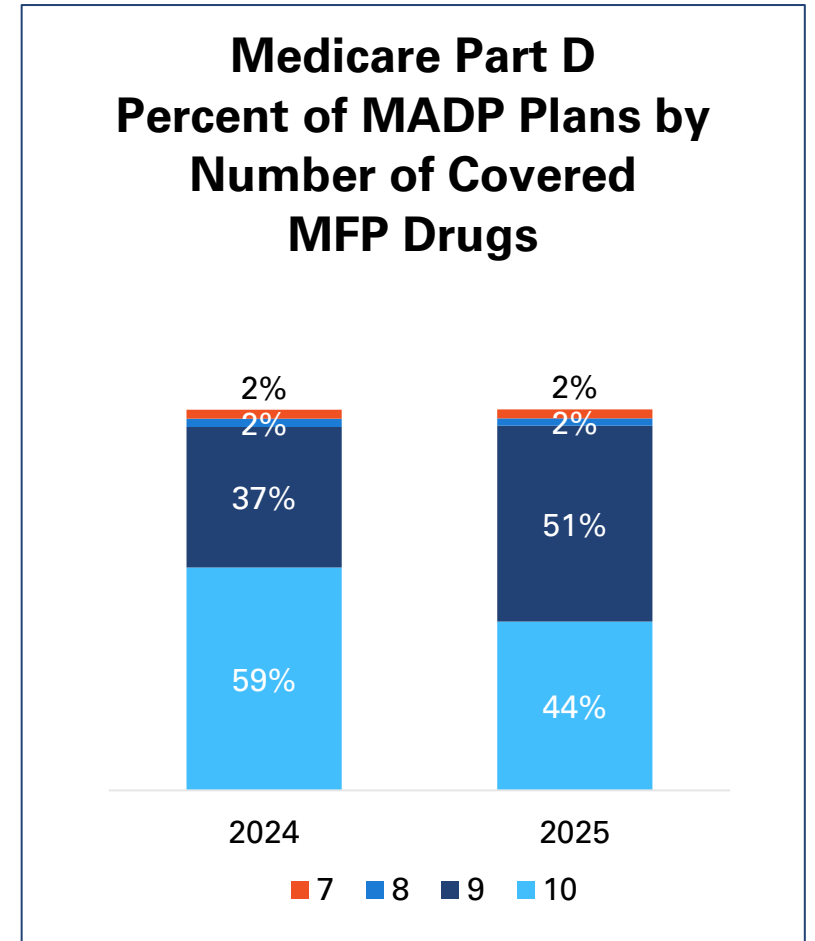
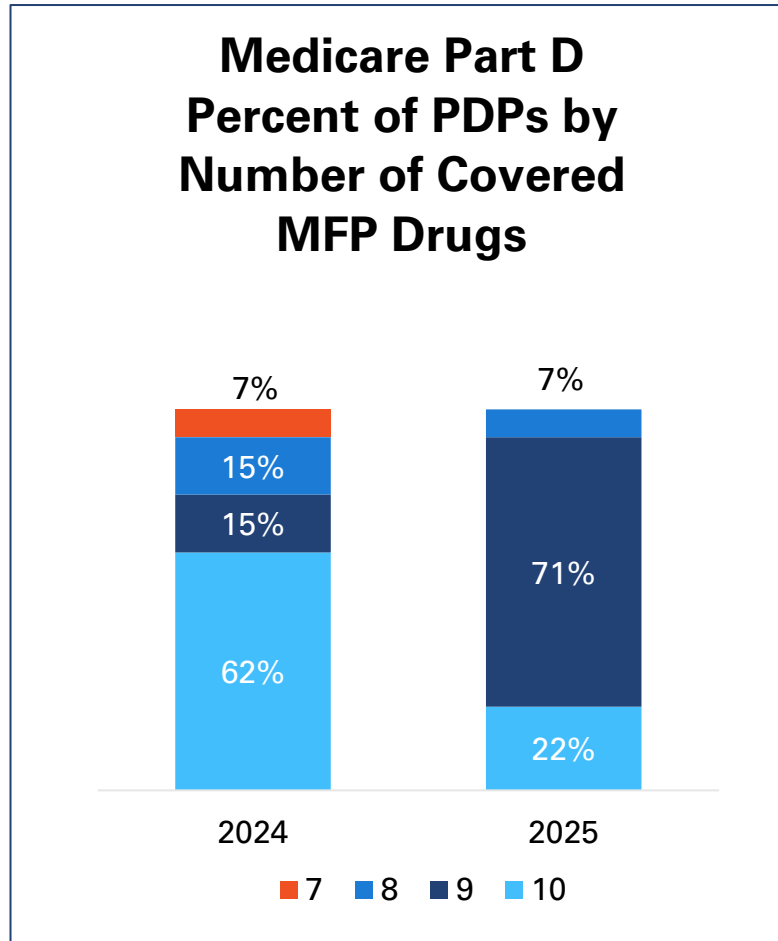
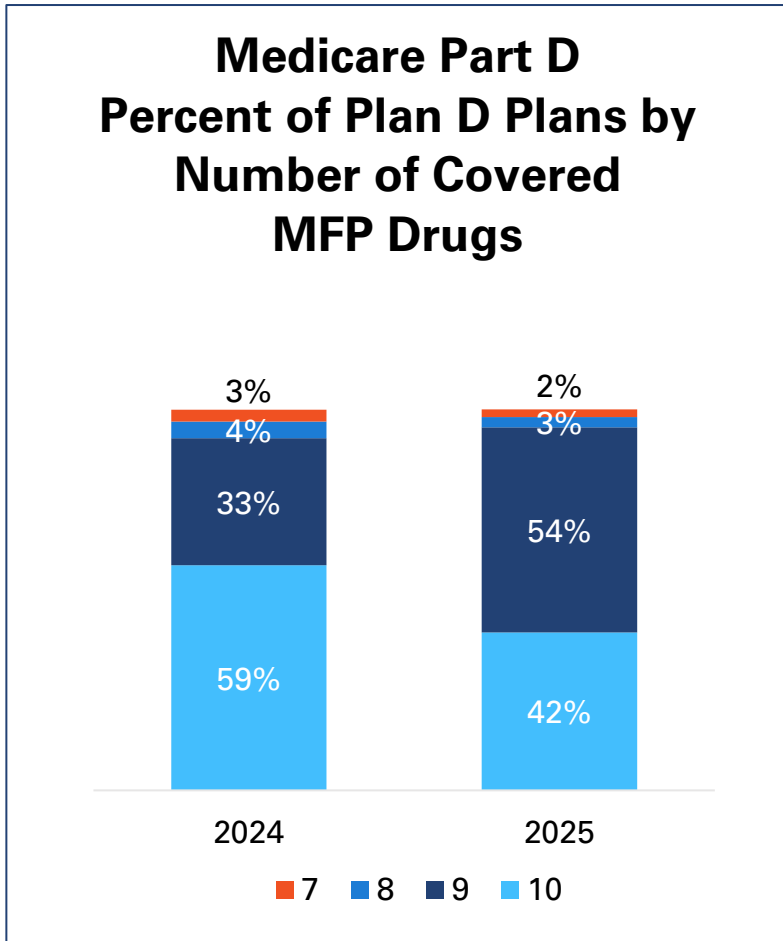
Medicare Part D Percent of PDPs by Cost Share Type



Medicare Part D Percent of MAPD Plans by Cost Share Type

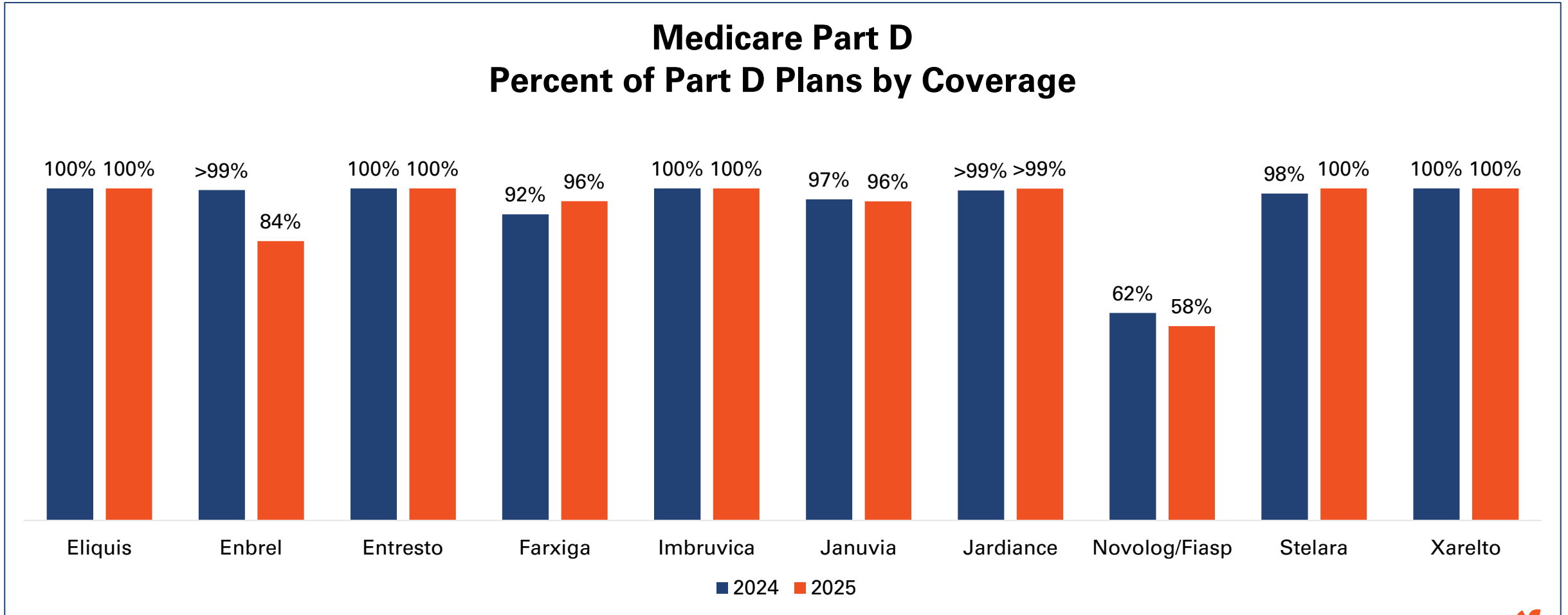


Part D Plans Cover at Least 7 of 10 MFP Drugs, with the Majority Covering 9 or More



Medicare Monthly Prescription Drug Plan Formulary and Pharmacy Network Information. CY 2024 and CY 2025. <https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/monthly-prescription-drug-plan-formulary-and-pharmacy-network-information>
Excludes PACE, Special Needs Plans, Part B Only Plans, and Employer sponsored plans

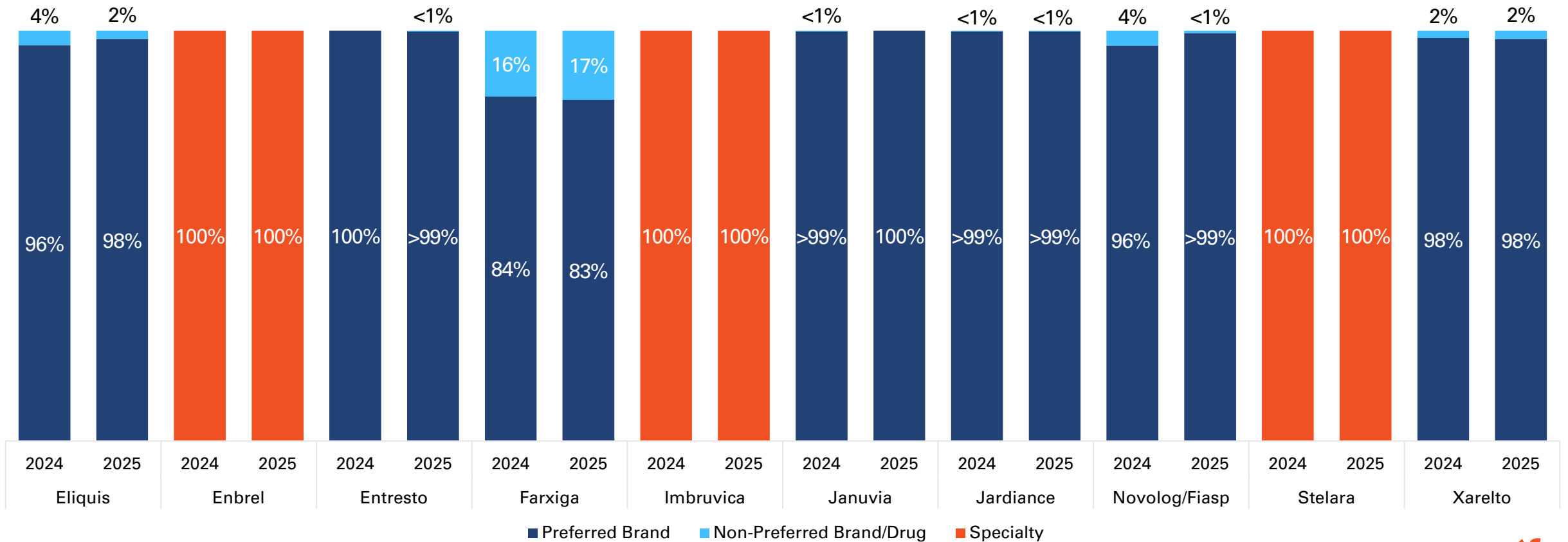
Coverage Remained Largely Consistent for Most MFP Drugs, with Enbrel Experiencing the Largest Decline



Medicare Monthly Prescription Drug Plan Formulary and Pharmacy Network Information. CY 2024 and CY 2025. <https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/monthly-prescription-drug-plan-formulary-and-pharmacy-network-information>

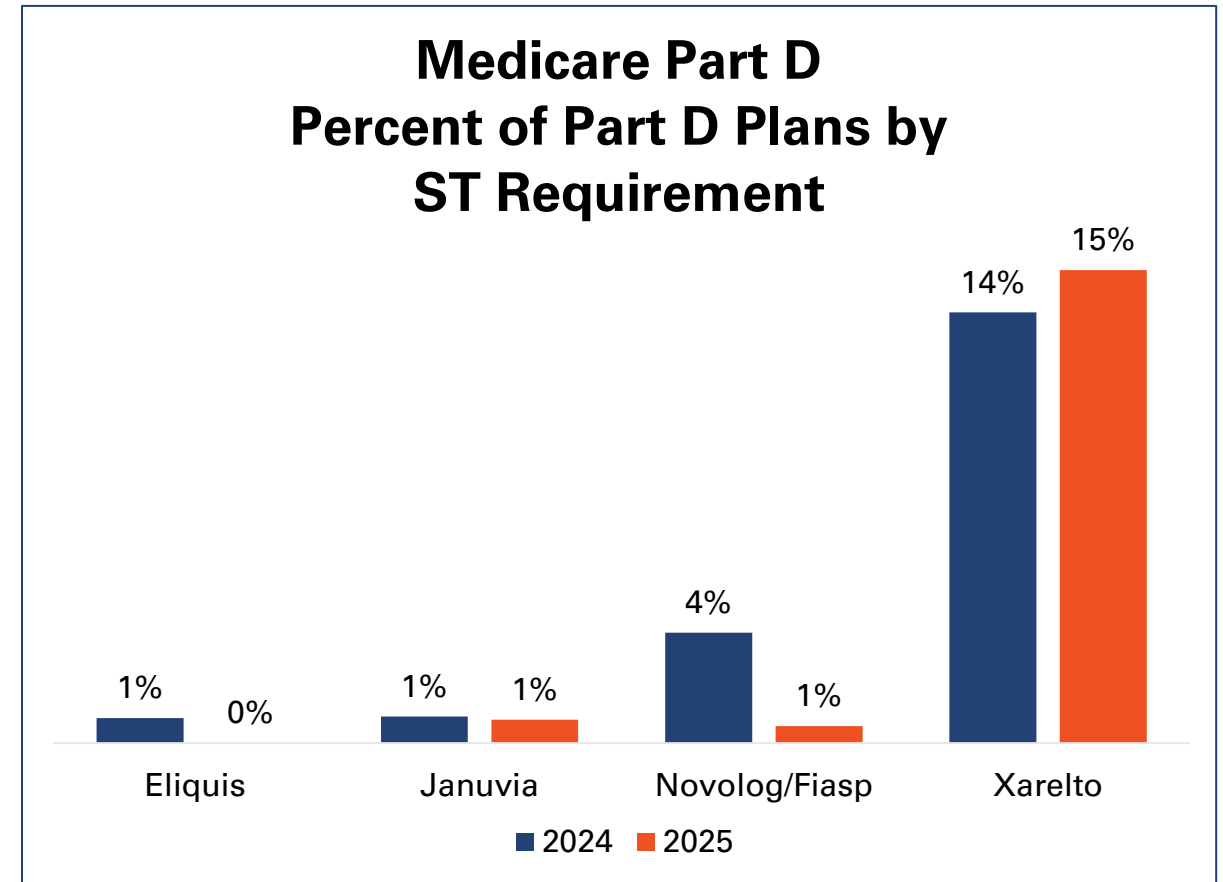
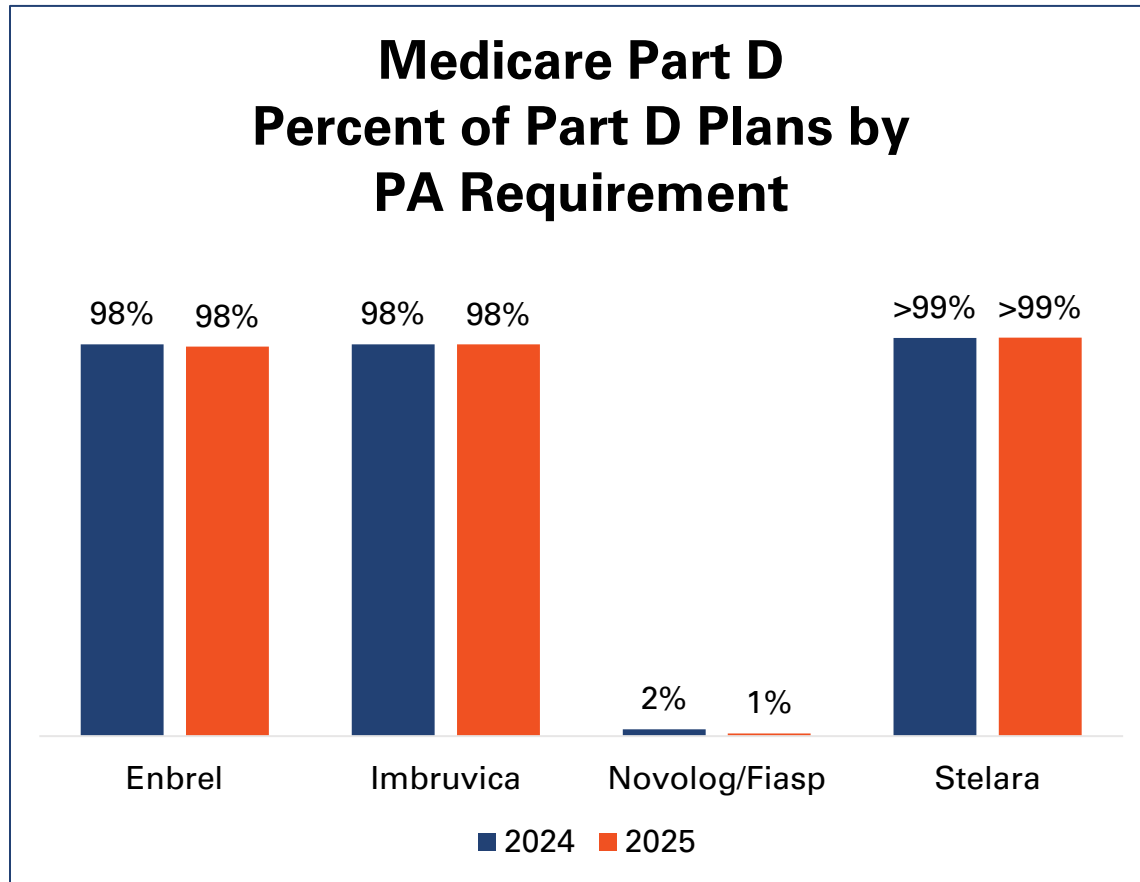
Part D Plans Overall Did Not Move MFP Drugs to a Different Formulary Tier

Medicare Part D Percent of Plan D Plans by Formulary Tier



Plans were excluded for each MFP drug if they did not provide coverage; only includes preferred brand, non-preferred brand/drug, and specialty tiers Medicare Monthly Prescription Drug Plan Formulary and Pharmacy Network Information. CY 2024 and CY 2025. <https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/monthly-prescription-drug-plan-formulary-and-pharmacy-network-information>

Most MFP Drugs Did Not Have Prior Authorization (PA) or Step Therapy (ST) Requirements Imposed by Part D Plans



Part D plans were excluded for each MFP drug if they did not provide coverage

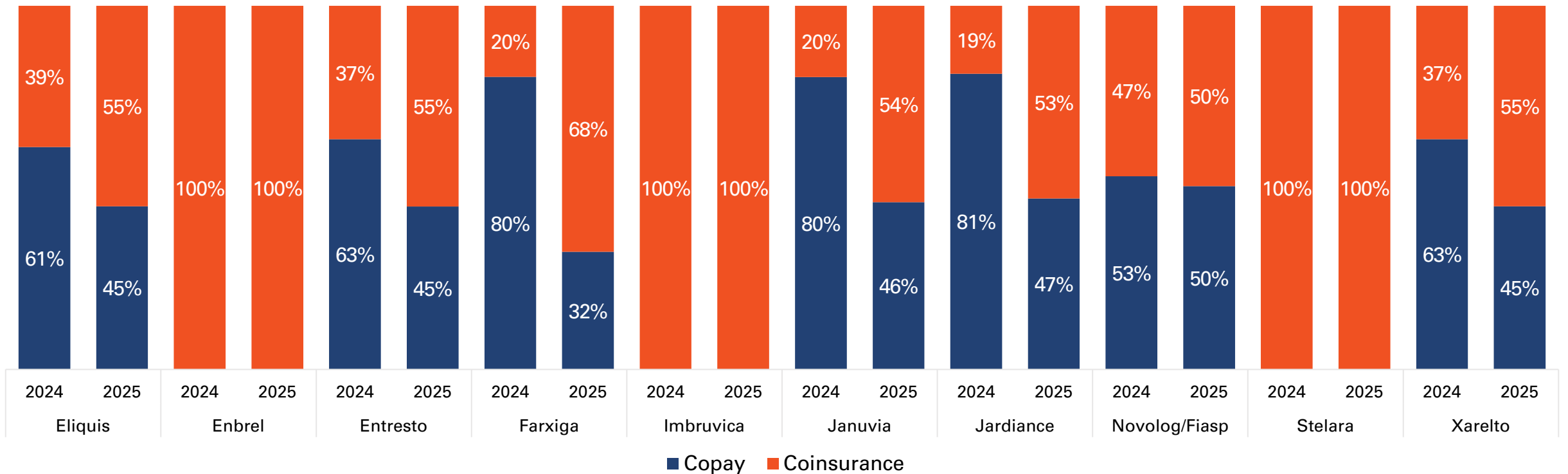
Part D plans did not require PA for Eliquis, Entresto, Farxiga, Januvia, Jardiance, and Xarelto

Part D plans did not require ST for Enbrel, Entresto, Farxiga, Imbruvica, Jardiance, and Stelara had no step therapy on any plans

Medicare Monthly Prescription Drug Plan Formulary and Pharmacy Network Information. CY 2024 and CY 2025. <https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/monthly-prescription-drug-plan-formulary-and-pharmacy-network-information>

There was a Substantial Increase in MFP Drugs Shifting from Copay to Coinsurance Across Part D Plans

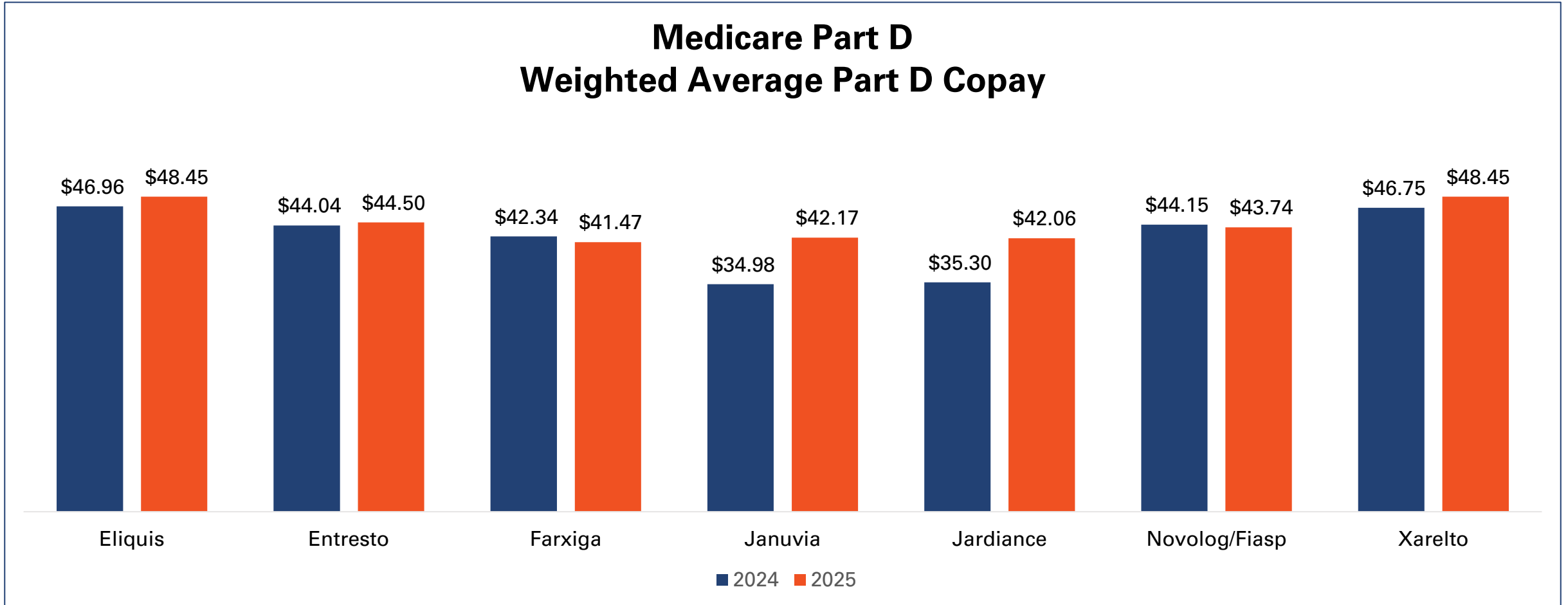
**Medicare Part D
Percent of Part D Enrollees by Cost Share Type**



Part D plans were excluded for each MFP drug if they did not provide coverage
Assumed enrollees remained in same plan in 2025

Medicare Monthly Prescription Drug Plan Formulary and Pharmacy Network Information. CY 2024 and CY 2025. <https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/monthly-prescription-drug-plan-formulary-and-pharmacy-network-information>

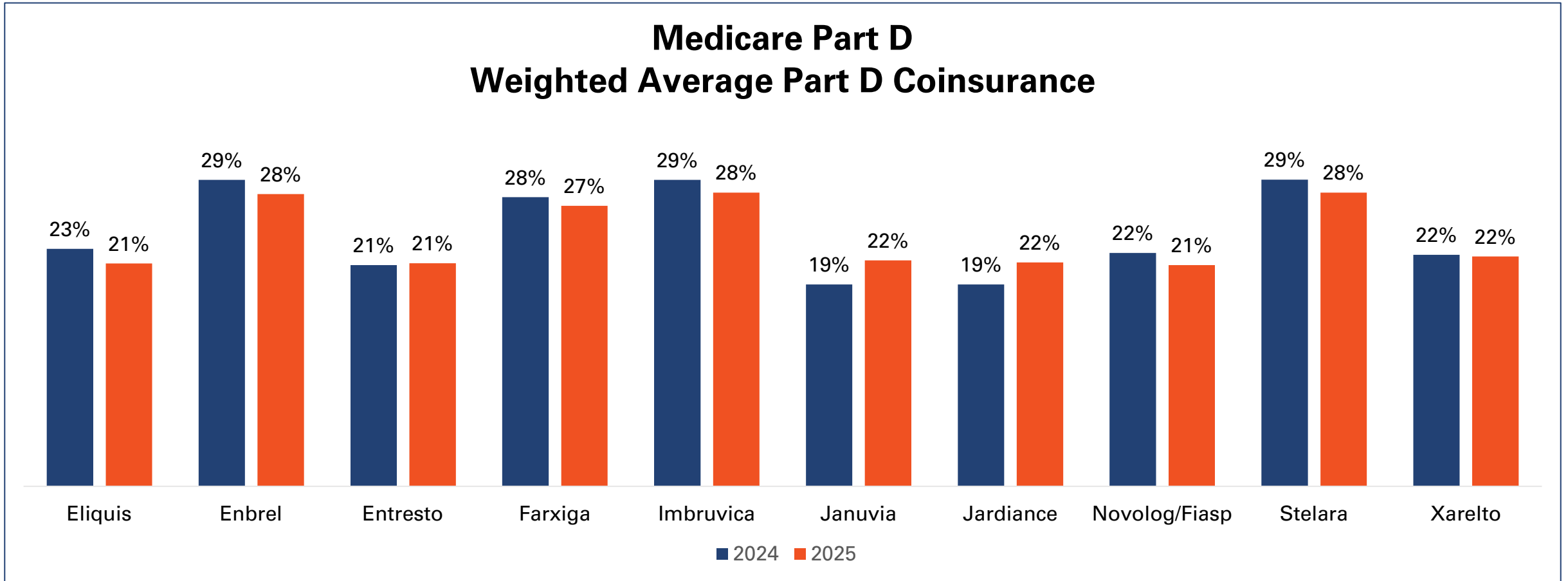
Average Part D Copays for MFP Drugs were Mostly Stable, with Januvia and Jardiance Experiencing the Largest Weighted Increase



All Part D plans use coinsurance for Enbrel, Imbruvica, and Stelara
Assumed enrollees remained in same plan in 2025

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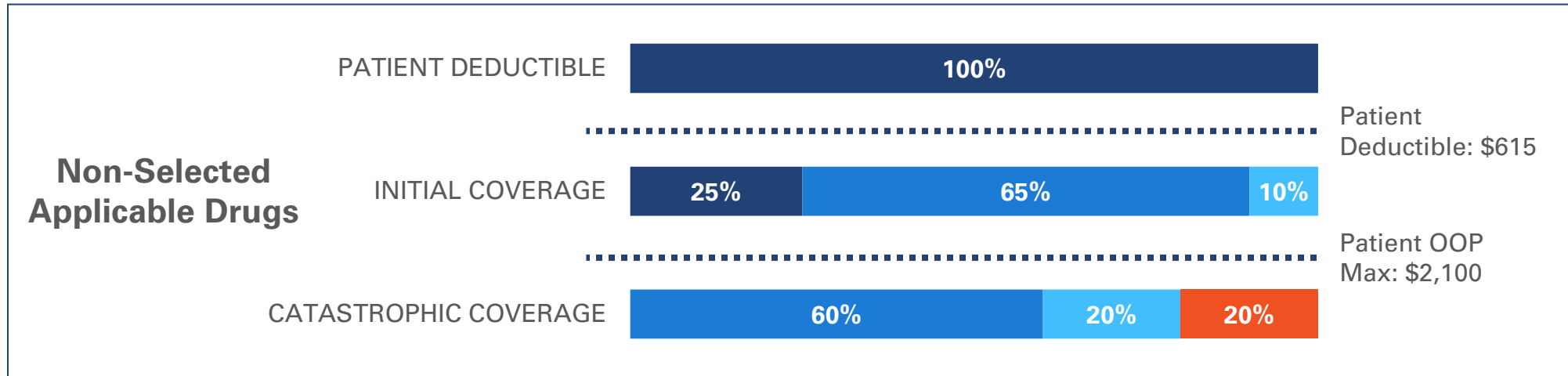
MFP Drugs Saw Slight Changes in Average Coinsurance Percentage, with the Largest Increase or Decrease of 2%-3%



Assumed enrollees remained in same plan in 2025

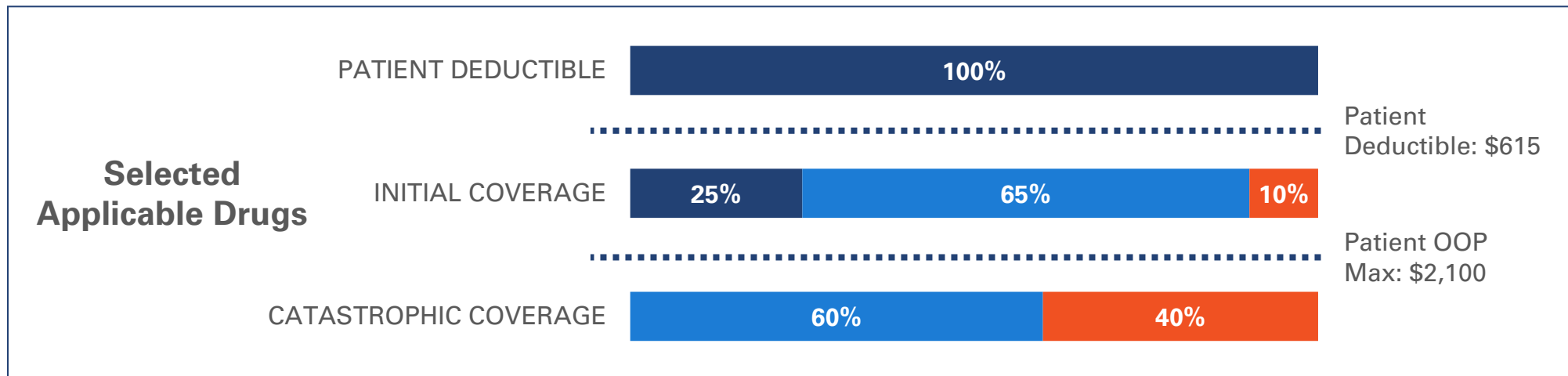
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Part D Standard Benefit for Applicable Drugs in CY 2026¹



Legend

- Patient
- Plan
- Manufacturer
- Medicare



[1] Draft CY 2026 Part D Redesign Program Instructions

[2] Selected drug subsidy within initial coverage phase may apply to certain drugs not subject to the defined standard deductible (e.g., insulins) – see Section 70 on the program instructions for more details

2025: Beyond Payers

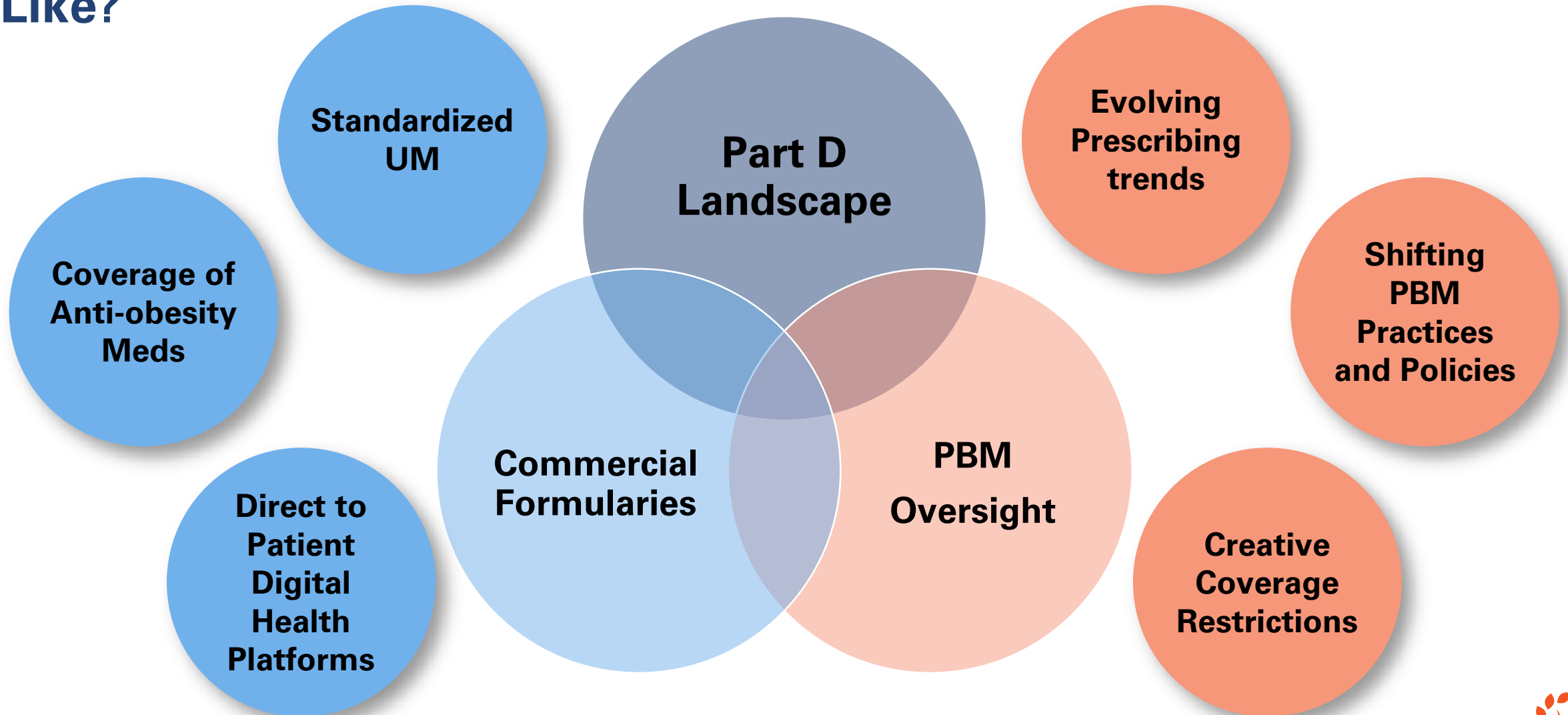
Lawsuit Update

Three suits remain in federal district court and four are awaiting a decision from various courts of appeal.

Trump Administration

Significant actions to **change Biden regulations and Executive Orders**. What action Medicaid, Medicare/IRA can be expected?

2026-27: Negotiated Prices Take Effect – What Does This Look Like?



Wrap-Up: Looking into your Crystal Ball

