Bimekizumab Real-World Use in Psoriasis: Insights From a Multicenter, Multi-Year Retrospective Cohort Study in Spain, Results from the RUBIES Study

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Objective

To evaluate real-world use of bimekizumab in adult psoriasis (PsO) patients in routine clinical practice in Spain by:

- **Describing baseline characteristics and prior rheumatology visits of patients initiating biologics in Spain;**
- **Describing treatment pathways prior to bimekizumab initiation**
- **Assessing time-to-next-treatment (TTNT) after bimekizumab initiation**
- **Assessing real-world maintenance dosing versus label**

Background

- PsO is a chronic immune-mediated disease with heterogeneous clinical presentation, including possible joint involvement.
- Randomized trials demonstrated the safety and efficacy of biologics in PsO.
- In routine clinical practice, biologic treatment selection may reflect differences in patient characteristics, previous treatment exposure, and disease manifestations. Real-world data are therefore needed to contextualise biologic treatment positioning and utilisation in routine PsO care.
- Bimekizumab (BKZ) is a humanized monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A. BKZ is approved for the treatment of PsO[1] and has demonstrated efficacy in treating adult patients with moderate-to-severe plaque psoriasis, but real-world evidence[2] on its use remains limited.

Methods

- RUBIES is a multicenter retrospective cohort study using routinely collected secondary care data from a PsO Observatory in Spain (hospital records and pharmacy dispensing), standardized to the OMOP Common Data Model (CDM).
- Adults initiating a biologic therapy between January 2020 and June 2025 were included and followed in their hospital.
- In Spain, biologics are prescribed and dispensed exclusively within the secondary care setting and therefore, hospital data represents a robust and appropriate source for analyzing real world treatment patterns and outcomes.
- Baseline characteristics (**Table 1**), prior rheumatology visits and prior treatment history were described across biologic treatment classes.
- Among bimekizumab initiators, treatment pathways prior to initiation, time-to-next-treatment (TTNT), and maintenance dosing intervals versus the EMA label were evaluated.
- For treatment pathways, TTNT and maintenance dosing analyses, patients whose first observed biologic initiation occurred up to 31 December 2024 were included, together with all their subsequent initiations up to June 2025 (295 patients; 315 bimekizumab initiations).

Results

- A total of 4,787 PsO patients initiated a biologic therapy (7,674 treatment initiations), of which 332 initiated bimekizumab.
- Among 295 patients starting bimekizumab, this treatment was used across all stages of the treatment pathway: 14.2% were biologic-naïve, 29.5% had received 1 prior biologic, 56.3% had received ≥2 prior biologics (**Figure 1**).
- Patients initiating IL-17A and IL-17A/F inhibitors had the highest prevalence of rheumatology visits in the year prior to treatment initiation (48.8% and 48.5%, respectively) (**Figure 2**).
- More than 75% of patients did not switch biologics, for at least 1.5 years, following bimekizumab initiation (**Figure 3**).
- Approximately 70% of patients received maintenance dosing intervals concordant with the EMA-approved regimen (**Figure 4**).

Summary & Conclusions

RUBIES, a multicentre retrospective cohort study of Spanish secondary care data standardized to the OMOP CDM (January 2020-June 2025), captured 4,787 adult patients with PsO initiating a new biologic (7,674 treatment initiations), of which 332 initiated bimekizumab. Bimekizumab was initiated across all lines of therapy: 14.2% of patients were biologic-naïve, 29.5% had received one prior biologic, and 56.3% had received ≥2. At 1.5 years, >75% of patients had not initiated a subsequent biologic, and approximately 70% were dosed in line with the EMA-approved regimen. Rheumatology visits in the preceding year were most frequent among IL-17A (48.8%) and IL-17A/F (48.5%) inhibitor initiators, compared with 27.2% for IL-23 and 20.3% for IL-12/23 inhibitors, suggesting use in patients with potential rheumatologic comorbidities.

- **In routine clinical practice in Spain, bimekizumab was initiated in PsO patients across all lines of therapy.**
- **Patients initiating IL-17A and IL-17A/F therapies had a higher prevalence of prior rheumatology visits compared with patients initiating IL-23 and IL-12/23 inhibitors.**
- **TTNT analyses demonstrated sustained treatment continuation following bimekizumab initiation, with more than three-quarters of patients not initiating another biologic after 1.5 years.**
- **Maintenance dosing was largely consistent with the EMA-approved regimen.**
- **These findings highlight the value of longitudinal multicentre real-world data for characterising PsO treatment pathways in routine clinical practice.**

Table 1 Baseline characteristics

		TNF-alfa inhibitors	PDE-4 inhibitors	IL-12/23 inhibitors	IL-23 inhibitors	IL-17A inhibitors	IL-17A/F inhibitors	TYK-2 inhibitors
Sex (%)	*Female*	895 (40.0%)	392 (45.3%)	185 (34.2%)	571 (28.8%)	509 (30.5%)	123 (37.0%)	11 (22.4%)
	Male	1036 (46.3%)	351 (40.6%)	210 (38.8%)	778 (39.3%)	482 (28.9%)	118 (35.5%)	7 (14.3%)
	Unknown	306 (13.7%)	122 (14.1%)	146 (27.0%)	631 (31.9%)	679 (40.7%)	91 (27.4%)	31 (63.3%)
Age (years)	*Mean (SD)*	49.5 (14.2)	56 (13.2)	48.9 (15.3)	52.9 (14.7)	50.7 (13.6)	50.8 (13)	62.2 (11.2)
	Median (IQR)	50 (19)	56 (16)	49 (21)	54 (20)	51 (19)	52 (18)	60 (16)
Age category in years (%)	*18-30*	203 (9.1%)	34 (3.9%)	45 (8.3%)	91 (4.6%)	78 (4.7%)	18 (5.4%)	0 (0.0%)
	31-40	309 (13.8%)	45 (5.2%)	82 (15.2%)	193 (9.7%)	156 (9.3%)	37 (11.1%)	0 (0.0%)
	41-50	479 (21.4%)	156 (18.0%)	96 (17.7%)	273 (13.8%)	247 (14.8%)	57 (17.2%)	<5
	51-60	525 (23.5%)	241 (27.9%)	87 (16.1%)	392 (19.8%)	262 (15.7%)	71 (21.4%)	7 (14.3%)
	61-70	283 (12.7%)	162 (18.7%)	52 (9.6%)	231 (11.7%)	183 (11.0%)	45 (13.6%)	5 (10.2%)
	71-80	110 (4.9%)	82 (9.5%)	26 (4.8%)	126 (6.4%)	50 (3.0%)	11 (3.3%)	<5
	81-90	20 (0.9%)	22 (2.5%)	<5	40 (2.0%)	12 (0.7%)	<5	<5
	>90	<5	<5	<5	<5	<5	0 (0.0%)	0 (0.0%)
	Unknown	306 (13.7%)	122 (14.1%)	146 (27.0%)	631 (31.9%)	679 (40.7%)	91 (27.4%)	31 (63.3%)
Treatment start year (%)	*2020*	277 (12.4%)	157 (18.2%)	130 (24.0%)	201 (10.2%)	253 (15.1%)	0 (0.0%)	0 (0.0%)
	2021	391 (17.5%)	143 (16.5%)	106 (19.6%)	367 (18.5%)	316 (18.9%)	<5	0 (0.0%)
	2022	438 (19.6%)	183 (21.2%)	78 (14.4%)	373 (18.8%)	308 (18.4%)	6 (1.8%)	0 (0.0%)
	2023	425 (19.0%)	138 (16.0%)	52 (9.6%)	396 (20.0%)	311 (18.6%)	78 (23.5%)	0 (0.0%)
	2024	489 (21.9%)	168 (19.4%)	86 (15.9%)	430 (21.7%)	312 (18.7%)	166 (50.0%)	24 (49.0%)
	2025	217 (9.7%)	76 (8.8%)	89 (16.5%)	213 (10.8%)	170 (10.2%)	78 (23.5%)	25 (51.0%)
PASI score	*Mean (SD)*	9.2 (5.7)	7.7 (4.5)	7.8 (6.8)	10 (7.3)	10.4 (7.9)	9.9 (7.4)	12.3 (7.8)
	Median (IQR)	8 (7)	7 (5)	7 (6)	8 (7)	9 (9)	8 (9)	10 (11)
PASI score category (%)	*Mild (0.0-5.0)*	129 (5.8%)	74 (8.6%)	27 (5.0%)	157 (7.9%)	79 (4.7%)	18 (5.4%)	<5
	Moderate (5.1-10.0)	221 (9.9%)	118 (13.6%)	30 (5.5%)	240 (12.1%)	105 (6.3%)	26 (7.8%)	<5
	Severe (>10.0)	199 (8.9%)	55 (6.4%)	19 (3.5%)	241 (12.2%)	127 (7.6%)	26 (7.8%)	<5
	Missing	1191 (53.2%)	460 (53.2%)	299 (55.3%)	562 (28.4%)	614 (36.8%)	156 (47.0%)	13 (26.5%)
	Unknown	497 (22.2%)	158 (18.3%)	166 (30.7%)	780 (39.4%)	745 (44.6%)	106 (31.9%)	31 (63.3%)
Prior rheumatology visit (%)	*Absent*	1294 (57.8%)	461 (53.3%)	315 (58.2%)	982 (49.6%)	507 (30.4%)	124 (37.3%)	13 (26.5%)
	Present	637 (28.5%)	282 (32.6%)	80 (14.8%)	367 (18.5%)	484 (29.0%)	117 (35.2%)	5 (10.2%)
	Unknown	306 (13.7%)	122 (14.1%)	146 (27.0%)	631 (31.9%)	679 (40.7%)	91 (27.4%)	31 (63.3%)
Prior time on biologics (%)	*< 1 year*	1936 (86.5%)	746 (86.2%)	422 (78.0%)	1217 (61.5%)	1209 (72.4%)	111 (33.4%)	19 (38.8%)
	1-2 years	104 (4.6%)	55 (6.4%)	42 (7.8%)	297 (15.0%)	188 (11.3%)	47 (14.2%)	8 (16.3%)
	2-3 years	54 (2.4%)	19 (2.2%)	23 (4.3%)	159 (8.0%)	89 (5.3%)	65 (19.6%)	8 (16.3%)
	3-4 years	54 (2.4%)	17 (2.0%)	17 (3.1%)	97 (4.9%)	59 (3.5%)	50 (15.1%)	6 (12.2%)
	4-5 years	11 (0.5%)	<5	11 (2.0%)	57 (2.9%)	22 (1.3%)	21 (6.3%)	8 (16.3%)
	≥ 5 years	5 (0.2%)	<5	<5	8 (0.4%)	<5	5 (1.5%)	0 (0.0%)
	Unknown	73 (3.3%)	23 (2.7%)	25 (4.6%)	145 (7.3%)	101 (6.0%)	33 (9.9%)	0 (0.0%)
Total patients		2237	865	541	1980	1670	332	49

Table 1. Baseline characteristics. <5: <5 patients in a single group, not reported for anonymization purposes; IQR: inter quartile range; PASI: Psoriasis Area and Severity Index; SD: Standard Deviation; Missing: information not reported for a specific patient; Unknown = information cannot be derived due to insufficient data quality or absence of data from a particular hospital; All day windows (e.g., Day −365, Day −30, Day +7) are defined relative to the treatment start date. PASI: Window Day −30 to Day +7; maximum score if multiple on same day; most recent within window. Observed treatment initiation counts in 2025 reflect data until end of June 2025, as the study period concluded in June 2025. Counts reflect treatment starts rather than unique patients; the same patient may be included multiple times if they initiated more than one treatment.

Figure 1 Treatment pathway positioning of bimekizumab

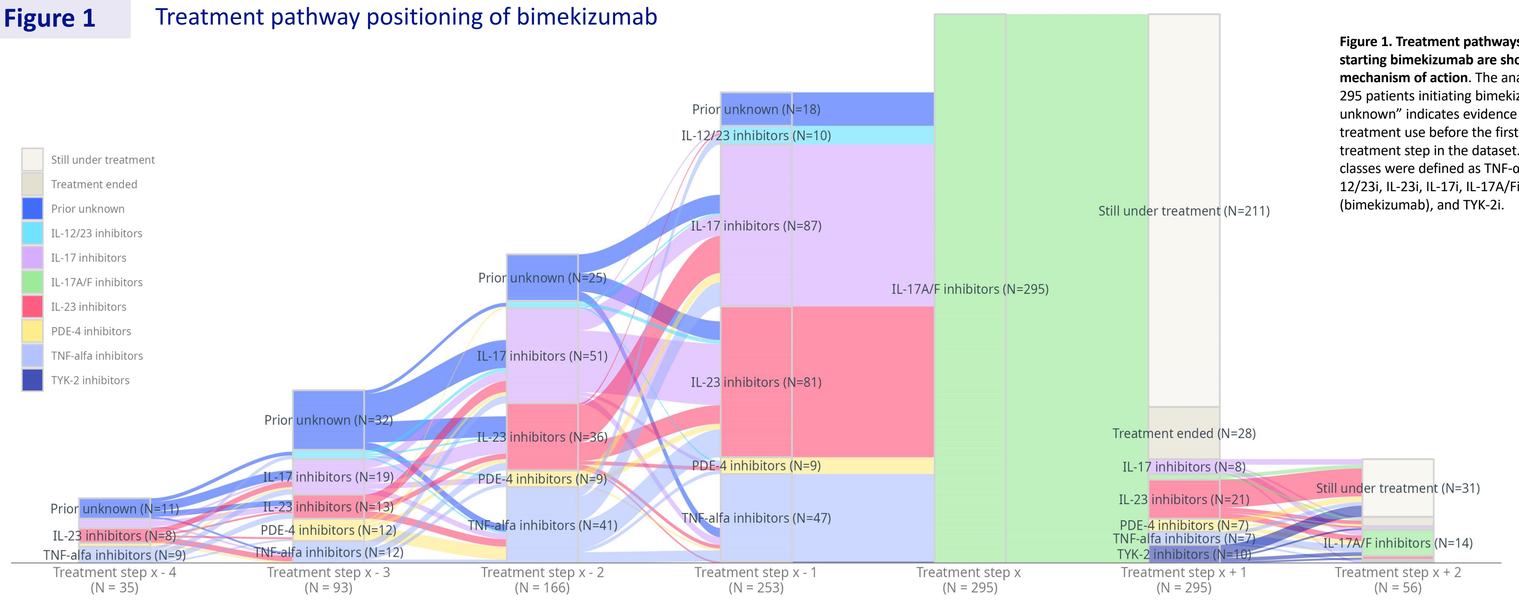


Figure 1. Treatment pathways of patients starting bimekizumab are shown by mechanism of action. The analysis includes 295 patients initiating bimekizumab. "Prior unknown" indicates evidence of previous treatment use before the first observable treatment step in the dataset. Treatment classes were defined as TNF-αi, PDE-4i, IL-12/23i, IL-23i, IL-17i, IL-17A/Fi (bimekizumab), and TYK-2i.

Figure 2 Prior rheumatology visits by therapy class

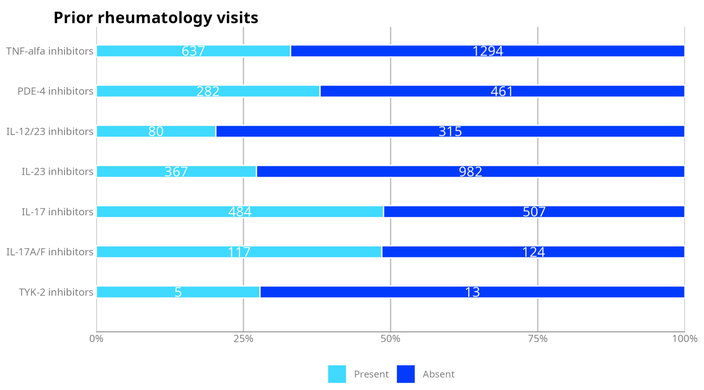


Figure 2. Bar chart shows visits to rheumatology within 365 days prior the start of treatment from patients included in 2020 and onwards. Unknowns are excluded.

Figure 3 TTNT post bimekizumab initiation

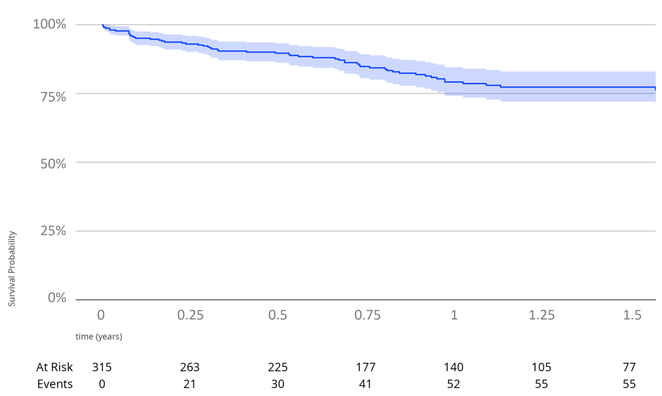
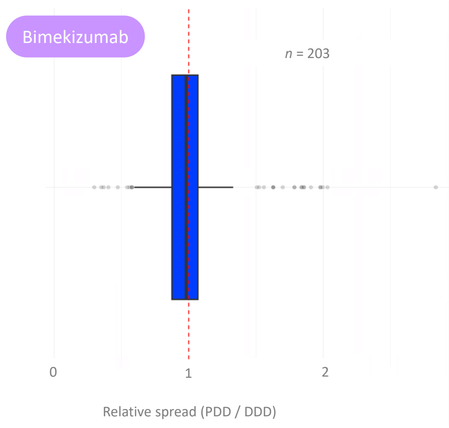


Figure 3. Kaplan-Meier analysis of time to next biologic among patients initiating bimekizumab. The analysis includes 315 bimekizumab initiations in 295 patients whose first observed biologic initiation occurred up to 31 December 2024. Patients who did not switch to another biologic during follow-up were censored at the end of available follow-up. The median time to next biologic was not reached during the observation period, indicating that more than 50% of patients did not initiate a new biologic throughout follow-up.

Figure 4 Maintenance dosing



Treatment	Bimekizumab
Total treatment lines with determinable dosing	203
Standard interval (±20%) n (%)	140 (69.0%)
Extended interval n (%)	34 (16.7%)
Shortened interval n (%)	29 (14.3%)

Figure 4. PDD/DDD was used as a proxy for maintenance dosing intensity. Ratio of 1 indicates label-consistent dosing; values <1 indicate extended intervals and values >1 indicate shortened intervals. Boxplot shows the median, interquartile range, whiskers, and outliers.

Abbreviations: BMK: bimekizumab; **DDD**: defined daily dose; **EMA**: European Medicines Agency; **IgG1**: immunoglobulin G1; **IL**: interleukin; **IQR**: interquartile range; **OMOP CDM**: Observational Medical Outcomes Partnership common data model; **PASI**: Psoriasis Area and Severity Index; **PDD**: prescribed daily dose; **PDE-4**: phosphodiesterase 4; **PsO**: psoriasis; **SD**: standard deviation; **TNF**: tumor necrosis factor; **TTNT**: time-to-next-treatment; **TYK-2**: tyrosine kinase 2.
*The term biologic refers to advanced systemic therapies.

References:
[1]https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf [Accessed September 2026]; [2]Blonde L et al. Adv Ther. 2018;35:1763–74.

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