Coverage, Formulary Placement, and Pricing for Negotiated Drugs and Within-Class Competitors in Medicare Part D

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ABSTRACT

The Medicare Drug Price Negotiation Program, established by the Inflation Reduction Act (IRA) of 2022,[1] selected 10 Part D drugs for the first round of negotiation and 15 for the second. Negotiated prices for the first 10 drugs took effect in January 2026 and for the next 15 in January 2027. Once negotiated prices apply, Part D plans must include the negotiated drugs on their formularies.

Negotiation changes the selected drug's price and access to formularies, which may have spillover effects on competing drugs in the same class. For example, plans may shift coverage toward the negotiated drug. Alternatively, because manufacturers of negotiated drugs would have less incentives to offer rebates due to their guaranteed formulary coverage, competitors may be incentivized to offer similar or lower net prices via rebates (which are financially beneficial to plans and pharmacy benefits managers).

Evidence related to formulary coverage and benefit design for negotiated drugs and their clinical comparators remains limited. One study examined Part D coverage of the 10 first-round negotiated drugs from 2019–2023 before negotiated prices took effect and suggested that plans might respond to negotiation by tightening utilization management or placing drugs on less favorable tiers.[2] Analyses of 2026 formularies found that negotiated drugs were less likely to be placed on preferred tiers compared with 2025.[3] Plans also added utilization management requirements for some negotiated drugs.[4] A recent study comparing utilization management requirements for first-round negotiated drugs and their within-class comparators from 2019–2026 found that step therapy requirements reemerged for negotiated cardiometabolic drugs (6 of 10 selected drugs) in 2026 but remained rare for comparator drugs.[5] The remaining 3 immunology and oncology drugs consistently faced prior authorization requirements before and after the negotiation. To date, no studies have examined changes in formulary coverage of competitors, potential formulary responses to the second round of negotiated prices, or differences in these responses by plan type (stand-alone prescription drug plans [PDPs] versus Medicare Advantage prescription drug plans [MA-PDs]).

We examined formulary coverage and utilization management changes for negotiated drugs and their within-class competitors in Medicare Part D, including PDPs and MA-PDs. We compared each negotiation cohort's initial price applicability year with the preceding year.

Methods

Data Sources

We used the CMS Monthly Prescription Drug Plan Formulary and Pharmacy Network data for contract years 2025–2027.[6] Because each year's plan formularies are released the fourth quarter of the preceding year and remain relatively constant throughout the plan year, we used

the October release preceding each contract year (i.e., October 2024 for 2025, October 2025 for 2026, and October 2026 for 2027). Plans were linked to enrollment using CMS Monthly Enrollment by Plan data for January of each contract year.[7] Because January 2027 enrollment data were not available at the time of analysis, we used the most recent enrollment data (October 2026) for 2027. We weighted each plan by its enrollment when summarizing plan coverage of study drugs. CMS suppresses enrollment for plans with 10 or fewer enrollees, and we excluded these plans. We also excluded plans whose formulary had no drug records in the formulary file (up to 11 plans per year, representing less than 0.1% of enrollment).

Cohort Identification

We included 23 negotiated drugs (8 from the first and 15 from the second negotiation round) and their within-class competitors. Of the 10 drugs selected in the first round, we excluded insulin products because of the IRA's $35 monthly cost-sharing cap, and Entresto (sacubitril and valsartan), which has no within-class clinical alternative. Within-class competitors were identified as clinical alternatives among drugs sharing a mechanistic class in either the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) level 4 or the US Pharmacopeia (USP) tier 3.[8,9] When drugs in the same mechanistic class did not share the same therapeutic use, we identified clinical alternatives for the treated condition. Two authors (NLK and JH) reviewed therapeutic alternatives and resolved any discrepancies. The clinical review identified 21 within-class competitors for the round 1 cohort and 74 for the round 2 cohort. Of these, 20 and 72, respectively, appeared on at least one Part D formulary before the initial price applicability year and were included in the analysis.

Products containing study drugs were identified in the Medicare formulary files using RxNorm concept unique identifiers (RxCUIs) from RxNav and classified as brand-name, generic, or biosimilar using the Food and Drug Administration (FDA) National Drug Code (NDC) Directory. We identified 1,399 RxCUIs for study drugs, of which 774 appeared in the formulary files during the study period, corresponding to 905 NDCs.

Outcomes

Our primary outcome was the percentage of plans covering each drug (defined as coverage of at least one formulation or strength), assessed both individually and for each negotiated drug–competitor pair. Our secondary outcomes were the percentage of plans covering a drug with utilization management (separately evaluating the presence of prior authorization and step therapy). One competitor drug from the round 1 cohort (edoxaban) and 3 competitors from the round 2 cohort (tegaserod, tenapanor, and exenatide) were not covered by any plan in the initial price applicability year and were excluded from the denominator for the secondary outcome. All outcomes were weighted by plan enrollment.

Analysis

We compared each cohort's initial price applicability year with the preceding year (i.e., 2025 vs 2026 for round 1; 2026 vs 2027 for round 2). We stratified outcomes by plan type: PDPs vs MA-PDs.

Results

In 2026, 5,534 plans representing 46.9 million enrollees were evaluated (98.3% of plans matched to the enrollment file) and in 2027, 4,008 plans representing 41.4 million enrollees were evaluated (79.6% of plans matched to the enrollment file).

Negotiated Drugs

All negotiated drugs reached full coverage in their first price applicability year. In round 1, mean coverage of the 8 drugs rose from 97.0% in 2025 to 100% in 2026. Coverage in 2025 was lowest for Enbrel (etanercept; 84.4%) followed by Januvia (sitagliptin; 95.0%). In round 2, mean coverage of the 15 negotiated drugs rose from 93.5% in 2026 to 100% in 2027. The drugs with the lowest 2026 coverage, Otezla (apremilast; 66.5%), Austedo (deutetrabenazine; 75.7%), and Breo Ellipta (fluticasone/vilanterol; 78.3%), all reached 100%.

Competitor Drugs

Competitor coverage was largely unchanged when negotiated prices took effect. Across the 20 competitor drugs from the round 1 cohort, the median change from 2025 to 2026 was 0.2 percentage points reduction in formulary coverage (mean, -1.5). Coverage changed by 5 percentage points or less for 15 out of 20 products. Across the 72 competitor drugs from the round 2 cohort, the median change from 2026 to 2027 was 0.0 percentage points (mean, +1.3), and coverage changed by 5 percentage points or less for 57 out of 72 products. The mean increase in round 2 cohort reflected mainly Zymfentra (subcutaneous infliximab), whose coverage rose from 3.9% to 100%. Change in individual competitors' coverage from the preceding year was greatest in 2025, the year of the Part D benefit redesign, rather than in either of the first negotiated price applicability years of 2026 or 2027 (median absolute change, 2.4 percentage points in 2025 vs 0.6 in 2026 for round 1 cohort [mean, 8.5 vs 5.2]; 1.0 in 2025 vs 0.0 in 2027 for the round 2 cohort [mean, 7.9 vs 4.3]).

Utilization Management

For negotiated drugs, mean percentage of covering plans requiring prior authorization for at least one dosage formulation remained similar (36.7% in 2025 vs 36.8% in 2026 for round 1 cohort; 60.2% in 2026 vs 61.1% in 2027 for round 2 cohort). Step therapy for round 1 negotiated drugs increased from 2.0% to 4.4%, mainly because of new step therapy for Jardiance (empagliflozin; 0.0% to 13.7%). Among round 1 competitor drugs, mean percentage of covering plans requiring prior authorization rose from 52.1% in 2025 to 62.5% in 2026. However, this rise was driven largely from competitors that most plans dropped in 2026: golimumab (212 to 39

covering plans), ertugliflozin (126 to 33), and mirikizumab (111 to 1). The plans that kept these drugs largely placed them under prior authorization. Step therapy remained rare (1.6% in 2025 vs 2.3% in 2026). For round 2 competitors, both prior authorization and step therapy requirements were stable; 51.4% in 2026 vs 50.7% in 2027 for prior authorization and 2.2% in both years for step therapy.

MA-PD versus PDP

Before negotiated prices took effect, PDPs covered round 1 negotiated drugs slightly more often than MA-PDs (mean 98.1% vs 96.2% in 2025). In contrast, PDPs covered several round 2 negotiated drugs less often than MA-PDs (mean 89.8% vs 95.8% in 2026). For example, Austedo (deutetrabenazine) was covered by 49.7% of PDPs versus 92.7% among MA-PDs, and Breo Ellipta (fluticasone/vilanterol) was covered by 53.6% of PDPs versus 94.6% among MA-PDs. For competitor drugs, PDPs covered them slightly less often than MA-PDs (40.3% vs 41.1% in 2025 for round 1; 63.6% vs 67.8% in 2026 for round 2). Among competitors covered by both plan types, PDPs required prior authorization for competitors more often than MA-PDs (66.7% vs 63.0% in 2025 for round 1; 60.1% vs 57.8% in 2026 for round 2), with little change in either plan type in the price applicability year. Step therapy for competitors was rare in both plan types.

Future Directions

Preliminary data suggest that drug price negotiation has resulted in increased formulary coverage for negotiated product with only minimal spillover on coverage and utilization management requirements for within class competitors. Future work will evaluate changes in net prices for competitor products and tier placement for negotiated products relative to within-class competitors. Sensitivity analyses will include yearly trends in formulary changes before negotiated prices took effect to account for pre-existing trends. Updated data on 2027 enrollment will be incorporated in advance of the February 2027 presentation date.

Acknowledgements

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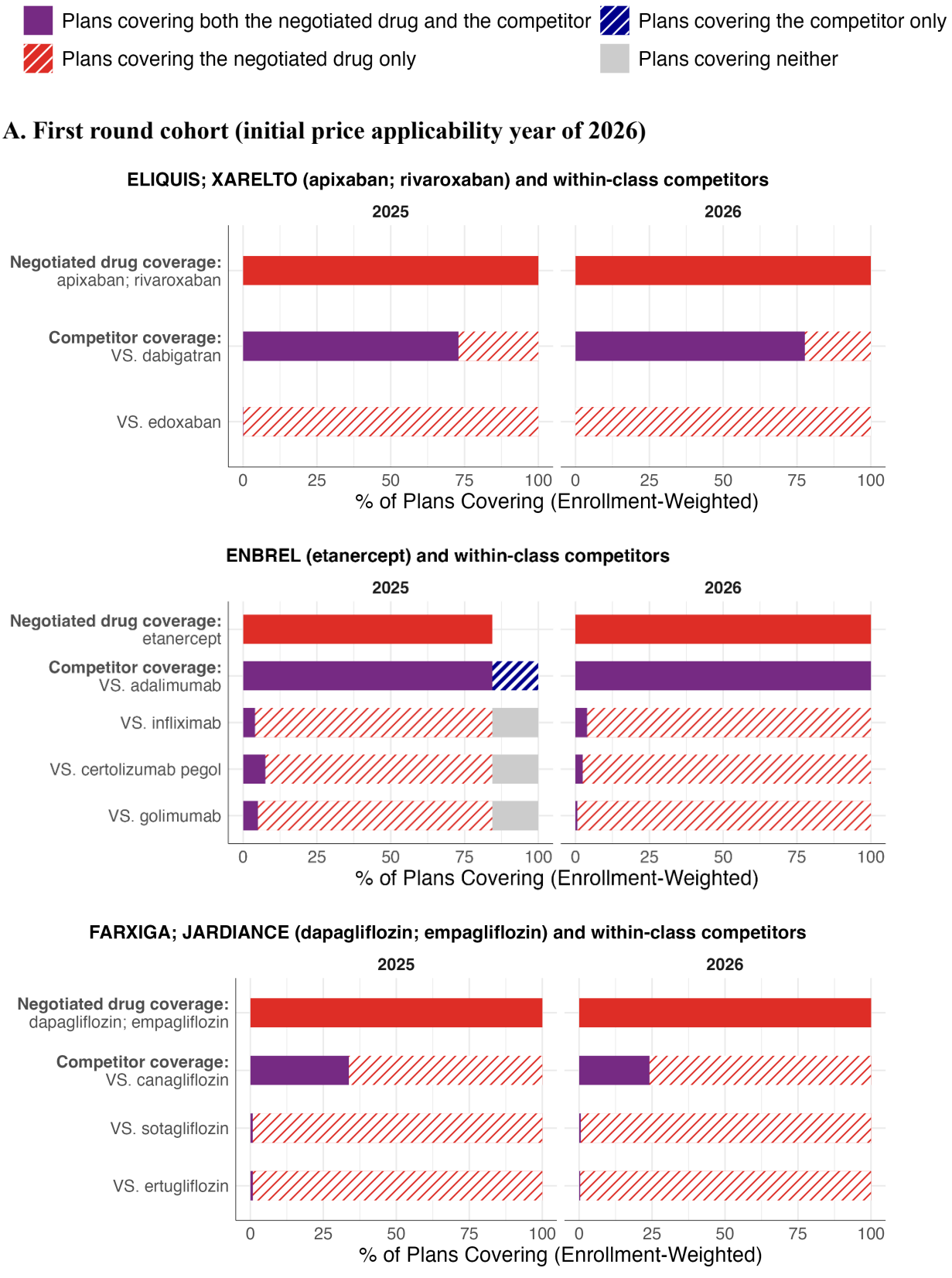
Access to Data and Data Analysis: Ms. Han had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

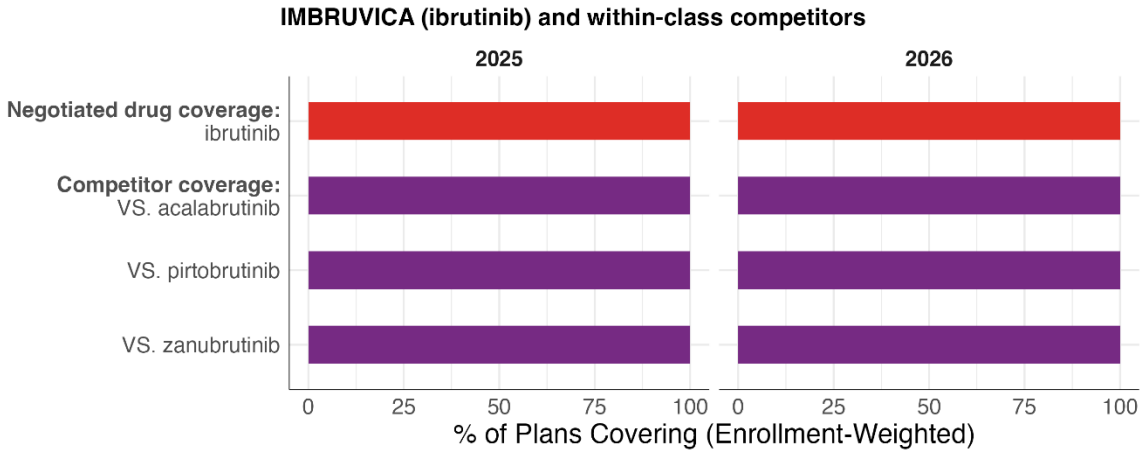
Disclosures: Ms. Han was previously employed by GSK before the initiation of this project. Dr. Dusetzina is also receiving grants from Arnold Ventures, Blood Cancer United, and the National Cancer Institute (NCI). Dr. Dusetzina is a member of the Institute for Clinical and Economic Review's (ICER) Midwestern Comparative Effectiveness Advisory Council and a member of the Medicare Payment Advisory Commission (MedPAC). This work does not necessarily represent the official position of ICER or MedPAC.

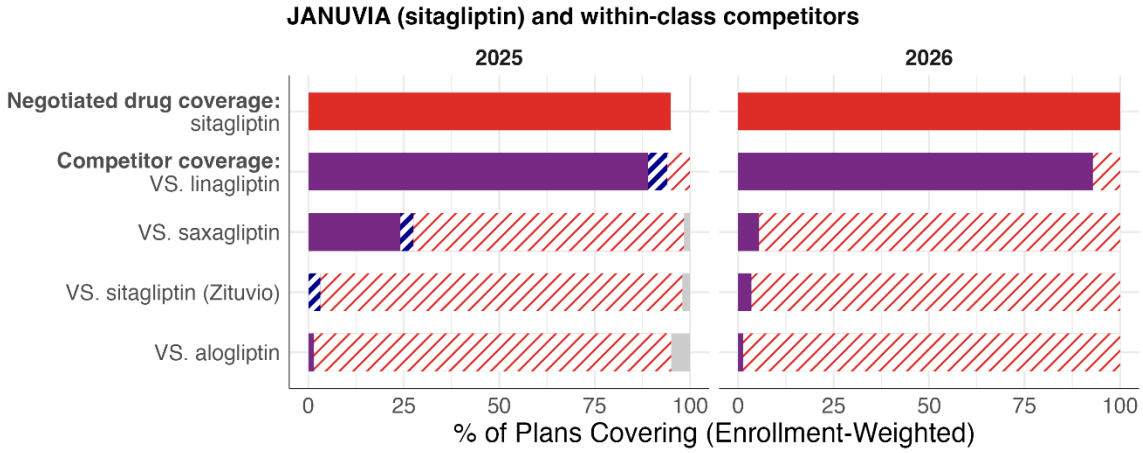
Table 1. Formulary coverage and utilization management for negotiated drugs and within-class competitors in the preceding year and the first year of negotiated prices

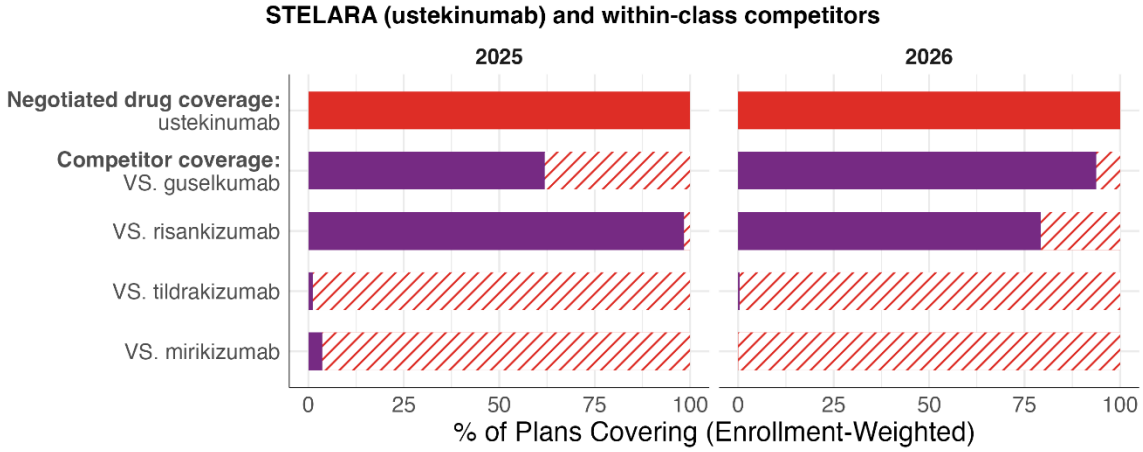
	Round 1 (negotiated prices from 2026)			Round 2 (negotiated prices from 2027)		
Measure	**2025**	**2026**	**Change**	**2026**	**2027**	**Change**
Study sample						
Plans matched to enrollment, n	5,145	5,003	—	5,003	4,008	—
Enrollees, millions	45.7	46.9	—	46.9	41.4	—
Negotiated drugs						
Drugs, n	8	8	—	15	15	—
Plans covering, mean %	97.0	100.0	+3.0	93.5	100.0	+6.5
Change in plans covering, median percentage points	—	—	+0.1	—	—	0.0
Prior authorization among covering plans, mean %	36.7	36.8	+0.1	60.2	61.1	+0.9
Step therapy among covering plans, mean %	2.0	4.4	+2.4	0.1	0.1	0.0
Within-class competitors						
Drugs, n	20	20	—	72	72	—
Plans covering, mean %	40.8	39.3	-1.5	66.1	67.4	+1.3
Change in plans covering, median percentage points	—	—	-0.2	—	—	0.0
Prior authorization among covering plans, mean %	52.1	62.5	+10.4	51.4	50.7	-0.7
Step therapy among covering plans, mean %	1.6	2.3	+0.6	2.2	2.2	0.0
Negotiated drug–competitor pairs, mean % of plans covering						
Both drugs	39.5	39.3	-0.2	59.1	66.6	+7.4
Negotiated drug only	56.4	60.7	+4.3	27.8	33.4	+5.6
Competitor only	1.4	0.0	-1.4	7.0	0.0	-7.0
Neither	2.8	0.0	-2.8	6.0	0.0	-6.0
By plan type						
Negotiated drugs, plans covering, mean %: MA-PD	96.2	100.0	+3.8	95.8	100.0	+4.2
Negotiated drugs, plans covering, mean %: PDP	98.1	100.0	+1.9	89.8	100.0	+10.2
Competitors, plans covering, mean %: MA-PD	41.1	40.0	-1.1	67.8	69.2	+1.5
Competitors, plans covering, mean %: PDP	40.3	38.3	-2.1	63.6	64.7	+1.1
Competitors, prior authorization, mean %: MA-PD	63.0	63.4	+0.4	57.8	56.9	-0.9
Competitors, prior authorization, mean %: PDP	66.7	66.7	0.0	60.1	59.6	-0.6

Figure 1. Formulary coverage of negotiated drugs and their competitors in the price applicability year versus the preceding year

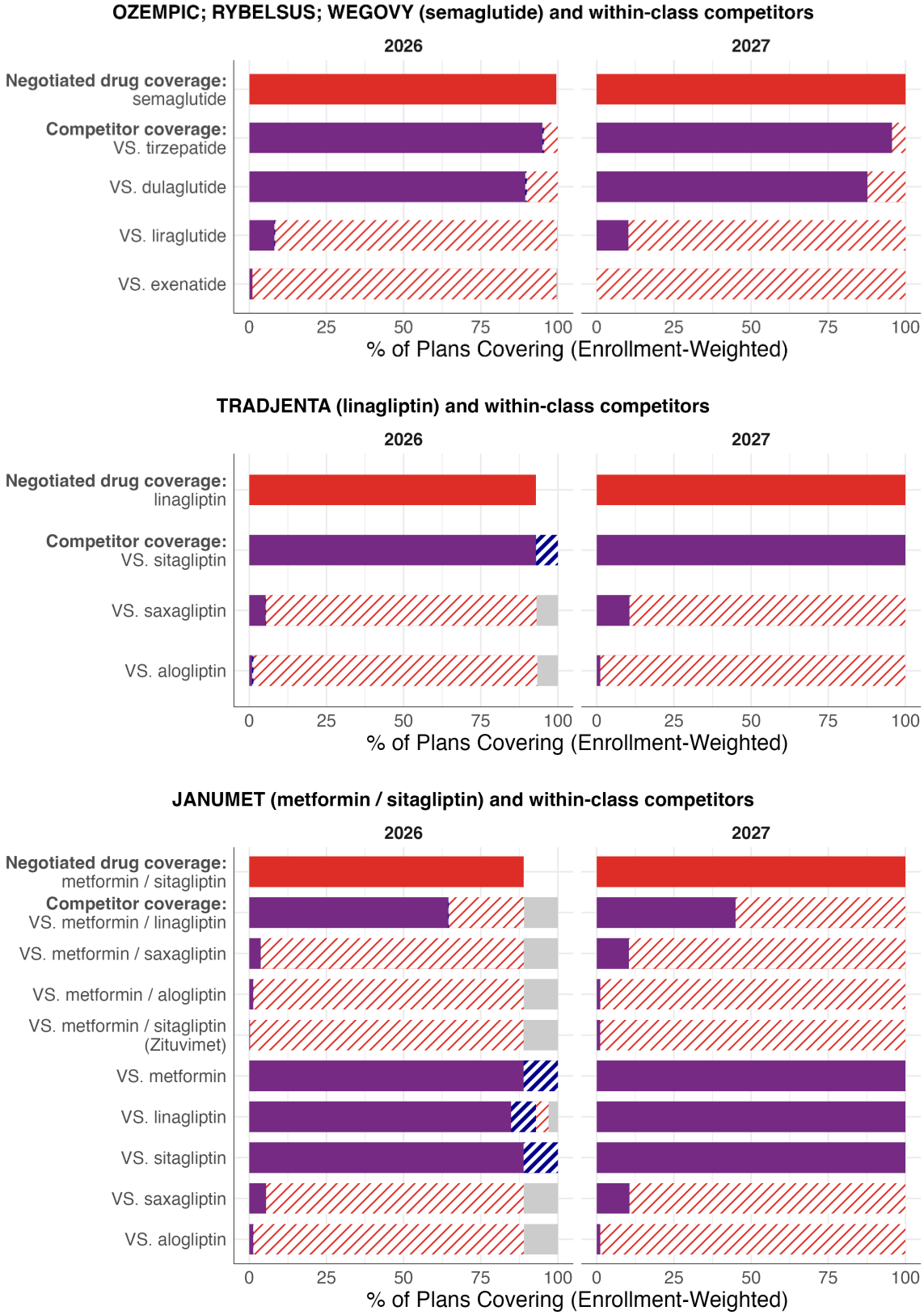



IMBRUVICA (ibrutinib) and within-class competitors
2025
2026
Negotiated drug coverage:
ibrutinib
Competitor coverage:
VS. acalabrutinib
VS. pirtobrutinib
VS. zanubrutinib
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)

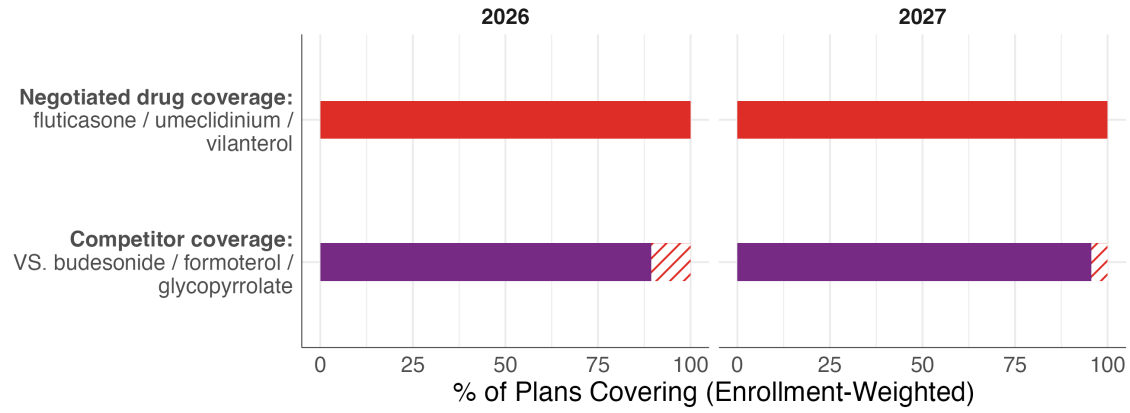

JANUVIA (sitagliptin) and within-class competitors
2025
2026
Negotiated drug coverage:
sitagliptin
Competitor coverage:
VS. linagliptin
VS. saxagliptin
VS. sitagliptin (Zituvio)
VS. alogliptin
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)


STELARA (ustekinumab) and within-class competitors
2025
2026
Negotiated drug coverage:
ustekinumab
Competitor coverage:
VS. guselkumab
VS. risankizumab
VS. tildrakizumab
VS. mirikizumab
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)

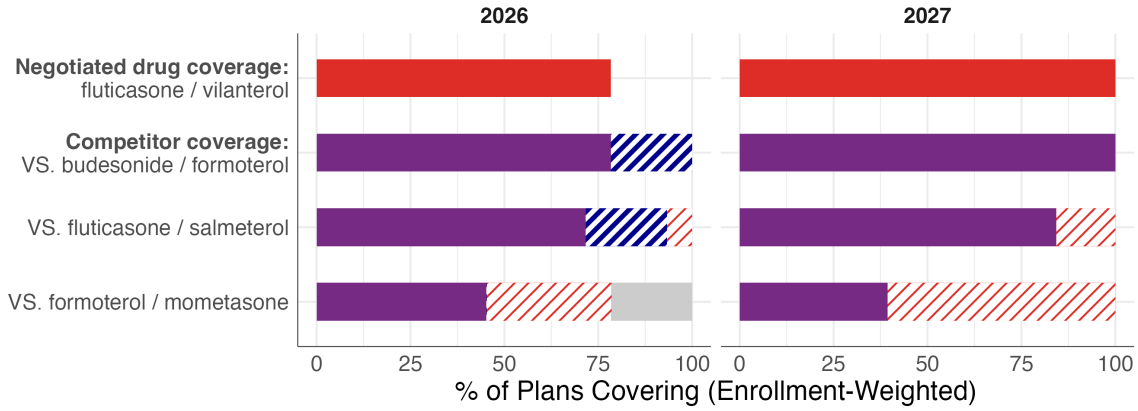
B. Second round cohort (initial price applicability year of 2027)



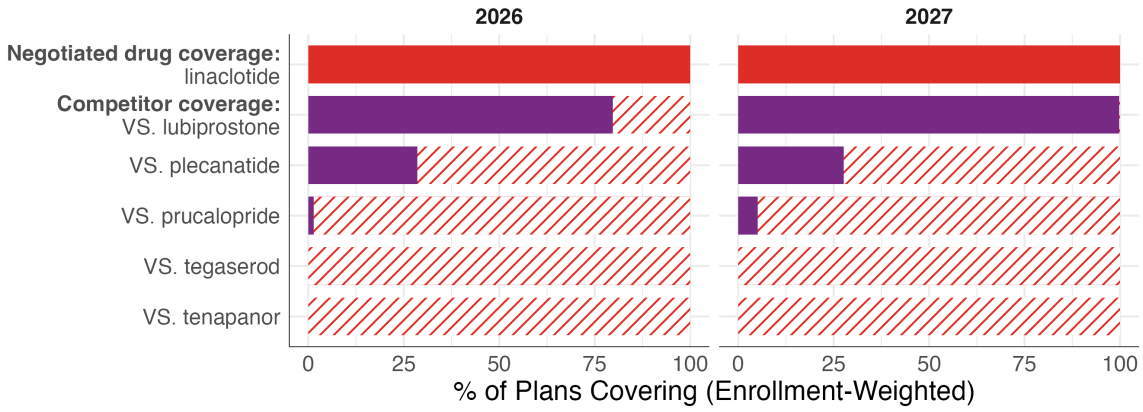
TRELEGY (fluticasone / umeclidinium / vilanterol) and within-class competitors



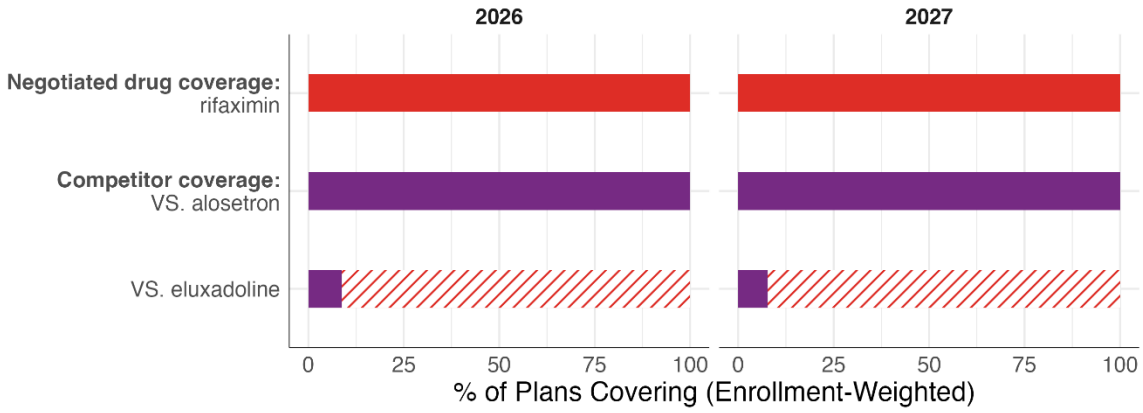
BREO (fluticasone / vilanterol) and within-class competitors



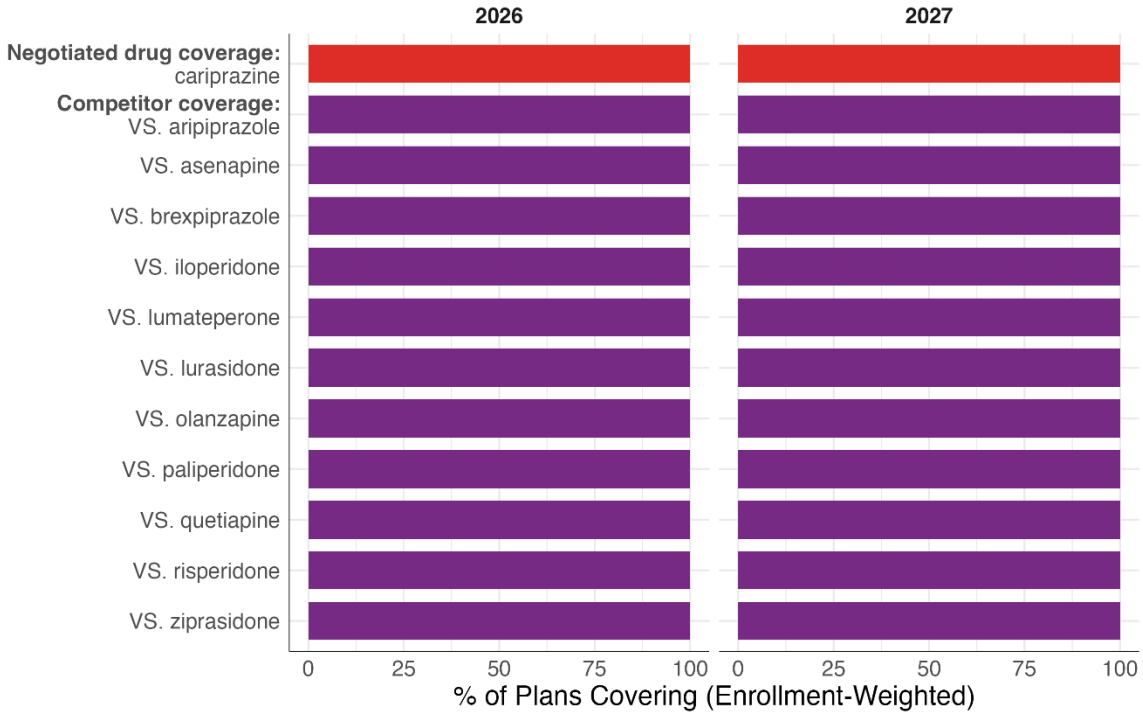
LINZESS (linaclotide) and within-class competitors



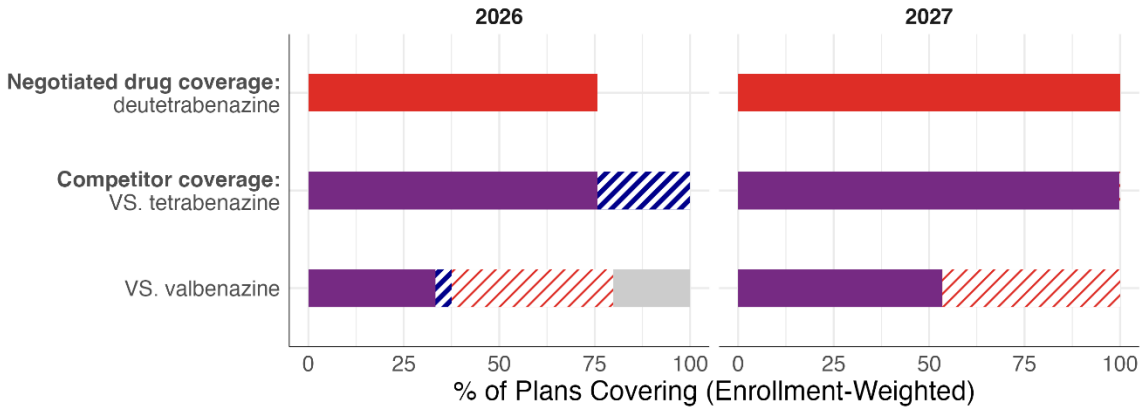
XIFAXAN (rifaximin) and within-class competitors

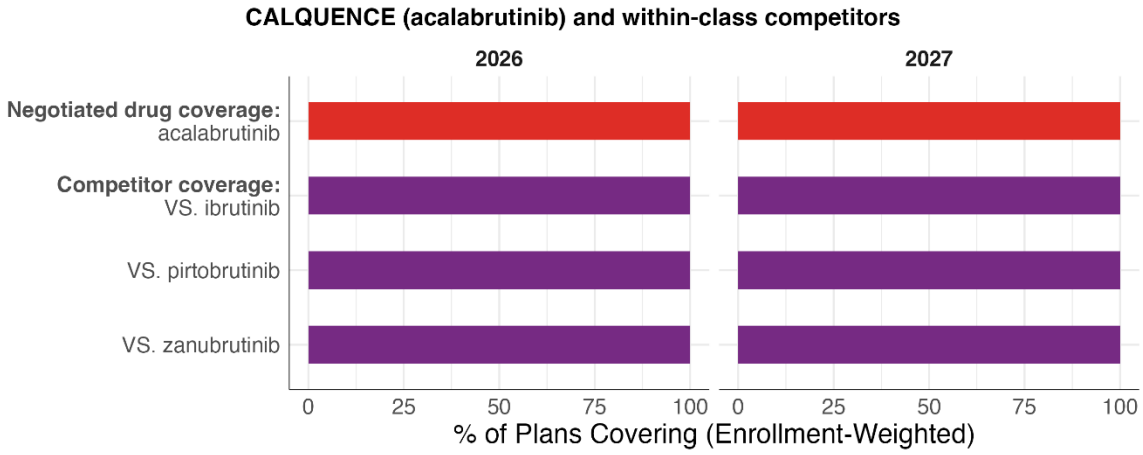


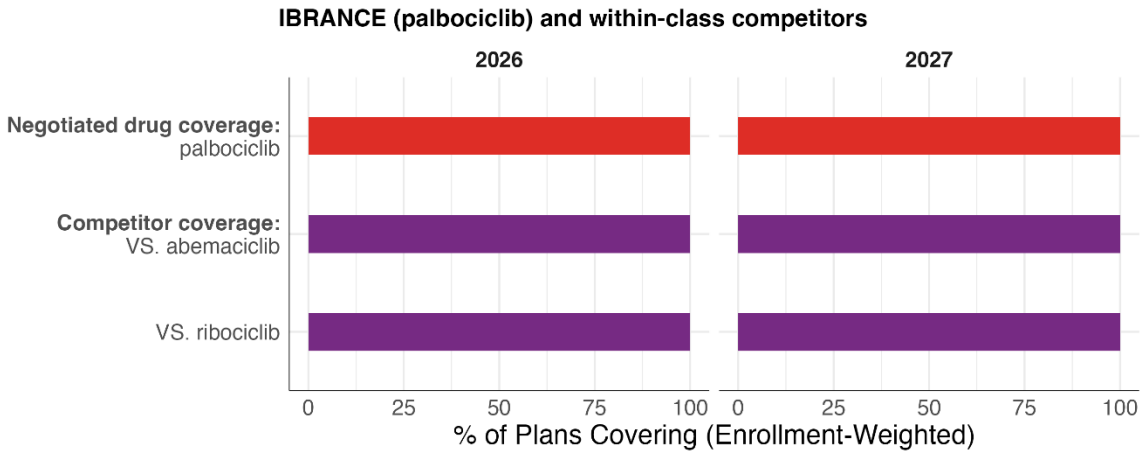
VRAYLAR (cariprazine) and within-class competitors

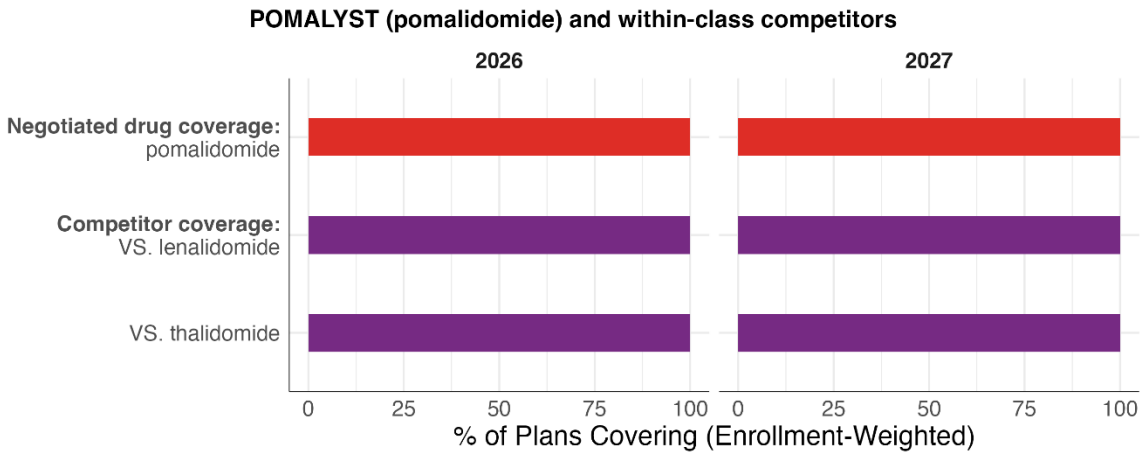


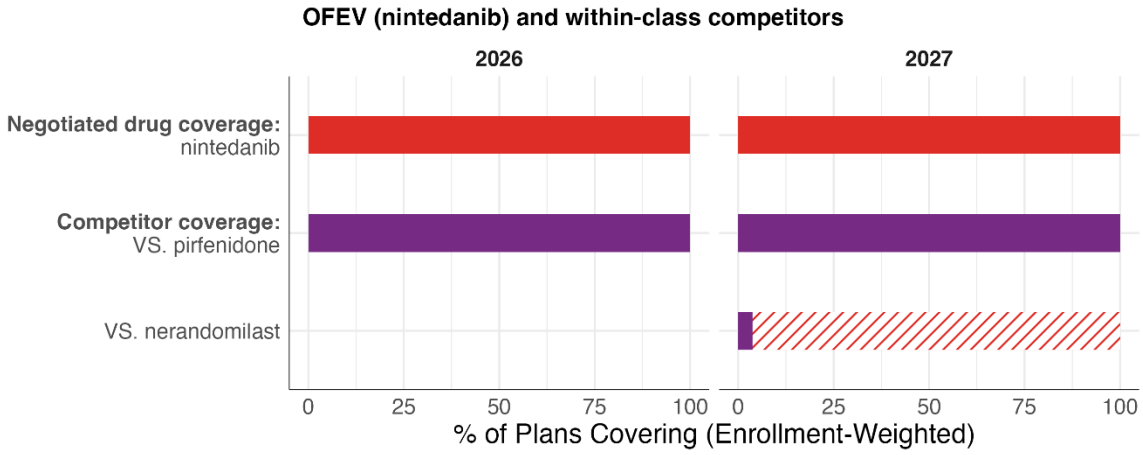
AUSTEDO (deutetrabenazine) and within-class competitors

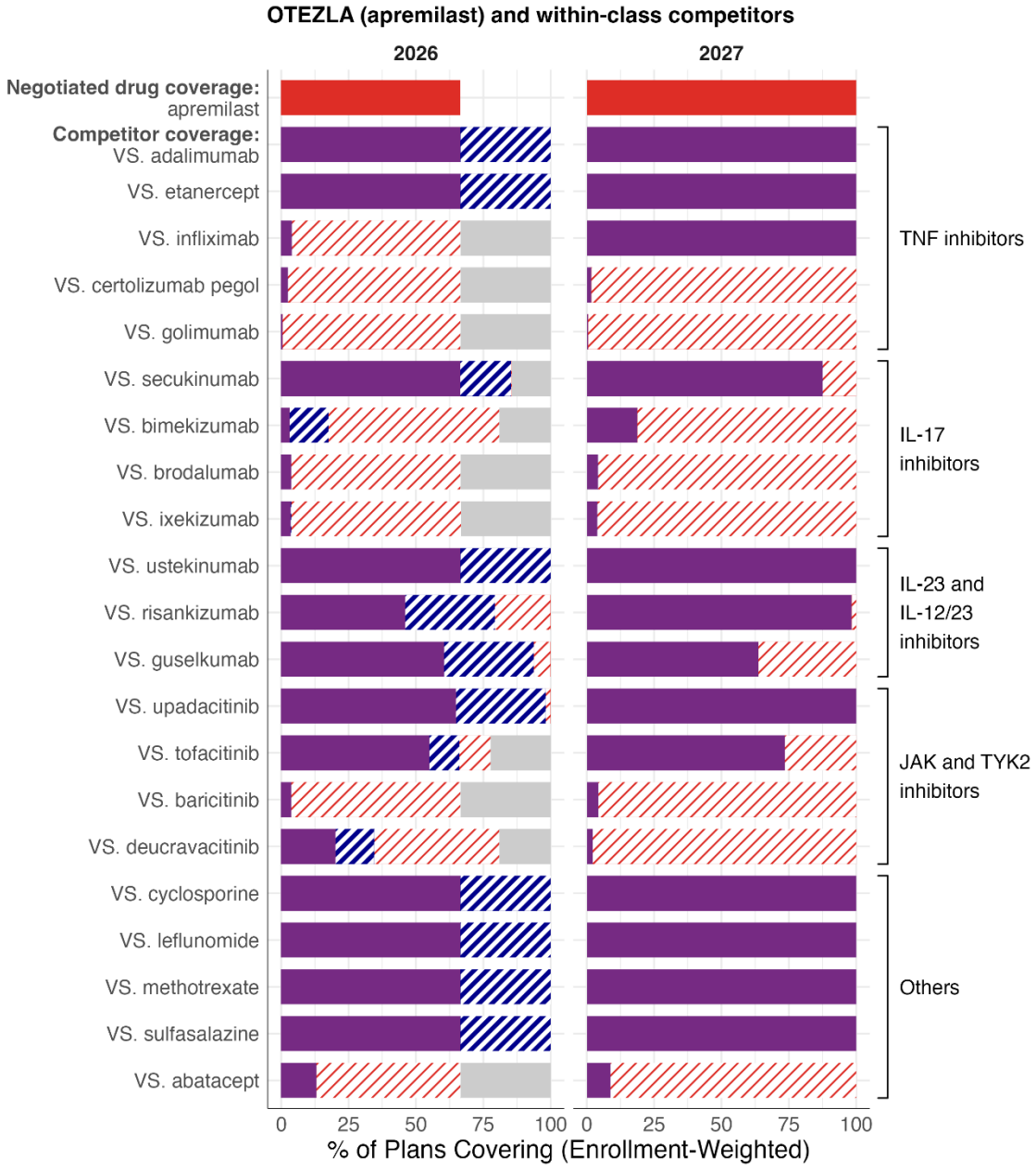


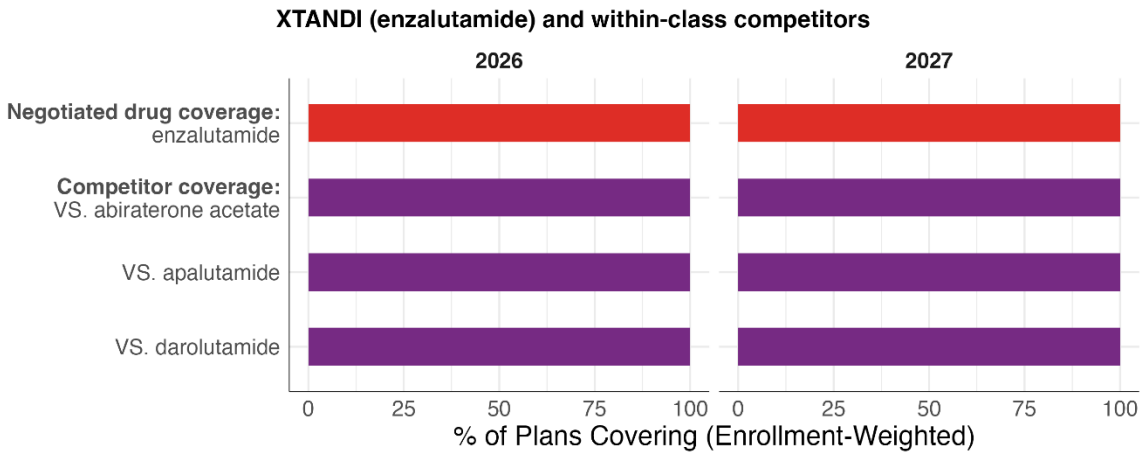

CALQUENCE (acalabrutinib) and within-class competitors
2026
2027
Negotiated drug coverage:
acalabrutinib
Competitor coverage:
VS. ibrutinib
VS. pirtobrutinib
VS. zanubrutinib
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)


IBRANCE (palbociclib) and within-class competitors
2026
2027
Negotiated drug coverage:
palbociclib
Competitor coverage:
VS. abemaciclib
VS. ribociclib
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)


POMALYST (pomalidomide) and within-class competitors
2026
2027
Negotiated drug coverage:
pomalidomide
Competitor coverage:
VS. lenalidomide
VS. thalidomide
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)

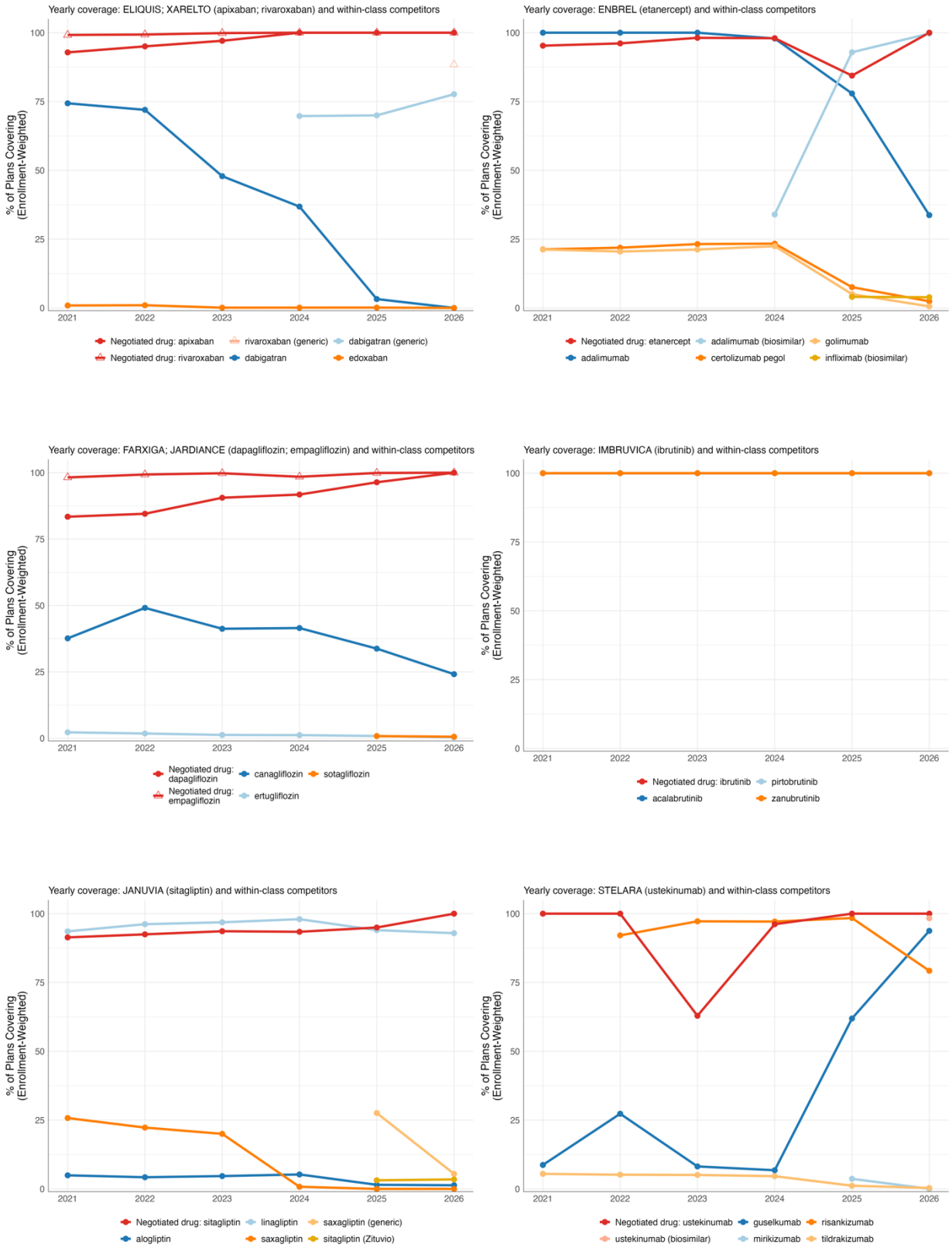

OFEV (nintedanib) and within-class competitors
2026
2027
Negotiated drug coverage:
nintedanib
Competitor coverage:
VS. pirfenidone
VS. nerandomilast
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)


OTEZLA (apremilast) and within-class competitors
2026
2027
Negotiated drug coverage:
apremilast
Competitor coverage:
VS. adalimumab
VS. etanercept
VS. infliximab
VS. certolizumab pegol
VS. golimumab
VS. secukinumab
VS. bimekizumab
VS. brodalumab
VS. ixekizumab
VS. ustekinumab
VS. risankizumab
VS. guselkumab
VS. upadacitinib
VS. tofacitinib
VS. baricitinib
VS. deucravacitinib
VS. cyclosporine
VS. leflunomide
VS. methotrexate
VS. sulfasalazine
VS. abatacept
TNF inhibitors
IL-17
inhibitors
IL-23 and
IL-12/23
inhibitors
JAK and TYK2
inhibitors
Others
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)

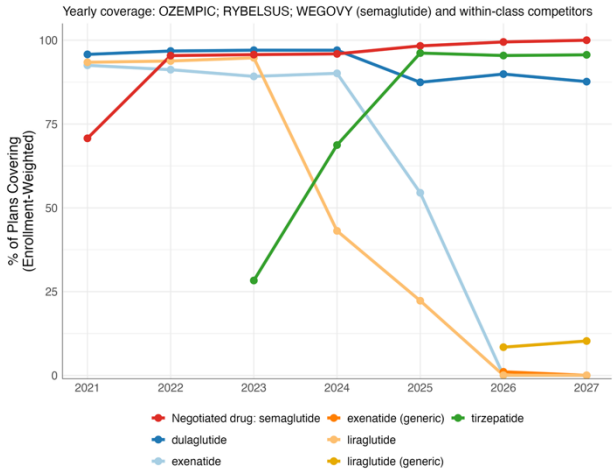

XTANDI (enzalutamide) and within-class competitors
2026
2027
Negotiated drug coverage:
enzalutamide
Competitor coverage:
VS. abiraterone acetate
VS. apalutamide
VS. darolutamide
0
25
50
75
100
% of Plans Covering (Enrollment-Weighted)

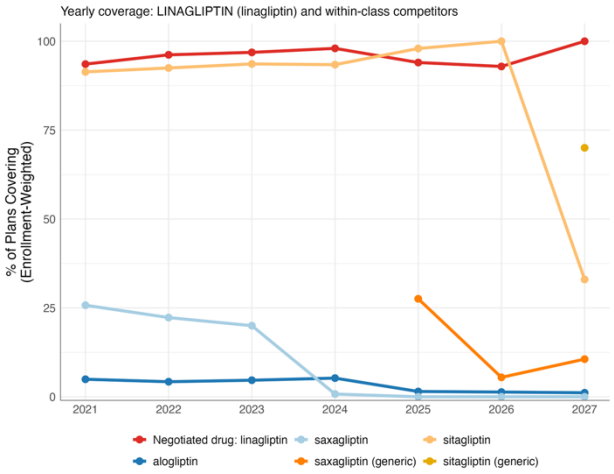
Appendix Figure. Formulary coverage of negotiated drugs and their competitors from 2021 through the initial price applicability year

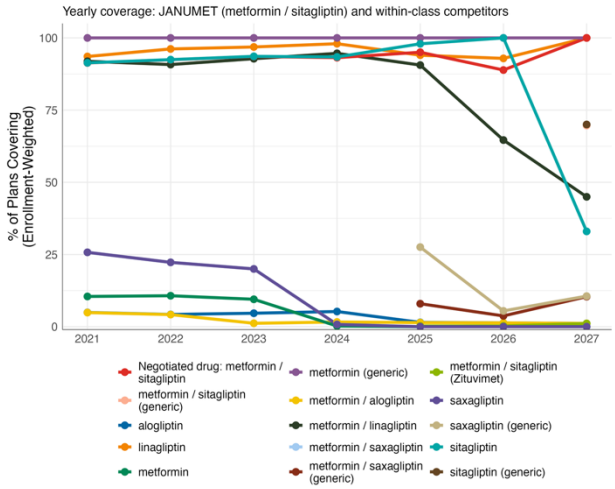
A. First round cohort (initial price applicability year of 2026)

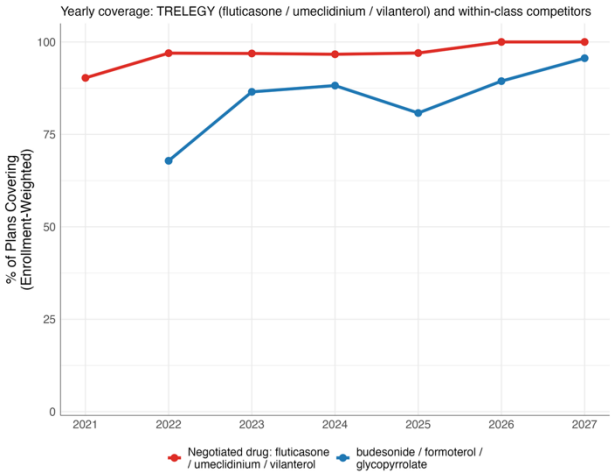


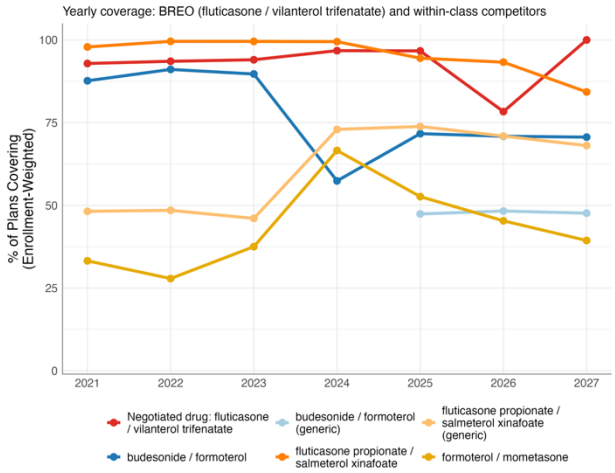
B. Second round cohort (initial price applicability year of 2027)

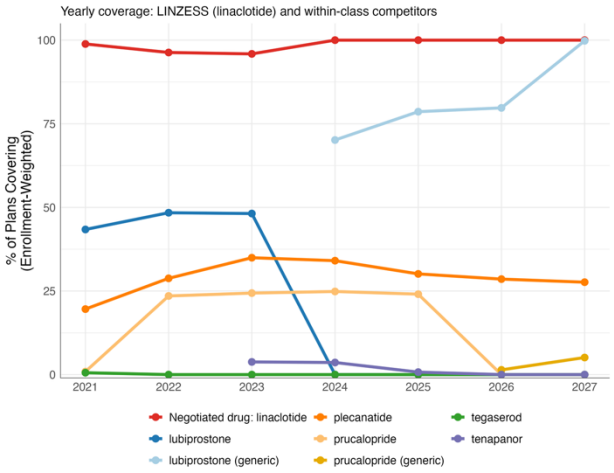


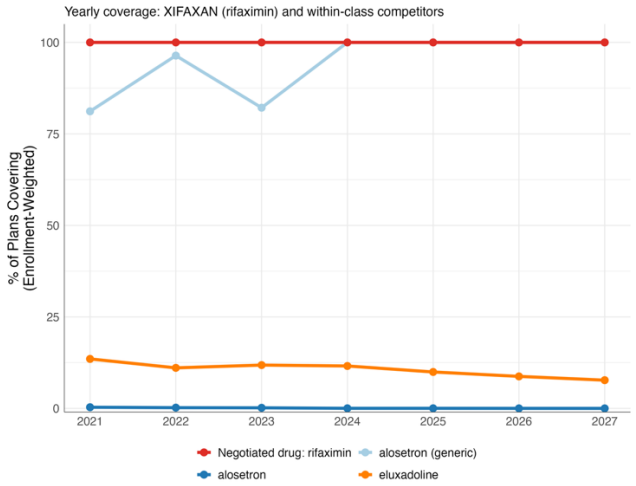


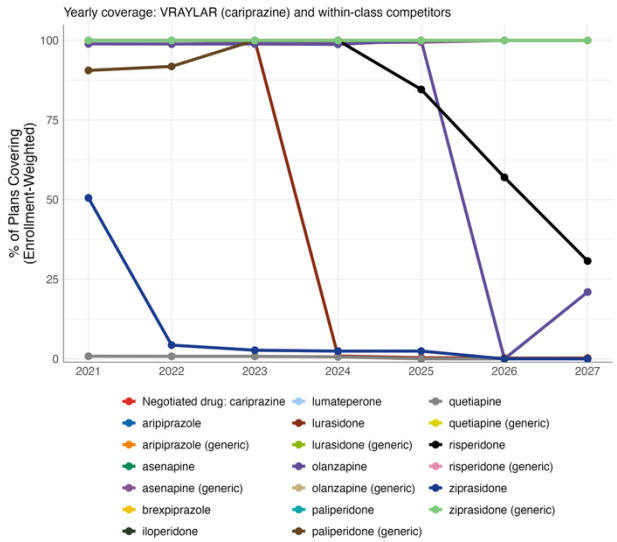


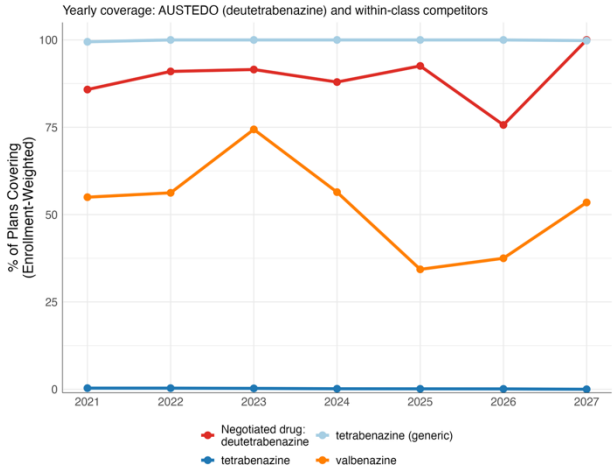


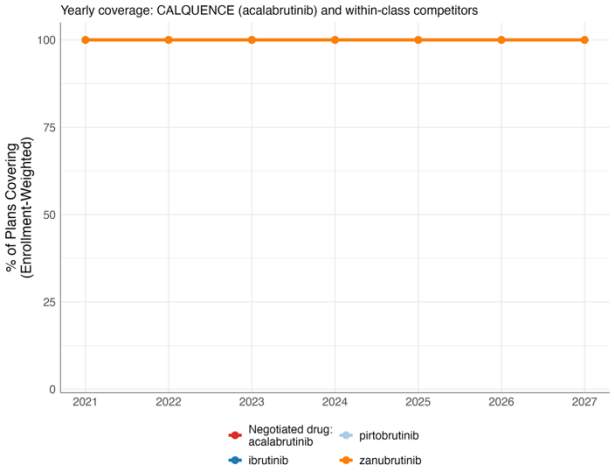


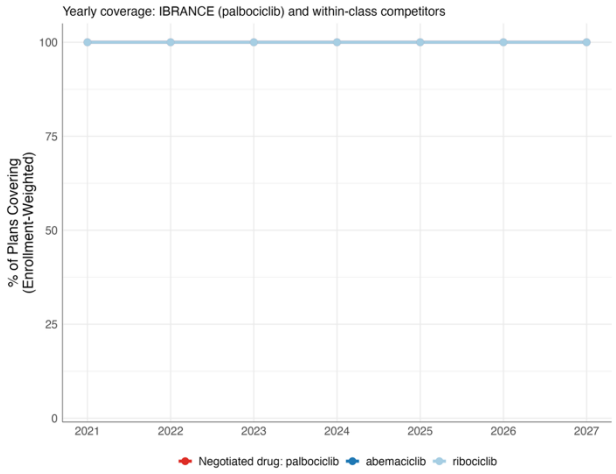


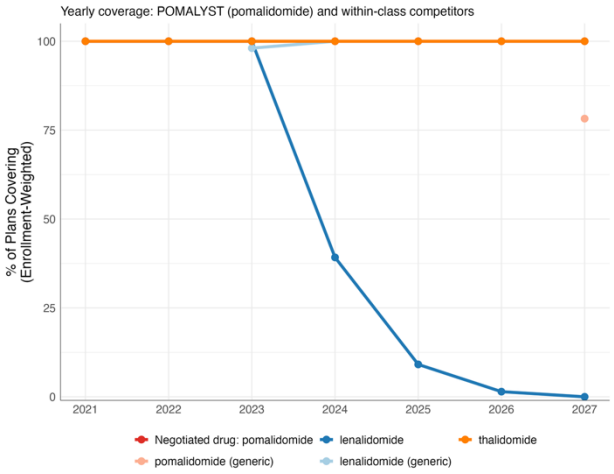

Yearly coverage: XIFAXAN (rifaximin) and within-class competitors
% of Plans Covering (Enrollment-Weighted)
100
75
50
25
0
2021
2022
2023
2024
2025
2026
2027
Negotiated drug: rifaximin
alosetron (generic)
alosetron
eluxadoline

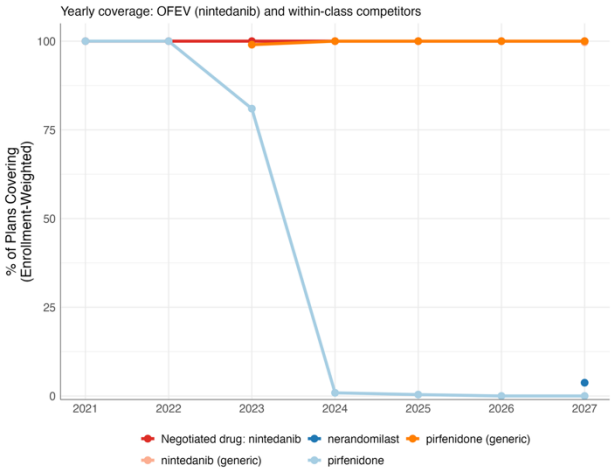

Yearly coverage: VRAYLAR (cariprazine) and within-class competitors
% of Plans Covering (Enrollment-Weighted)
100
75
50
25
0
2021
2022
2023
2024
2025
2026
2027
Negotiated drug: cariprazine
aripiprazole
aripiprazole (generic)
asenapine
asenapine (generic)
brexpiprazole
iloperidone
lumateperone
lurasidone
lurasidone (generic)
olanzapine
olanzapine (generic)
paliperidone
paliperidone (generic)
quetiapine
quetiapine (generic)
risperidone
risperidone (generic)
ziprasidone
ziprasidone (generic)

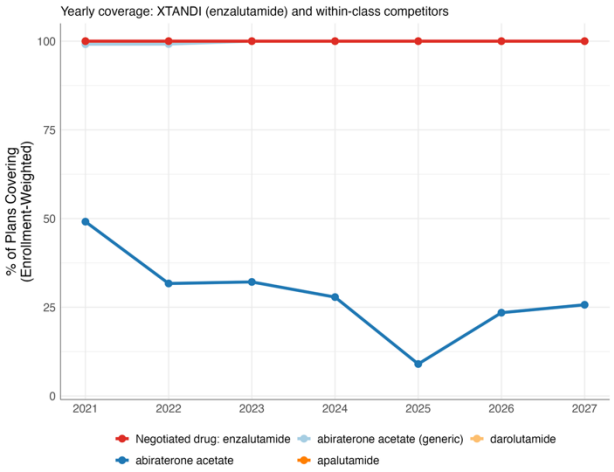

Yearly coverage: AUSTEDO (deutetrabenazine) and within-class competitors
% of Plans Covering (Enrollment-Weighted)
100
75
50
25
0
2021
2022
2023
2024
2025
2026
2027
Negotiated drug: deutetrabenazine
tetrabenazine (generic)
tetrabenazine
valbenazine


Yearly coverage: CALQUENCE (acalabrutinib) and within-class competitors
% of Plans Covering (Enrollment-Weighted)
100
75
50
25
0
2021
2022
2023
2024
2025
2026
2027
Negotiated drug: acalabrutinib
pirtobrutinib
ibrutinib
zanubrutinib

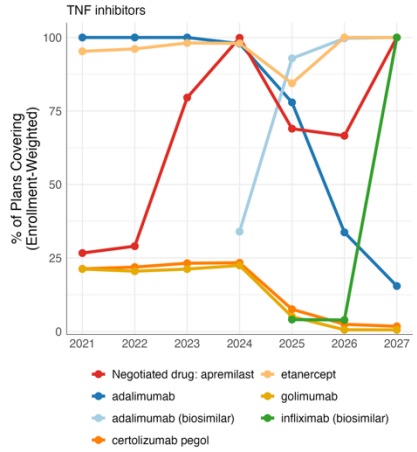

Yearly coverage: IBRANCE (palbociclib) and within-class competitors
% of Plans Covering (Enrollment-Weighted)
100
75
50
25
0
2021
2022
2023
2024
2025
2026
2027
Negotiated drug: palbociclib
abemaciclib
ribociclib

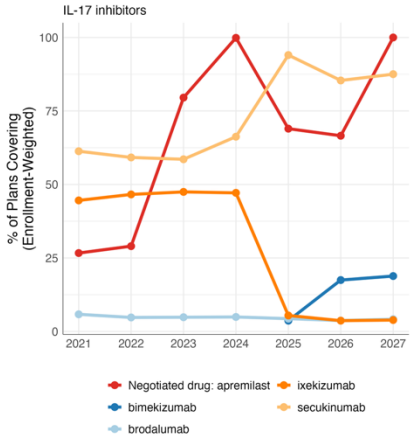

Yearly coverage: POMALYST (pomalidomide) and within-class competitors
% of Plans Covering (Enrollment-Weighted)
100
75
50
25
0
2021
2022
2023
2024
2025
2026
2027
Negotiated drug: pomalidomide
lenalidomide
thalidomide
pomalidomide (generic)
lenalidomide (generic)

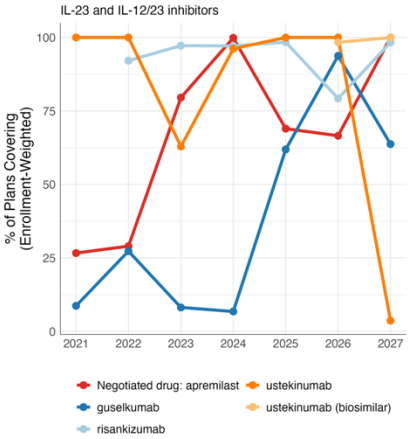


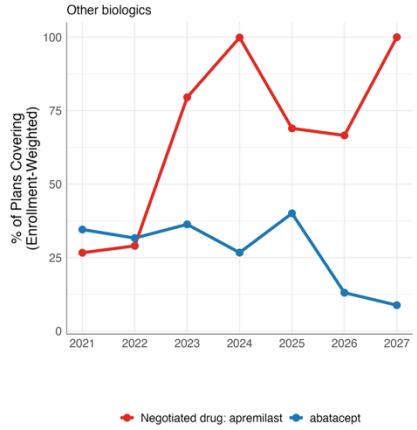


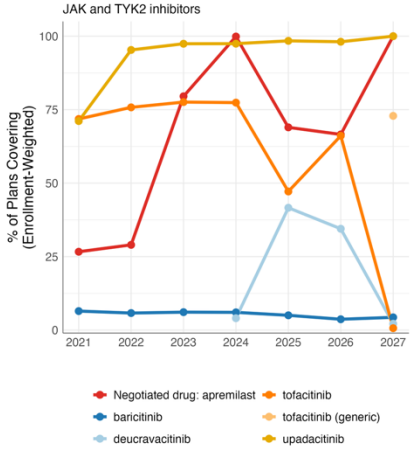
Yearly coverage: OTEZLA (apremilast) and within-class competitors

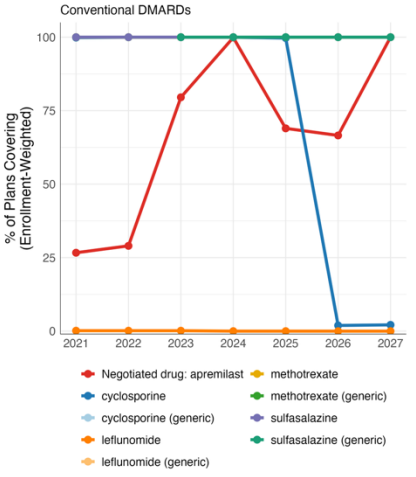












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