Global Value Assessment for Biologics in Psoriatic Arthritis in the time of IRA and MFN: Does Cost per Incremental ACR50 Responder Analysis Provide a Clinically Meaningful and Practical Cross-Market Metric?

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FOCUSED VALUE

BACKGROUND

- US drug pricing initiatives, including Inflation Reduction Act (IRA) negotiation (discounts ranging from 38% to 85%) and Most-Favored-Nation (MFN) international benchmarking, have heightened the need to interpret relative value of drugs in the context of clinical benefit
- In psoriatic arthritis (PsA), cost per incremental ACR50 responder provides a standardized value metric for comparing costs across therapies and markets
- ACR50 was selected as the primary efficacy threshold because it is widely reported across PsA trials and provides a clinically meaningful measure of joint response, balancing the lower stringency of ACR20 with the more restrictive ACR70 threshold
- ACR50 provides a consistent primary metric for comparing treatment value, while a more comprehensive assessment, aligned with the ISPOR value flower, may incorporate additional clinical outcomes and broader elements of value

OBJECTIVE

- To compare cost per incremental ACR50 responder at Week 24 across six advanced PsA therapies in the US, UK, France, and Germany, and assess how a hypothetical US price reduction affects cross-market differences
- To support a more holistic assessment of treatment value by comparing cost-adjusted performance across joint, skin, and disease activity outcomes

METHODS

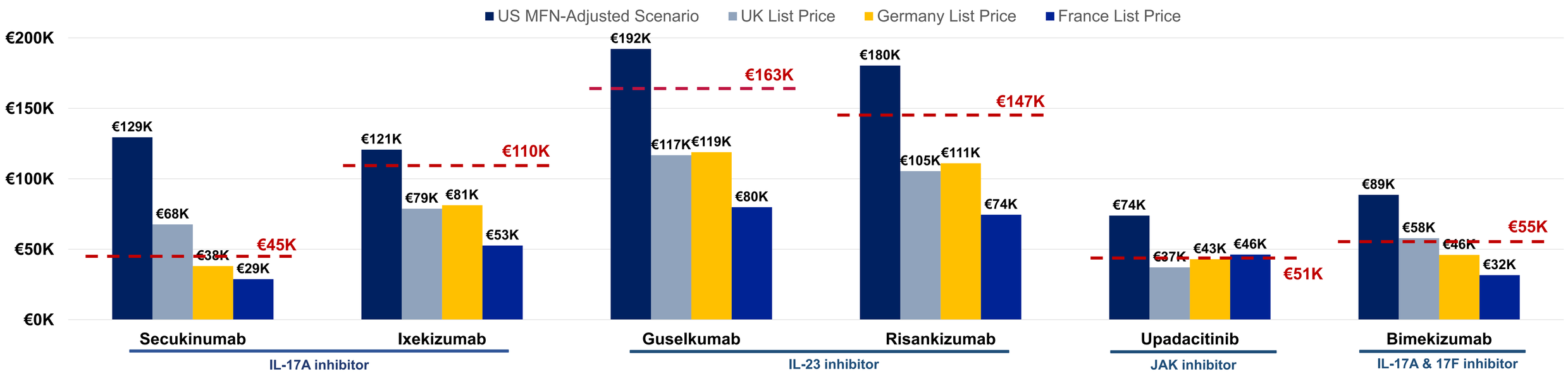
- **Therapy Selection:** Six US FDA-approved advanced therapies (2015–2025) were selected: secukinumab, ixekizumab, guselkumab, upadacitinib, risankizumab, and bimekizumab (**Table 1**)
- **Clinical Input:** Week 24 ACR50 data for active and placebo arms were extracted from clinical trials[1–5] to derive placebo-adjusted response rates for the cost-per-responder analysis (**Table 1**)
- **Cost Inputs:** Year 1 acquisition costs (2025) were gathered using Wholesale Acquisition Cost (WAC) from Analysource™ for the US, the BNF for the UK,[6] BdM_IT for France,[7] and AOK Nordost for Germany[8,9] (Table 1)
- **Cost Standardization:** All cross-market costs were converted to Euros (€) using 2025 average exchange rates (1 USD = €0.886[10]; 1 GBP = €1.1674[11]) for comparative assessment (**Figure 1**)
- **US MFP-Adjusted Scenario:** A hypothetical 66.5% discount was applied to US WAC based on recent IRA price-negotiation cycles to estimate an MFP-adjusted treatment cost
- **Hypothetical US MFN Scenario:** An adapted KFF/CMS GENEROUS-version benchmark[12] was estimated for each therapy using the second-lowest observed price across the selected European markets, adjusted for GDP per capita (PPP)[13]
- **Multidimensional Profile:** Week 24 placebo-adjusted response rates across joint (ACR20/50/70), skin (PASI90/100), and Minimal Disease Activity (MDA) endpoints were derived from published clinical trials. For each endpoint, placebo-adjusted response was divided by annual treatment cost to derive a cost-adjusted response. Values were normalized within each endpoint to a 0–100 scale for visualization, with higher values indicating greater clinical response relative to treatment cost (**Figure 2**)

Table 1. Clinical Response and 2025 List Price for Psoriatic Arthritis Therapies

Generic Name	Mechanism of Action	FDA Approval Year for PsA	Placebo-Adjusted ACR50 (W24)	US WAC	US MFN-Adjusted Scenario	UK List Price	France List Price	Germany List Price
Secukinumab	IL-17A inhibitor	2016	28.0%	$122,099.68	$40,903.39	£16,223.00	€ 8,060.55	€ 10,665.54
Ixekizumab	IL-17A inhibitor	2017	25.0%	$101,661.07	$34,056.46	£16,875.00	€ 13,161.00	€ 20,301.92
Guselkumab	IL-23 inhibitor	2020	18.0%	$116,531.52	$39,038.06	£18,000.00	€ 14,370.40	€ 21,396.92
Upadacitinib	JAK1 inhibitor	2021	33.0%	$82,158.70	$27,523.16	£10,501.05	€ 15,244.83	€ 14,174.00
Risankizumab	IL-23 inhibitor	2022	22.1%	$134,300.94	$44,990.81	£19,957.00	€ 16,456.80	€ 24,528.46
Bimekizumab	IL-17A & 17F inhibitor	2024	34.5%	$102,997.57	$34,504.19	£17,101.00	€ 10,912.20	€ 15,873.00

Note: *ACR50 response rates were evaluated at Week 24. For bimekizumab, an estimated Week 24 placebo response is used to calculate the placebo-adjusted response. All pricing inputs reflect 2025 prices*

Figure 1: Cost per Incremental ACR50 Responder at Week 24 Across Selected Markets (€, 2025)

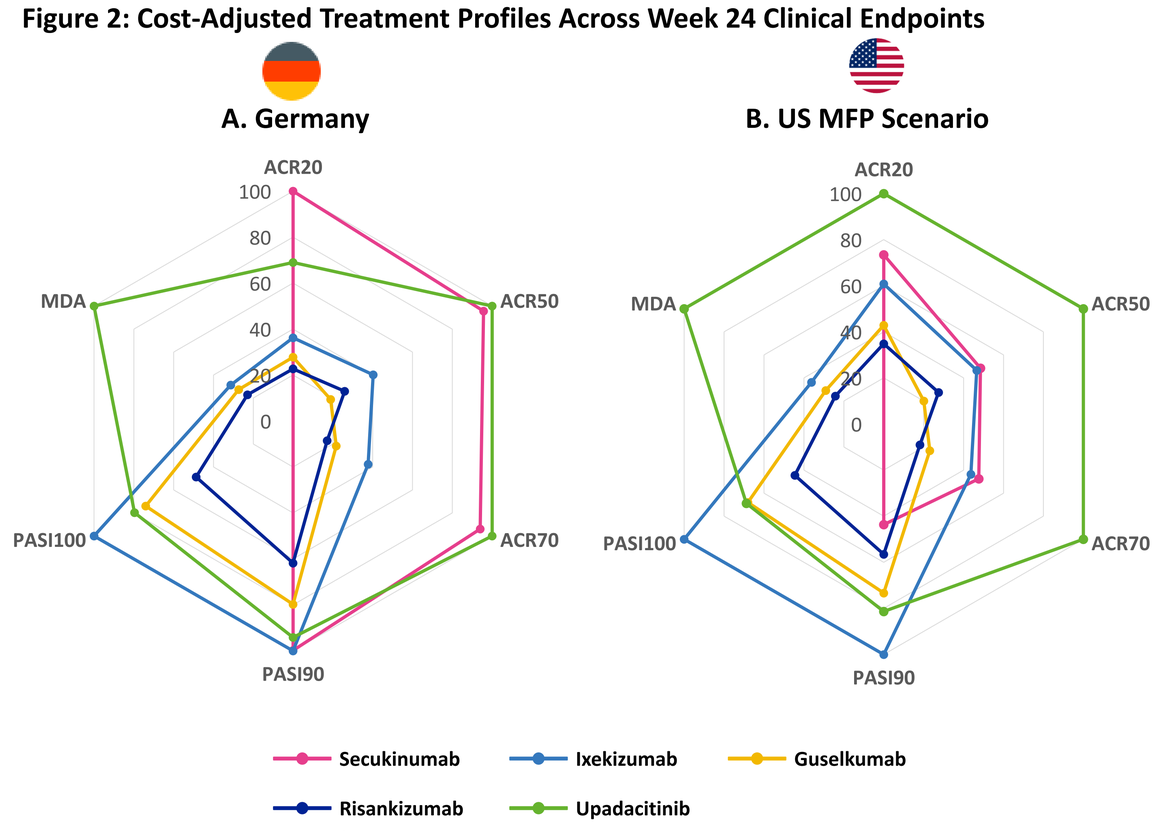


Note: *All costs were converted to euros using 2025 exchange rates (USD 1 = €0.886 and GBP 1 = €1.1674).* Hypothetical US MFN price (red dash line) based on the KFF-described methodology, using the second-lowest observed list price and GDP per capita (PPP) adjustment.
Net prices after rebates were not available; results should be interpreted with caution.

RESULTS

- Clinical efficacy inputs and Year 1 drug acquisition costs across markets are summarized in **Table 1** and were used to derive the cost-per-incremental-responder analyses
- **Cost per Incremental Responder (Figure 1):**
  - **US (WAC):** Ranged from €220K ($249K; upadacitinib) to €574K ($647K; guselkumab)
  - **US (MFP-Adjusted Scenario):** A 66.5% IRA discount reduced US cost per ACR50 responder to €74K ($83K; upadacitinib) to €192K ($217K; guselkumab), substantially narrowing the transatlantic gap
  - **Europe:** €37K (£32K; upadacitinib) to €117K (£100K; guselkumab) in the UK (pre-PAS); €29K (secukinumab) to €80K (guselkumab) in France; and €38K (secukinumab) to €119K (guselkumab) in Germany
  - **Hypothetical US MFN Scenario:** The MFN benchmarks, shown as red dashed lines, ranged from approximately €45K to €163K across therapies and generally fell below the US MFP-adjusted estimates, although the magnitude varied by therapy
- **Cost-Adjusted Clinical Profiles (Figure 2):**
  - In Germany, secukinumab had the highest or near-highest cost-adjusted scores for ACR20 (100), ACR50 (95.7), ACR70 (94.0), and PASI90 (99.9), while upadacitinib scored highest for ACR50, ACR70, and MDA (100 each) and remained high for PASI90 (94.2).
  - Under the US MFP scenario, upadacitinib had the highest cost-adjusted scores for ACR20, ACR50, ACR70, and MDA (100 each), while ixekizumab ranked highest for PASI90 and PASI100 (100 each).
  - The profiles shifted between Germany and the US MFP scenario; for example, secukinumab's ACR50 score decreased from 95.7 to 44.8 and its PASI90 score from 99.9 to 43.7, showing how market-specific treatment costs can change the relative value profile across endpoints

Figure 2: Cost-Adjusted Treatment Profiles Across Week 24 Clinical Endpoints



Note: *Cost-adjusted response was calculated for each treatment and endpoint as the placebo-adjusted Week 24 response rate divided by annual treatment cost. Values were subsequently normalized within each endpoint to a 0–100 scale, with the treatment having the highest cost-adjusted response assigned a value of 100. Higher values indicate greater placebo-adjusted response relative to annual treatment cost. Bimekizumab was excluded because Week 24 data were not available for all included endpoints.*

LIMITATIONS

- Analysis utilized publicly disclosed drug pricing; confidential commercial rebates, discounts, and UK Patient Access Schemes (PAS) were not captured
- Clinical outcomes were derived from individual published trials rather than head-to-head comparisons; differences in study populations and trial design may affect cross-treatment comparisons

CONCLUSIONS

- Cost per incremental ACR50 responder varied substantially across therapies and markets
- A hypothetical 66.5% US discount narrowed cross-market differences, although US estimates remained above the corresponding European estimates for every therapy
- Cost-adjusted profiles across multiple clinical endpoints demonstrated that relative treatment value varied by both endpoints and markets
- In the context of IRA negotiation and MFN pricing discussions, cost per incremental ACR50 responder offers a focused economic benchmark that should be interpreted alongside broader clinical evidence and market-specific net prices
- Thus providing useful empirical benchmark for IPAY negotiations and for anchoring value to benefit dimensions beyond just net price (ISPOR value flower dimensions as case in point)

POSTER & REFERENCES

Abbreviations: *ACR20/50/70, American College of Rheumatology 20%/50%/70% response; b/tsDMARD, biologic/targeted synthetic disease-modifying antirheumatic drug; FDA, US Food and Drug Administration; IL, interleukin; IRA, Inflation Reduction Act; JAK, Janus kinase; MDA, minimal disease activity; MFP, Maximum Fair Price; PAS, Patient Access Scheme; PASI90/100, Psoriasis Area and Severity Index 90%/100% improvement; PsA, psoriatic arthritis; WAC, wholesale acquisition cost*

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