Longitudinal Analysis of Medicare Part D Formulary Design for High-Cost Dermatology Systemics

Rachel Day, MD[1,3] · Neil Jairath, MD[2,3] · Frannie McGowan, PharmD[3] · Stephen Pianin, MPH[3]

[1]George Washington University School of Medicine & Health Sciences · [2]Indiana University School of Medicine · [3]Zest Health

Background

Dermatologic specialty drugs are among Medicare's fastest-growing costs – $2.95B in Part D by 2022 (81% specialty),[1] >16% annual growth,[1] +42% agents (2022-2025). Adalimumab biosimilars (2023) promised price competition, yet one year on only 1.5% of plans placed them on preferred tiers[2] and just 35% of dermatologists felt confident in biosimilar interchangeability.[3] Whether formulary design rewards lower-cost biosimilars remains uncharacterized.

Objective

To quantify formulary tier placement, utilization management, and cross-plan concordance for dermatologic biologics and oral targeted therapies in Medicare Part D (2022-2025), and to evaluate whether formulary design preferentially places high-value therapies – including adalimumab and ustekinumab biosimilars.

Methods

- **Study design.** Longitudinal cross-sectional analysis of CMS Medicare Part D Prescription Drug Plan Formulary Files.
- **Data source.** Basic Drugs Formulary File (tier and utilization management flags) and Plan Information File (plan-to-formulary linkage); publicly available, NDC level.
- **Time periods.** Four annual Q4 snapshots, 2022-2025 (CY2023-CY2026).
- **Inclusion/exclusion.** All PDP and MA-PD plans listing ≥1 of 27 FDA-approved dermatologic biologics and oral targeted therapies (11 mechanistic classes); matched via RxNorm; biosimilar vs. reference by NDC labeler code.
- **Outcome measures.** Tier (1-5); prior authorization, step therapy, quantity limits; cross-plan concordance (normalized Shannon entropy, 0 = agreement, 1 = maximum disagreement).
- **Statistical analyses.** Biosimilar vs. reference tier by Mann-Whitney U. Public, de-identified data – IRB exempt.

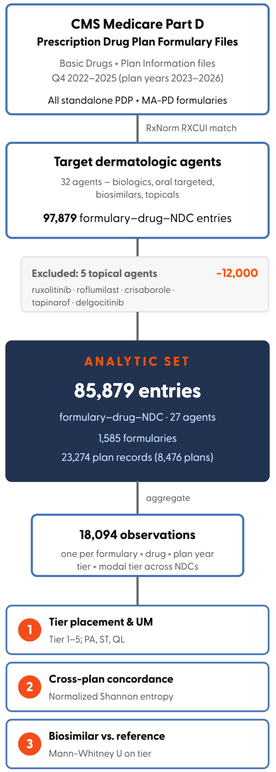

Figure 1. Data assembly and study window. From CMS Part D Formulary Files to the 27-agent, 85,879-entry cohort; timeline marks the four snapshots and the January 2025 redesign.

Results

TIER PLACEMENT & UTILIZATION MANAGEMENT

- Specialty **Tier 5 dominated** – 72-76% of entries across all years.
- Prior authorization **near universal (~99%)**; coded step therapy rare (<1%); quantity limits **rose 43%** (54.6% → 78.2%).

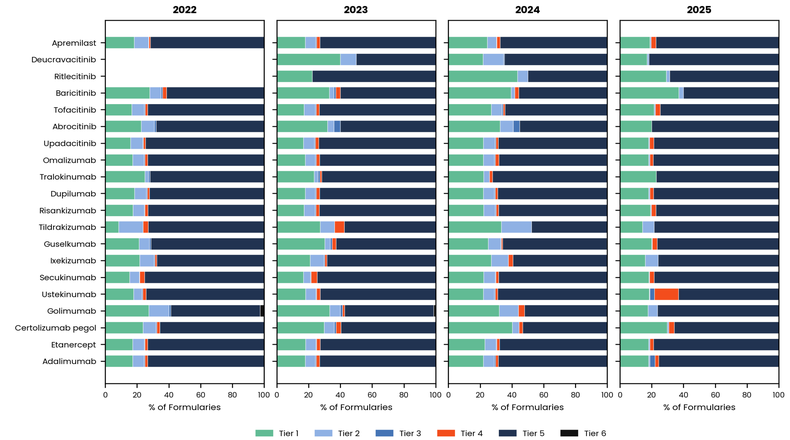

Figure 2. Tier distribution, 2022-2025. Share of formulary entries by tier for the 20 most-covered agents (of 27). Tier 5 dominated for nearly all agents; ustekinumab shows the widest spread. Blank rows = agent not yet listed that year (deucravacitinib, ritlecitinib).

BIOSIMILAR POSITIONING

- **Adalimumab:** biosimilars and reference both median Tier 5 – no advantage after 3 years and 9 biosimilars (P=0.67).
- **Ustekinumab:** biosimilars opened 2 tiers better at launch (median Tier 3 vs. 5; P<0.001).

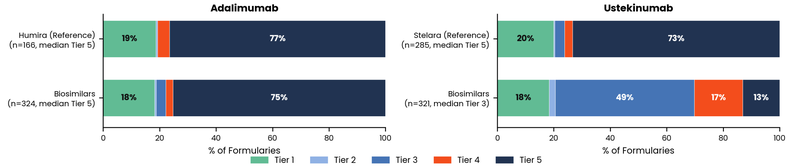

Figure 3. Biosimilar vs. reference tier placement (2025). Adalimumab: reference and biosimilars both median Tier 5 – no advantage after 9 biosimilars (P=0.67). Ustekinumab: biosimilars median Tier 3 vs. reference Tier 5 – a 2-tier advantage (P<0.001), coincident with the January 2025 redesign.

CROSS-PLAN CONCORDANCE

- Cross-plan agreement was **poor** – mean normalized entropy **0.35-0.50** across years.
- Modal-tier agreement as low as **63%**; even adalimumab (≥99% coverage) spanned 5 tiers (75.5% modal, 18.1% on Tier 1).

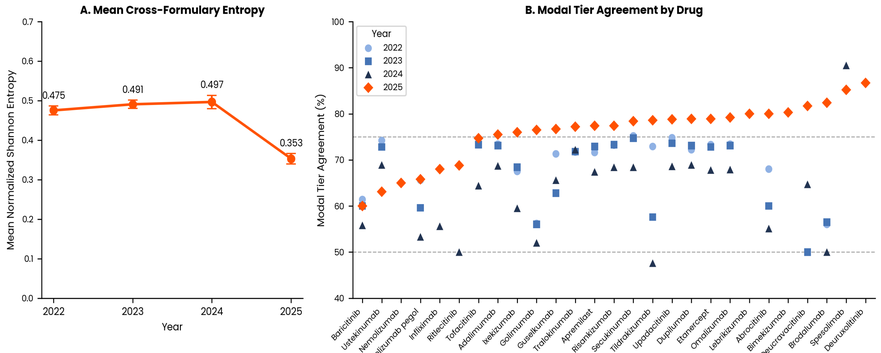

Figure 4. Cross-formulary concordance. (A) Mean normalized Shannon entropy by year (0.353-0.497; higher = more disagreement). (B) Modal-tier agreement by drug and year; agreement fell as low as 63% (ustekinumab, 2025), and even adalimumab spanned 5 tiers. H_{norm} range 0-1 (0 = agreement, 1 = maximum disagreement).

Conclusions

- Medicare Part D formularies did **not** differentiate dermatologic biosimilars from reference products – near-universal Tier 5 placement and prior authorization flatten the price signal that would favor lower-cost biosimilars.
- Plans varied widely on **which** tier a drug occupied, yet not on **whether** it was a biosimilar.
- The lone exception – ustekinumab biosimilars' 2-tier advantage – coincided with the 2025 benefit redesign, suggesting formulary design responds to plan financial exposure. **Formulary design alone is insufficient to steward high-value care.**

References

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