



Cost-per-Responder Analysis of Bimekizumab (IL-17A/F Inhibitor) Against IL-Inhibitors for Psoriatic Arthritis in Spain, Based on Matching-Adjusted Indirect Comparisons

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ABSTRACT

Introduction: Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F and IL-17A and was approved to treat patients with active psoriatic arthritis (PsA) in the European Union in 2023. This study compares the cost per responder (CPR) of bimekizumab against IL-17A (secukinumab), IL-12/23 (ustekinumab) and IL-23 (guselkumab

and risankizumab) targeted therapies to treat patients with PsA in Spain.

Methods: The CPR was calculated by dividing the average annual drug cost per patient by the response rates for minimal disease activity (MDA) and American College of Rheumatology (ACR) 50 and ACR70 at week 52 in patients who were biological disease-modifying antirheumatic drug (bDMARD) naïve or who had experienced inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IR). Response rates from four published matching-adjusted indirect comparisons (MAIC) were used. Spanish list prices and Royal Decree Law 8/2010 discounts were considered.

Results: In bDMARD-naïve patients, bimekizumab had a lower CPR for MDA and ACR70 versus all comparators except for secukinumab 150 mg, where the CPR for bimekizumab was higher for all three efficacy measures. The incremental CPR ranged between 17.2% (95% confidence interval [CI] –26.1%, 50.6%) for ACR70 and 92.7% (95% CI 60.0%, 119.4%) for ACR50. The incremental CPR for ACR50 for bimekizumab compared to secukinumab 300 mg was also slightly higher (2.3% [95% CI –12.5%, 14.3%]). In patients with TNFi-IR, bimekizumab was more cost-efficient than all comparators for the three response rate measures at week 52.

Conclusion: CPR analyses based on MAIC response rates at week 52 suggest that bimekizumab is more cost-efficient than IL-12/23

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and IL-23 therapies, including ustekinumab, guselkumab and risankizumab, for treating PsA in Spain across both bDMARD-naïve patients and patients with TNFi-IR for all outcomes (MDA, ACR50/70). Compared to IL-17A (secukinumab), bimekizumab is consistently cost-efficient in patients with TNFi-IR for all outcomes and is cost-efficient in bDMARD-naïve patients versus those taking 300 mg regarding MDA and ACR70.

Keywords: Cost-per-responder; Interleukin inhibitors; Matching-adjusted indirect comparison; Psoriatic arthritis; Spain

Key Summary Points

Why carry out this study?

Psoriatic arthritis is a chronic immune-mediated disease, characterized by inflammation of the joints and skin

To our knowledge, there are no studies comparing the cost per responder (based on matching-adjusted indirect comparisons) for bimekizumab [interleukin (IL)-17A/F] versus other approved interleukin targeted therapies for the longer-term treatment of patients with psoriatic arthritis at week 52 in Spain

What was learned from the study?

Bimekizumab has demonstrated cost-efficiency in Spain compared to various IL-targeted therapies in biological disease-modifying antirheumatic drug-naïve patients

In patients with inadequate response or intolerance to tumour necrosis factor inhibitors, it shows significantly higher efficiency than all IL-targeted treatments, emphasising its high value in this patient population

a significant clinical burden, since it presents heterogeneous manifestations including cutaneous (psoriasis of skin and nails), musculoskeletal (peripheral joint inflammation, enthesitis) and involving dactylitis and axial joint inflammation (sacroiliitis and spine involvement). It is associated with extra-musculoskeletal symptoms (uveitis, inflammatory bowel disease) and comorbidities (including cardiovascular and obesity, among others) [1, 2]. The prevalence of PsA in Europe is estimated at 207 per 100,000 adults [3].

Pharmacological treatment of PsA includes two principal groups: (1) non-steroidal anti-inflammatory drugs (NSAIDs) and local corticosteroid injections as initial therapy for symptom control and (2) disease-modifying antirheumatic drugs (DMARDs) for patients with progressive disease [4]. Clinical practice guidelines recommend the use of biological DMARDs (bDMARDs) for patients with PsA who have not achieved their therapeutic targets with conventional synthetic DMARD therapy, followed by using targeted synthetic DMARDs, such as Janus kinase inhibitors, if bDMARD failure occurs [4–6]. In Spain, the approved bDMARD treatments include tumour necrosis factor (TNF) inhibitors, interleukin (IL) inhibitors (IL-17A, IL-17A/F, IL-23, IL-12/23) and abatacept (CTLA4 inhibitor) [4–6].

Bimekizumab is the first humanized IgG1/k monoclonal antibody that selectively inhibits IL-17F and IL-17A. It was approved to treat patients with active PsA by the European Medicines Agency in 2023 [7]. To date, no head-to-head clinical trials have compared the efficacy of bimekizumab versus other PsA therapies. However, indirect comparison analyses, such as a network meta-analyses (NMA), have compared the efficacy of bimekizumab vs other bDMARDs over a short treatment period (up to 24 weeks) [8], and four detailed matching-adjusted indirect comparison (MAIC) analyses compared bimekizumab with other bDMARDs for 52 weeks [9–12].

The annual cost per patient with PsA in Europe, including direct and indirect costs, ranges from €7254 to €13,368 [13]. Therefore, early diagnosis and initiation of treatment are essential to avoid long-term damage, disability

INTRODUCTION

Psoriatic arthritis (PsA) is a heterogeneous and complex inflammatory disease associated with

and mental health complications [14]. The increasing number of treatments that are raising the standard of care in PsA, together with the limited healthcare budget, makes comparative efficiency studies such as cost per responder (CPR) necessary.

Consequently, the aim of this study was to compare the CPR of bimekizumab against commonly used bDMARDs, IL-17A (secukinumab), IL-12/23 (ustekinumab) and IL-23 (guselkumab and risankizumab), to treat patients with PsA in Spain, based on the published MAIC results.

METHODS

A CPR model was developed in Microsoft Excel to compare the average annual costs per patient receiving bimekizumab versus other bDMARDs (IL-17A, IL-12/23 and IL-23) using efficacy data from four MAIC analyses at 52 weeks [9–12]. The CPR was calculated by dividing the average annual drug cost per patient by the response rate using the following equation:

$$\text{CPR} = \frac{\text{annual cost}}{\% \text{ of responding patients}}$$

The analysis was conducted from the perspective of the hospital pharmacy of the Spanish National Health System.

Cost-efficiency is a measure of how well the resources used (costs) are aligned with the results achieved. A cost-efficient solution is one that achieves the desired outcome at a lower cost. Therefore, the most cost-efficient comparator in this analysis is the one with the lowest CPR.

Average Annual Costs

The average annual drug costs were calculated considering the unit cost and dosage regimens of each treatment. Spanish actual list prices per unit from the Bot Plus 2.0 database published by the General Council of Official Colleges of Pharmacist and the Royal Decree Law 8/2010 discount were included, since these are hospital pharmacy drugs [15–17]. Dosing regimens were informed by each treatment's Summary of

Product Characteristics [18]. Doses are higher in the first year of administration because of the induction phase. Therefore, to adopt a conservative approach, the average number of vials, syringes and pre-filled pens required annually in the first and second year of treatments was used. On the other hand, a 100% persistence rate (the time of continuous therapy, from initiation of treatment to its discontinuation) was conservatively assumed for all therapeutic alternatives. Average annual drug costs are shown in Table 1.

Efficacy Data

This analysis was based on the longer-term efficacy results (52 weeks) that IL therapies have obtained in previously published MAIC analyses [9–12], comparing bimekizumab with secukinumab, ustekinumab, risankizumab and guselkumab, respectively. The MAIC analyses included a total of ten clinical trials: BE OPTIMAL, BE COMPLETE and BE VITAL for bimekizumab; FUTURE-2 for secukinumab; PSUMMIT-1 and PSUMMIT-2 for ustekinumab; KEEPSAKE-1 and KEEPSAKE-2 for risankizumab; and DISCOVER-2 and COSMOS for guselkumab. Baseline characteristics of patients included in each of these studies are reported in Table S1. Efficacy was measured by achievement of 50% and 70% improvement in the American College of Rheumatology (ACR50/70) response and Minimal Disease Activity (MDA) to assess disease activity, commonly used in this therapeutic area [19–24]. More details on these criteria are given in Supplementary Table S2. The results were evaluated for patients who are bDMARD-naïve and for those who had previously experienced inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IRs) [9–12]. The mean adjusted response rates of patients with bimekizumab, as well as the confidence intervals (CI), versus each of the comparators obtained from the MAIC analysis at week 52 are shown in Table 2.

Our study did not require approval from any ethics committee. Applying the Helsinki Declaration was not necessary, because the efficacy data we used are from previously published studies where confirmation of compliance with the

Table 1 Average annual drug costs (year 1 and year 2)

Biological drug	List price per unit ^a	Dose	Year 1 (units)	Year 2 (units)	Average annual (units)	Average annual drug costs
Bimekizumab 160 mg	€1236.73	160 mg Q4W	14	13	13.5	€16,695.79
Secukinumab 150 mg	€528.69	150 mg wk 0–1–2–3–4 150 mg Q4W	17	13	15	€7930.40
Secukinumab 300 mg	€1057.38	300 mg wk 0–1–2–3–4 300 mg Q4W	17	13	15	€15,860.65
Ustekinumab 45 mg	€2541.31	45 mg wk 0–4 45 mg Q12W	6	4	5	€12,706.54
Guselkumab 100 mg	€2345.89	100 mg wk 0–4 100 mg – Q8W	8	6	7	€16,421.25
Risankizumab 150 mg	€3545.98	150 mg wk 0–4 150 mg – Q12W	6	4	5	€17,729.89

^aAll treatments prices include the Royal Decree Law 8/2010 discount of 7.5% [17]. Dose source: Spanish Agency of Medicines and Medical Devices, 2024[18]

Declaration of Helsinki and Good Clinical Practice had been performed.

RESULTS

bDMARD-Naïve Patients

The results of the CPR analysis for MDA and ACR 50/70 response rates in bDMARD-naïve patients receiving bimekizumab against secukinumab, ustekinumab, guselkumab and risankizumab at week 52 are reported separately for each efficacy measure in Fig. 1. Bimekizumab had a lower CPR than its comparators in 10 of the 14 comparisons conducted for MDA (Fig. 1A), ACR 50 (Fig. 1B) and ACR 70 (Fig. 1C) when measured against ustekinumab, guselkumab and risankizumab. In particular, for MDA, bimekizumab's incremental CPR was –34.5% (95% CI –38.3%, –33.4%) and –20.7% (95% CI –19.9, –21.3%) compared to those of guselkumab and risankizumab,

respectively; for ACR 50, it was –27.2% (95% CI –34.8%, –21.3%), –12.7% (95% CI –14.0%, –11.7%) and –24.2% (95% CI –24.1%, –24.3%) compared to ustekinumab, guselkumab and risankizumab, respectively; for ACR 70, it was –44.9% (95% CI –54.5%, –37.9%), –36.4% (95% CI –40.4%, –31.7%) and –36.8% (95% CI –37.6%, –36.2%) compared to ustekinumab, guselkumab and risankizumab, respectively. Compared to secukinumab, bimekizumab showed an incremental CPR reduction of –16.5% (95% CI –34.6%, –2.0%) and –33.9% (95% CI –54.6%, –17.8%) for MDA and ACR 70, respectively, relative to its 300 mg dosage.

Finally, bimekizumab incremental CPR was 52.3% (95% CI 14.36%, 82.7%), 92.7% (95% CI 60.0%, 119.4%) and 17.2% (95% CI –26.1%, 50.6%) higher than secukinumab 150 mg for MDA, ACR 50 and ACR 70, respectively, and slightly higher (2.3% [95% CI –12.5%, 14.3%]) versus secukinumab 300 mg in ACR 50. Results are shown in Fig. 3A.

Table 2 Bimekizumab MAIC-based adjusted response rates versus comparators at 52 weeks

		MDA		ACR 50		ACR 70	
		Mean	95% CI	Mean	95% CI	Mean	95% CI
bDMARD -naïve	Bimekizumab 160 mg versus secukinumab 150 mg	50.49%	(44.92–56.06%)	53.75%	(48.19–59.31%)	42.76%	(37.24–48.27%)
		36.52%	(24.40–48.65%)	49.21%	(36.62–61.80%)	23.81%	(13.08–34.54%)
	Bimekizumab 160 mg versus secukinumab 300 mg	50.49%	(44.92–56.06%)	53.75%	(48.19–59.31%)	42.76%	(37.24–48.27%)
		40.03%	(27.89–52.17%)	52.24%	(40.06–64.42%)	26.87%*	(16.05–37.68%)
	Bimekizumab 160 mg versus ustekinumab 45 mg	N.A	N.A	53.70%	(47.25–60.16%)	40.71%	(34.35–47.06%)
				29.76%	(23.46–36.05%)	17.07%*	(11.89–22.25%)
TNFi-IR	Bimekizumab 160 mg versus guselkumab 100 mg	48.14%	(41.55–54.73%)	56.35%	(49.81–62.89%)	44.42%	(37.87–50.97%)
		31.00%*	(25.22–36.78%)	48.40%*	(42.15–54.65%)	27.80%	(22.20–33.40%)
	Bimekizumab 160 mg versus risankizumab 150 mg	44.99%	(39.45–50.53%)	53.75%	(48.20–59.30%)	38.55%	(33.13–43.96%)
		37.89%*	(33.55–42.23%)	43.27%	(38.84–47.70%)	25.88%*	(21.96–29.80%)
	Bimekizumab 160 mg versus secukinumab 300 mg	40.54%	(33.66–47.43%)	47.82%	(40.82–54.82%)	31.58%	(25.06–38.09%)
		18.94%	(5.88–32.00%)	27.27%*	(11.48–43.06%)	18.18%	(4.51–31.86%)
	Bimekizumab 160 mg versus ustekinumab 45 mg	N.A*	N.A	49.98%	(42.45–57.52%)	34.13%	(26.99–41.28%)
				16.67%*	(7.04–26.29%)	5.00%	(– 0.63– 10.63%)
	Bimekizumab 160 mg versus guselkumab 100 mg	41.94%	(35.33–48.55%)	50.06%	(43.36–56.76%)	34.13%	(27.78–40.48%)
		26.98%	(20.61–33.35%)	39.15%*	(32.15–46.16%)	23.81%*	(17.70–29.92%)
	Bimekizumab 160 mg versus risankizumab 150 mg	36.12%	(29.58–42.66%)	45.77%	(38.99–52.56%)	29.92%	(23.69–36.16%)
		18.87%	(11.33–26.40%)	21.70%*	(13.76–29.64%)	10.38%*	(4.50–16.25%)

Sources: Mease et al. 2024 [9], Mease et al. 2024 [10], Mease et al. 2024 [11], Warren et al. 2024 [12]

ACR American College of Rheumatology, bDMARD biological disease-modifying antirheumatic drugs, CI confidence interval, MDA minimal disease activity, TNFi-IR tumour necrosis factor inhibitors-inadequate response or intolerance

*Statistically significant: $p \leq 0.05$; N.A not applicable

Patients with TNFi-IR

In patients with TNFi-IR (in this case, 11 comparisons in total), bimekizumab was more cost-efficient than all comparators at week 52 for MDA, ACR 50 and ACR 70. Figure 2 shows the

results of the CPR analysis for MDA and ACR 50/70 response rates across all comparators at week 52 in patients with TNFi-IR. Bimekizumab has a lower incremental CPR, with –80.8% (95% CI –103.1%, –66.2%) compared to ustekinumab for ACR 70 and –20.5% (95% CI –24.6%,

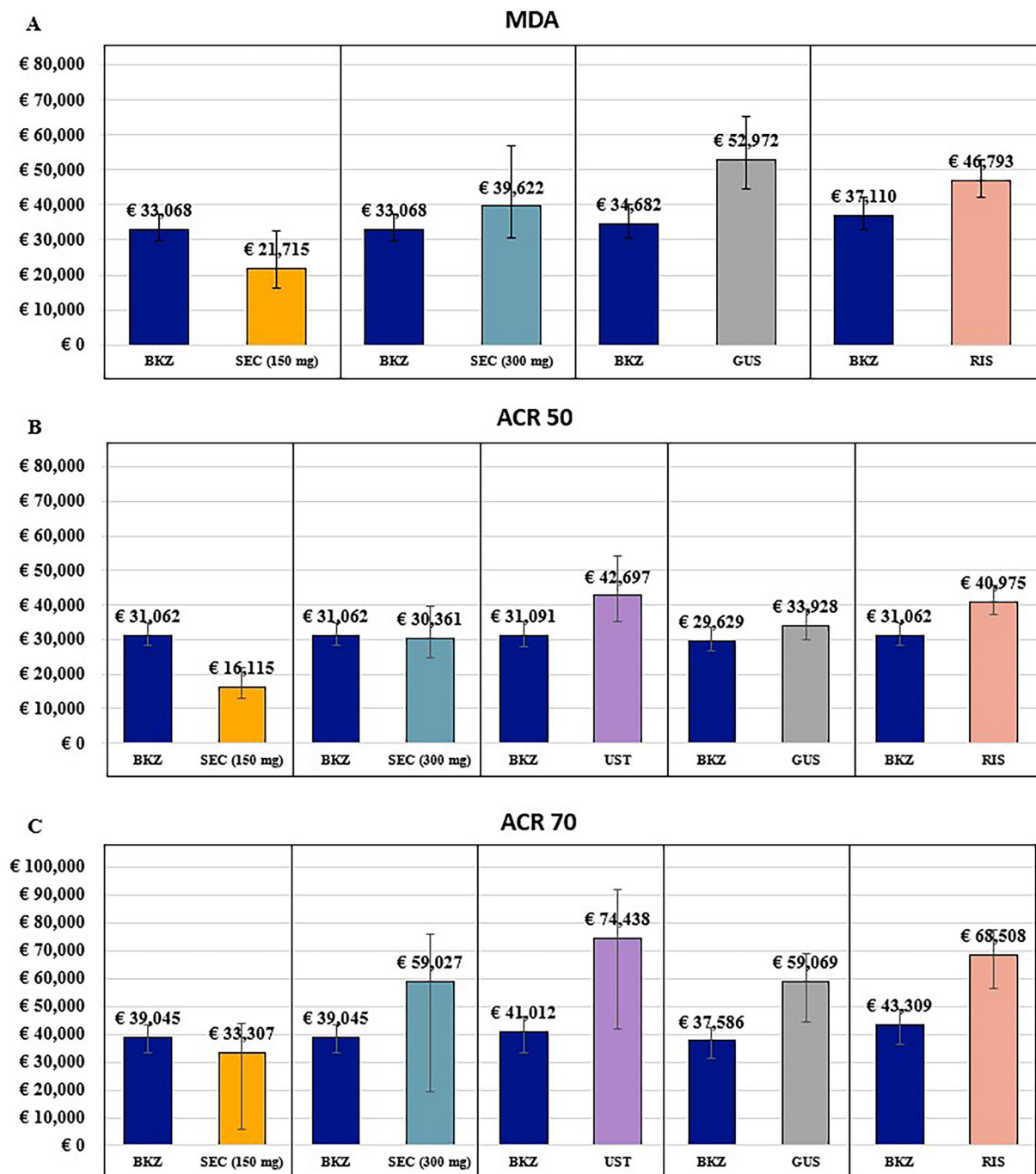


Fig. 1 Cost-per-responder analysis for MDA, ACR50 and ACR70 in bDMARD-naïve patients at 52 weeks. *ACR* American College of Rheumatology, *bDMARD* biologi-

cal disease-modifying antirheumatic drugs, *BKZ* bimekizumab, *GUS* guselkumab, *MDA* minimal disease activity, *RIS* risankizumab, *SEC* secukinumab, *UST* ustekinumab

–17.3%) compared to guselkumab for ACR 50 (Fig. 3B).

DISCUSSION

To our knowledge, this is the first CPR study based on 52-week MAICs comparing bimekizumab (IL-17A/F) versus other approved IL-targeted therapies for the longer-term treatment of patients with PsA. Overall, bimekizumab was more cost-efficient in 21 of 25 comparisons conducted in this analysis. In bDMARD-naïve patients, our results suggested that bimekizumab has numerically lower incremental CPR than the evaluated comparators, except for secukinumab 150 mg, across all endpoints (MDA, ACR50/70) and a slightly higher incremental CPR (2.3%) compared to secukinumab 300 mg for ACR 50 (Fig. 3). Moreover, the 95% CI for the incremental CPR indicated that the differences observed were not statistically significant in bimekizumab versus secukinumab 150 mg for achieving ACR 70 and versus secukinumab 300 mg for achieving ACR 50 (Fig. 3).

In patients with TNFi-IR, the incremental CPR results associated with PsA favour bimekizumab compared to all IL therapies evaluated for all outcomes (MDA, ACR 50, ACR 70). In patients with TNFi-IR, bimekizumab demonstrated a statistically significant incremental CPR advantage in all clinical endpoints versus comparators (Fig. 3).

Since the European Medicines Agency approval of bimekizumab in PsA, there have been no published studies analysing its CPR compared to other treatments in the Spanish healthcare system. In PsA, only two studies have been published analysing the CPR among several treatments. However, neither study compared IL inhibitors, rather comparing biological treatments that inhibit TNF alpha, such as adalimumab, for which biosimilars are already available. In Germany, Strand et al. conducted a CPR analysis at 24 weeks in patients with PsA considering ACR 20/50/70 response and Psoriasis Area Severity Index (PASI) 75/90, including exclusively adalimumab and secukinumab (150 mg

and 300 mg) [25]. Adalimumab was associated with lower CPR compared with secukinumab at week 24 among patients with PsA. Another study carried out in Italy also compared the cost per ACR 20/50/70, MDA and PASI 75/90/100 at 52 weeks in the treatment of PsA between adalimumab and secukinumab (300 mg) [26]. The CPRs associated with the ACR 20/50/70 endpoints were similar for adalimumab compared to secukinumab but lower for secukinumab using PASI and MDA criteria for efficacy.

This study is not without limitations. First, there are currently no head-to-head studies that directly compare bimekizumab with other IL inhibitors in PsA. The efficacy and safety of bimekizumab against IL inhibitors have been indirectly compared via NMA and MAIC. However, comparison via NMA is not feasible beyond week 16/24 because of the lack of placebo data in phase 3 trials of bimekizumab compared to the other IL inhibitors, respectively [8]. Therefore, an unanchored (non-placebo adjusted) MAIC has been developed up to week 52 [9–12]. The results of this CPR analysis should be considered in the context of the limitations of an indirect comparison, intrinsic to the methodology and specific to this analysis. Second, we could not include PASI response rate measures in the analysis, given that this could not be analysed using the MAIC method because the baseline characteristics for the subset of patients who received treatment up to 52 weeks for this efficacy outcome were not reported by the comparators. Third, the cost per MDA response for bimekizumab compared to ustekinumab could not be calculated because there was no MDA endpoint in the ustekinumab trials. Another limitation, considering that the efficacy data were reported at 52 weeks, is the conservative approach, including the average number of vials, syringes and pre-filled pens used in the first and second years to account for induction doses in all comparators. This may underestimate the potential CPR advantage of bimekizumab, which does not require an induction dose, unlike the other treatments, requiring higher induction doses (Table 1). Lastly, we used the accessible list prices since the reimbursed prices are not public. We were conservative using the maximum price to be paid, since list prices are higher than

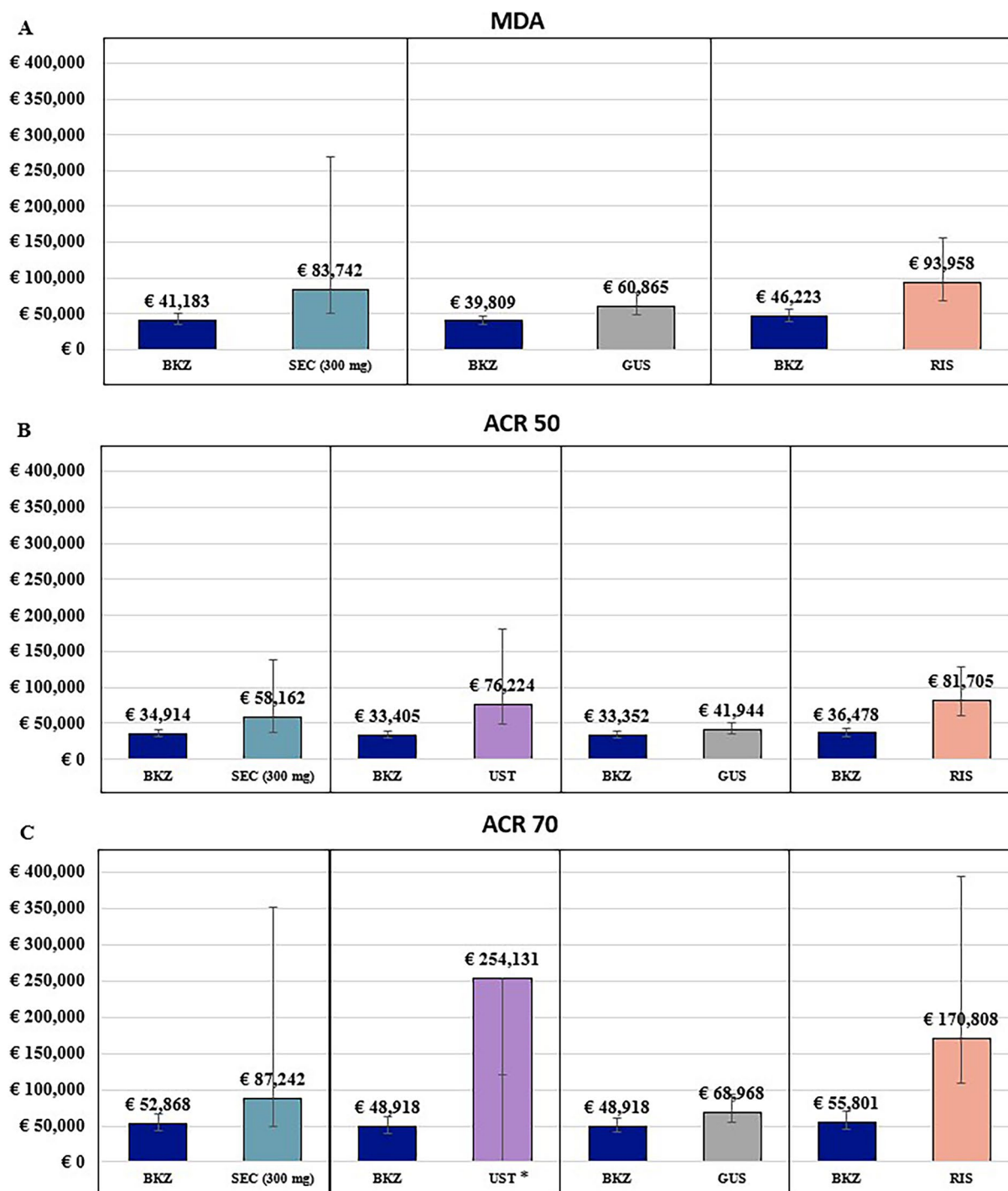


Fig. 2 Cost-per-responder analysis for MDA, ACR50 and ACR70 in patients with TNFi-IR at 52 weeks. *The inferior 95 CI% of the cost per responder for ustekinumab in ACR70 is –€2,016,911.11. *ACR* American College of Rheumatology, *BKZ* bimekizumab, *CI* confidence inter-

val, *GUS* guselkumab, *MDA* minimal disease activity, *RIS* risankizumab, *SEC* secukinumab, *TNFi-IR* tumour necrosis factor inhibitors-inadequate response or intolerance, *UST* ustekinumab

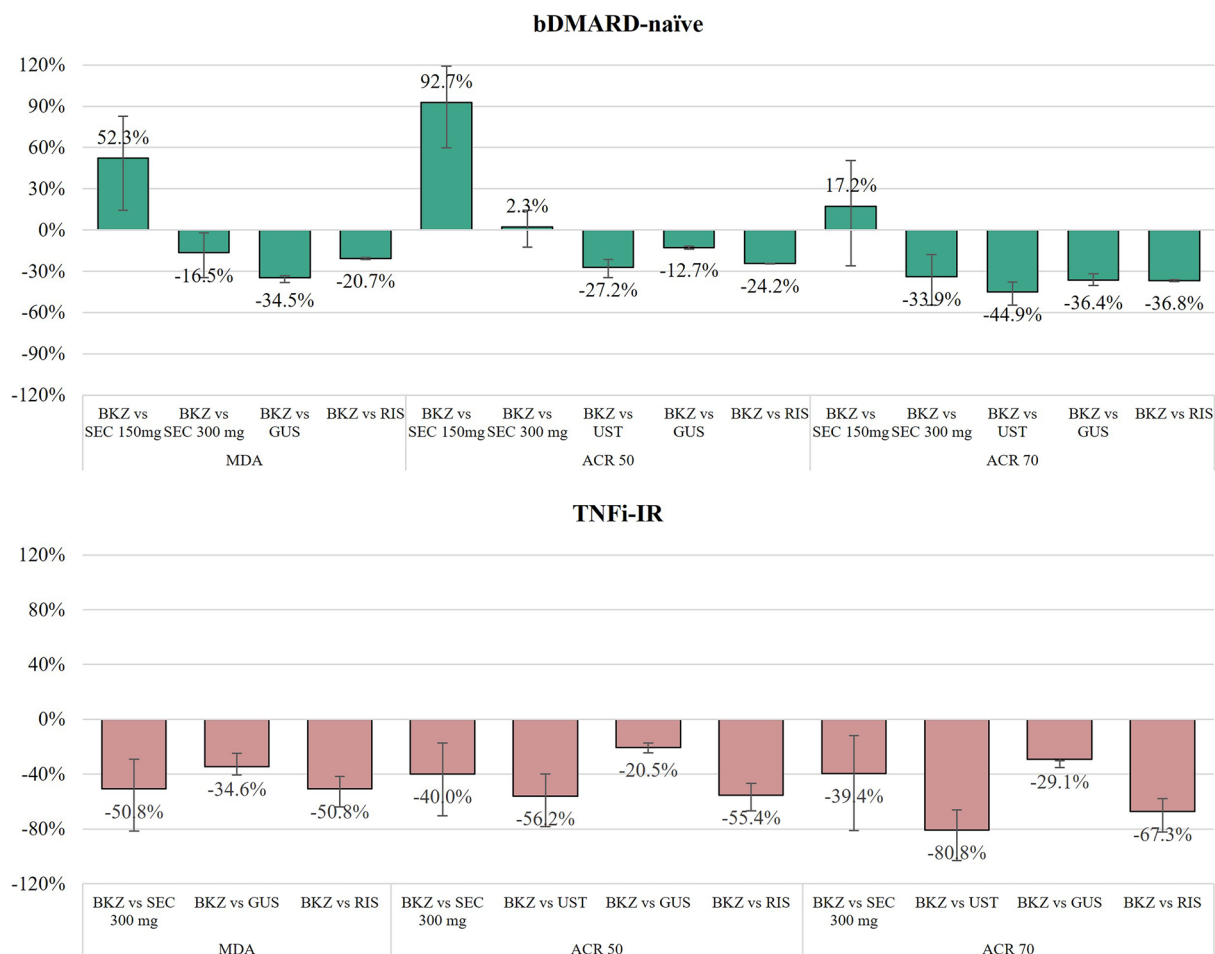


Fig. 3 Incremental cost-per-responder analysis of bimekizumab versus comparators at 52 weeks. *ACR* American College of Rheumatology, *bDMARD* biological disease-modifying antirheumatic drugs, *BKZ* bimekizumab, *MDA*

minimal disease activity, *RIS* risankizumab, *SEC* secukinumab, *TNFi-IR* tumour necrosis factor inhibitors-inadequate response or intolerance, *UST* ustekinumab

reimbursed prices [27]. To facilitate the reproduction of the calculations, summary tables of inputs and results are included in Supplementary Table S3 for bDMARD-naïve patients and Table S4 for patients with TNFi-IR. This analysis can be adapted using country-specific reimbursed cost data.

CONCLUSION

Based on published MAIC response rates for MDA, ACR 50 and ACR 70 at week 52, the CPR analyses suggest that it is more cost-efficient to

treat patients in Spain with PsA with bimekizumab than with the available IL17-A, IL-12/23 and IL-23 targeted therapies in most situations. This includes ustekinumab, guselkumab and risankizumab in both bDMARD-naïve patients and patients with TNFi-IR for all outcomes. Compared to secukinumab, bimekizumab is consistently cost-efficient in patients with TNFi-IR for all outcomes, while in bDMARD-naïve patients, it is only cost-efficient compared to secukinumab 300 mg for MDA and ACR 70.

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Declarations

Conflict of Interest. Jorge Mestre-Ferrándiz: Consultant fees from UCB; Victoria Navarro-Compán has received consulting fees, research or institutional support and educational grants from: AbbVie, Alfasigma, Bristol Myers Squibb, Eli Lilly, Fresenius Kabi, Galapagos, Janssen, Johnson & Johnson, Moonlake, MSD, Novartis, Pfizer, Roche, UCB; Yoana Ivanova-Markova and Almudena González-Domínguez: Employees of Weber; Stefano Maratia: Employee of UCB. Almudena González-Domínguez changed affiliation during the completion of this manuscript. Her current affiliation is Lead, Health Economics & Market Access, Theorema4h, Madrid, Spain.

Ethical Approval. Our study did not require approval from any ethics committee. Applying the Helsinki Declaration not necessary, because the efficacy data we used were from previously published studies where confirmation of compliance with the Declaration of Helsinki and Good Clinical Practice had been performed.

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