



Patient-Level Cumulative Clinical Benefit of Brodalumab Over 52 Weeks: A Multicentre Real-World Study-IL PSO (Italian Landscape Psoriasis)

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ABSTRACT

Introduction: Conventional Psoriasis Area and Severity Index (PASI) response rates provide a

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cross-sectional assessment of treatment effectiveness but do not capture the speed, magnitude, and persistence of clinical improvement. This study evaluated the patient-level cumulative clinical benefit of brodalumab over 52 weeks in routine clinical practice.

Methods: This multicentre, retrospective, observational study included adults with moderate-to-severe plaque psoriasis treated with brodalumab within the Italian Landscape Psoriasis

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database. The primary analysis included patients with PASI assessments at baseline and Weeks 16, 32, and 52. Individual percentage PASI improvement trajectories were integrated using the trapezoidal area under the curve and expressed as normalized cumulative clinical benefit and clearance-equivalent days. Baseline factors associated with cumulative benefit were assessed using multivariable median quantile regression.

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Results: Among 858 patients eligible for the 52-week analysis, 764 had complete longitudinal PASI data, and 645 were included in the multivariable analysis. Median PASI decreased from 14.7 at baseline to 0.0 at Weeks 16, 32, and 52. At Week 52, 93.1%, 86.1%, and 70.4% of patients achieved PASI 75, PASI 90, and PASI 100, respectively. Median normalized cumulative clinical benefit was 97.4% (interquartile range, 90.0–100.0), corresponding to 300.0 clearance-equivalent days

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(277.2–308.0). Palmoplantar involvement was independently associated with lower cumulative benefit (adjusted median difference, – 3.21 percentage points; 95% confidence interval, – 6.29 to – 0.87), whereas scalp or facial involvement was associated with modestly higher benefit (+ 1.39; 0.38–3.27). Longer psoriasis duration was associated with a small increase in cumulative benefit.

Conclusion: Brodalumab provided rapid, deep, and sustained disease control over 52 weeks. Patient-level cumulative outcomes may complement conventional PASI response rates by capturing the overall longitudinal treatment benefit.

Keywords: Brodalumab; Plaque psoriasis; Cumulative clinical benefit; Area under the curve; Clearance-equivalent days; Real-world evidence

Key Summary Points

Why carry out this study?

Conventional Psoriasis Area and Severity Index (PASI) response rates assess treatment effectiveness at predefined time points but do not capture the speed, magnitude, and persistence of clinical improvement over time

Cumulative clinical benefit, derived from longitudinal PASI trajectories, may provide a more comprehensive assessment of treatment effectiveness by integrating both the extent and duration of improvement

This study aimed to evaluate the 52-week patient-level cumulative clinical benefit of brodalumab in patients with moderate-to-severe plaque psoriasis and to identify baseline demographic and clinical factors associated with greater or lower cumulative benefit

What was learned from the study?

Brodalumab provided rapid, deep, and sustained disease control over 52 weeks, with a median normalized cumulative clinical benefit of 97.4%, corresponding to 300 clearance-equivalent days; at Week 52, PASI 75, PASI 90, and PASI 100 were achieved by 93.1%, 86.1%, and 70.4% of patients, respectively

Palmoplantar involvement was consistently associated with lower cumulative clinical benefit, whereas scalp or facial involvement was associated with a modestly higher benefit. These findings suggest that patient-level cumulative PASI-based outcomes may complement conventional cross-sectional PASI response rates by providing a more complete representation of treatment benefit over time

INTRODUCTION

Psoriasis is a chronic immune-mediated inflammatory disease associated with substantial clinical, psychological, and social burden, and its persistent course may contribute to cumulative life course impairment [1–3]. Accordingly, contemporary treatment goals extend beyond improvement at individual time points and increasingly emphasize rapid, deep, and sustained disease control [3]. Biologic therapies have transformed the management of moderate-to-severe psoriasis, with inhibition of the interleukin (IL)-17 pathway representing one of the most effective therapeutic strategies [4, 5]. Brodalumab, a fully human monoclonal antibody targeting IL-17 receptor A [6], has demonstrated rapid and sustained efficacy in Phase III trials and subsequent real-world studies, including in biologic-experienced patients and difficult-to-treat disease [7–11]. Treatment effectiveness is conventionally assessed using absolute Psoriasis Area Severity Index (PASI) and PASI 75, PASI 90, or PASI 100 responses at predefined time points [12]. Although clinically informative, these cross-sectional endpoints do not capture differences in speed of response, magnitude of improvement, or persistence of disease control over time. Cumulative clinical benefit, estimated through the area under the curve (AUC) of longitudinal response, has therefore emerged as a complementary measure integrating both the magnitude and duration of therapeutic improvement [3]. Previous cumulative benefit studies in psoriasis have mainly evaluated population-level AUCs based on PASI

75, PASI 90, or PASI 100 response rates, including analyses of brodalumab in clinical trial and real-world settings [3, 13–17]. However, evidence based on continuous individual patient-level PASI trajectories remains limited, and the baseline demographic and clinical factors associated with greater or lower cumulative benefit have not been fully characterized. The cumulative AUC may also be translated into clearance-equivalent days, providing an intuitive mathematical representation of the integrated longitudinal treatment effect, although this should not be interpreted as directly observed days of complete clearance. Therefore, the primary aim of this multicentre real-world study was to evaluate the 52-week cumulative clinical benefit of brodalumab using the AUC of individual percentage PASI improvement. Secondary objectives were to describe clearance-equivalent days and investigate baseline factors associated with cumulative clinical benefit.

METHODS

Study Design and Population

This multicentre, retrospective, observational study used data from the Italian Landscape Psoriasis database and included adult patients with moderate-to-severe plaque psoriasis treated with brodalumab in routine clinical practice. Patients were eligible for the 52-week analysis if they had initiated brodalumab early enough to potentially complete 52 weeks of follow-up by the database-lock date. Patients who could not have reached Week 52 by database lock, or whose eligibility for the 52-week assessment could not be verified, were excluded from the 52-week estimand. The primary longitudinal and cumulative benefit analyses used a complete case approach and included patients with available PASI assessments at baseline and Weeks 16, 32, and 52. The multivariable analysis was further restricted to patients with complete information for all pre-specified demographic and clinical covariates. Brodalumab was prescribed according to routine clinical practice and the approved indication for moderate-to-severe plaque psoriasis.

Treating dermatologists made treatment decisions, set follow-up schedules, and performed clinical assessments without deviating from standard care. Notably, the Italian Landscape Psoriasis database has previously been used to compare cumulative clinical benefit across eight biologic treatments [14]. The present cohort partially overlaps with that study: the 128 patients treated with brodalumab included in the previous analysis were drawn from the same database and are included within the substantially larger brodalumab cohort evaluated here. However, the present study used an expanded database extraction and was specifically designed to address a different patient-level estimand, as detailed below.

Data Collection

Demographic and clinical characteristics were collected at baseline, including sex, age, psoriasis duration, body mass index (BMI), baseline PASI, presence of psoriatic arthritis, previous exposure to biologic therapies, comorbidities, and involvement of difficult-to-treat areas.

Difficult-to-treat areas included palmoplantar, nail, scalp or facial, and genital involvement. Patients were classified as biologic-naïve if they had not previously received any biologic therapy and as biologic-experienced otherwise.

Disease severity was assessed using the PASI at baseline and at Weeks 16, 32, and 52. At each follow-up visit, PASI 75, PASI 90, and PASI 100 responses were defined as improvements of at least 75%, 90%, and 100%, respectively, from baseline PASI.

Study Outcomes

The primary outcome was the normalized cumulative clinical benefit achieved during the 52-week observation period, calculated from the individual longitudinal percentage PASI improvement trajectory. Secondary outcomes included absolute PASI and percentage PASI improvement at each follow-up visit; PASI 75, PASI 90, and PASI 100 response rates; clearance-equivalent days; and baseline demographic and

clinical factors associated with cumulative clinical benefit.

Statistical Analysis

Before analysis, prespecified clinical, range, consistency, and temporal checks were applied. Continuous variables were summarized as median and interquartile range [Q1–Q3], while categorical variables were reported as number and percentage. Denominators were reported whenever they differed from the analysis population. Obesity was defined as BMI ≥ 30 kg/m².

For patients with baseline PASI > 0, percentage PASI improvement at week t was calculated as:

$$\text{PASIimprovement}_t(\%) = 100 \times \frac{\text{PASI}_{\text{baseline}} - \text{PASI}_t}{\text{PASI}_{\text{baseline}}}$$

Negative values, indicating worsening from baseline, were retained. With assessment times of 0, 112, 224, and 364 days and improvement fixed at 0% at baseline, the trapezoidal area under the PASI improvement curve was calculated as:

$$\text{AUC} = 56I_{16} + 56(I_{16} + I_{32}) + 70(I_{32} + I_{52})$$

where I_t denotes percentage PASI improvement at week t . Normalized cumulative clinical benefit was calculated as $100 \times \text{AUC}/30,800$ percentage-days. Clearance-equivalent days were calculated as $\text{AUC}/100$ and were interpreted as a mathematical equivalent rather than directly observed daily clearance.

Longitudinal changes in absolute PASI were assessed using the Friedman test, followed by paired Wilcoxon signed-rank tests with Holm correction. Comparisons of cumulative benefit between two independent groups used the Mann-Whitney U test. Hodges-Lehmann location shifts and rank-biserial correlations were calculated as effect size measures. Associations with continuous variables were assessed using Spearman rank correlations with bootstrap 95% confidence intervals (CI). These unadjusted comparisons were considered exploratory and hypothesis-generating. Accordingly, no adjustment for multiple testing was applied, and individual unadjusted p -values should be

interpreted descriptively rather than as confirmatory evidence.

Independent associations with cumulative clinical benefit were examined using multivariable median quantile regression. Covariates were prespecified as age, obesity, psoriasis duration, psoriatic arthritis, palmoplantar involvement, nail involvement, scalp/face involvement, genital involvement, biologic-naïve status, and baseline PASI. Automated variable selection was not used. Results were expressed as adjusted median differences with bootstrap 95% confidence intervals. Confidence intervals for the primary model were estimated using 1000 patient-level bootstrap samples.

Because cumulative benefit accumulated to its theoretical maximum, we performed a two-part sensitivity analysis. Logistic regression was used to model attainment of maximum benefit, followed by median quantile regression among patients below the ceiling. Additional sensitivity analyses restricted the population to baseline PASI ≥ 10 and replaced the percentage-based outcome with the AUC of absolute longitudinal PASI, expressed as PASI-days. All tests were two-sided. Holm correction was applied to post hoc pairwise comparisons. Interpretation was based primarily on effect estimates and 95% confidence intervals. All statistical analyses were performed using Stata version 19.0 (StataCorp LLC, College Station, TX, USA). Centre-level clustering could not be accounted for because the centre identifier was unavailable in the analysis dataset.

Ethical Statement

Ethical approval was obtained from the Territorial Ethics Committee of the Calabria Region (Comitato Etico Territoriale Regione Calabria) for the LANDSCAPE study amendment (protocol no. 164/2026), which was approved on June 22, 2026. The study was conducted in accordance with the principles of the Declaration of Helsinki. All participants had provided written informed consent for the use of their anonymized clinical data.

RESULTS

Study Population

The source cohort included 861 patients. Of these, 858 were eligible for the 52-week estimand, and 764 had PASI assessments available at all four time points. The multivariable complete-case population comprised 645 patients.

In the eligible population, median age was 49.7 [39.0–60.3] years, median psoriasis duration was 15.0 [6.0–24.0] years, and median BMI was 25.8 [23.5–28.7] kg/m². Obesity was present in 134 of 756 patients with available BMI (17.7%). Median baseline PASI was 14.0 [10.0–20.0].

Overall, 606 patients (70.6%) were male, 128 (14.9%) had psoriatic arthritis, 185 (21.6%) had palmoplantar involvement, 196 (22.8%) nail involvement, 378 (44.1%) scalp/face involvement, and 166 (19.3%) genital involvement. A total of 446 patients (52.0%) were biologic-naïve, and 52 (6.1%) discontinued treatment. Baseline demographic and clinical characteristics are summarized in Table 1.

PASI Response

Among the 764 patients with complete PASI assessments, median absolute PASI decreased from 14.7 [10.0–20.0] at baseline to 0.0 [0.0–2.0] at Week 16, 0.0 [0.0–1.0] at Week 32, and 0.0 [0.0–1.0] at Week 52. PASI differed significantly across visits (Friedman $p < 0.001$), and values at all follow-up visits were lower than at baseline after Holm correction (Supplementary Figure S1).

Median percentage PASI improvement was 100.0% [85.7–100.0] at Week 16, 100.0% [92.8–100.0] at Week 32, and 100.0% [95.0–100.0] at Week 52. At Week 16, PASI 75, PASI 90, and PASI 100 responses were achieved by 86.8%, 67.4%, and 50.7% of patients, respectively. Response rates further increased at Week 32, reaching 93.1% for PASI 75, 83.1% for PASI 90, and 64.8% for PASI 100. At Week 52, PASI 75 was maintained by 93.1% of patients, while PASI 90 and PASI 100 responses increased to 86.1% and 70.4%, respectively (Table 2 and Fig. 1).

Table 1 Baseline demographic and clinical characteristics of the 52-week eligible population

Characteristic	Summary	Available <i>n</i>
Age, years	49.7 [39.0–60.3]	855
Psoriasis duration, years	15.0 [6.0–24.0]	793
BMI, kg/m ²	25.8 [23.5–28.7]	756
Obesity	134 (17.7%)	756
Baseline PASI	14.0 [10.0–20.0]	858
Previous biologic therapies, <i>n</i>	0 [0–1]	858
Male sex	606 (70.6%)	858
Female sex	252 (29.4%)	858
Psoriatic arthritis	128 (14.9%)	858
Palmoplantar involvement	185 (21.6%)	858
Nail involvement	196 (22.8%)	858
Scalp/face involvement	378 (44.1%)	858
Genital involvement	166 (19.3%)	858
Arterial hypertension	244 (28.4%)	858
Type 2 diabetes	92 (10.7%)	858
Dyslipidaemia	105 (12.2%)	858
Previous major adverse cardiovascular event	62 (7.2%)	858
Thyroid disorder	44 (5.1%)	858
Malignancy	15 (1.7%)	858
Biologic-naïve	446 (52.0%)	858
Treatment discontinued	52 (6.1%)	858

BMI, body mass index; *PASI*, Psoriasis Area and Severity Index

Cumulative Clinical Benefit

Median normalized cumulative clinical benefit was 97.4% [90.0–100.0], and 43.7% of patients attained the theoretical maximum (Fig. 2). Median clearance-equivalent time was 300.0 [277.2–308.0] days. Overall, 50.3% of patients accumulated 300–308 clearance-equivalent

Table 2 Longitudinal PASI and cumulative benefit outcomes in the complete case population ($n=764$)

Outcome	<i>n</i>	Median	Q1	Q3
PASI at baseline	764	14.7	10.0	20.0
PASI at Week 16	764	0.0	0.0	2.0
PASI at Week 32	764	0.0	0.0	1.0
PASI at Week 52	764	0.0	0.0	1.0
Normalized cumulative benefit, %	764	97.4	90.0	100.0
Clearance-equivalent days	764	300.0	277.2	308.0
Absolute PASI AUC, PASI-days	764	1064.0	672.0	1568.0

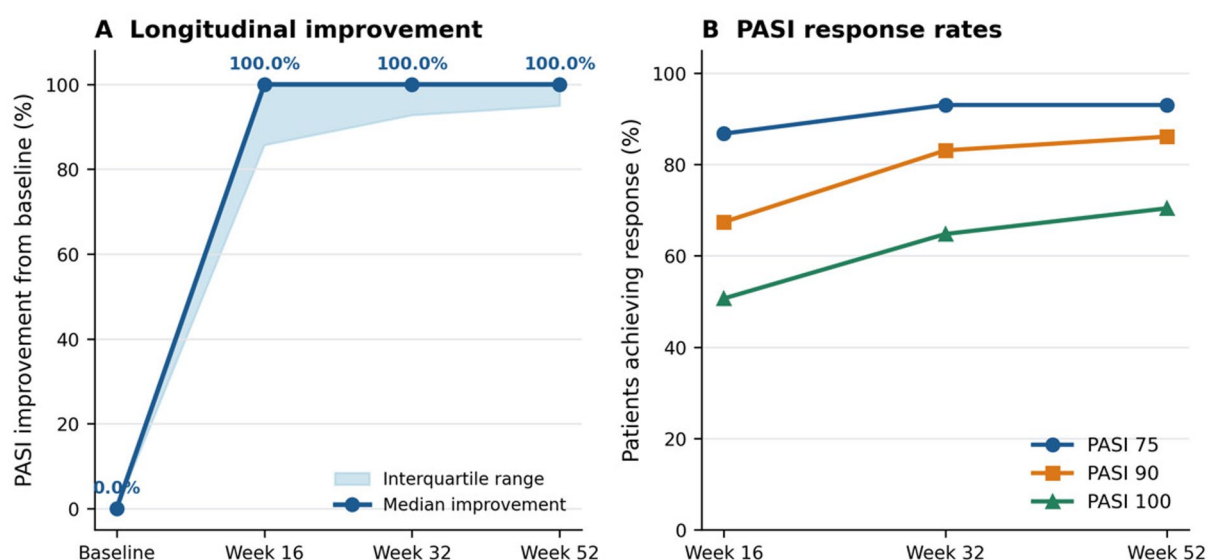


Fig. 1 PASI response through Week 52 in patients with complete PASI assessments ($n=764$). Panel A shows median percentage improvement with the interquartile

range; Panel B shows PASI 75, PASI 90, and PASI 100 response rates. *PASI*, Psoriasis Area and Severity Index

days and 38.5% accumulated 250–< 300 days (Fig. 3). No patient in the complete case population had a negative clearance-equivalent value.

Exploratory Unadjusted Associations

In exploratory unadjusted analyses, lower cumulative benefit distributions were observed in patients with palmoplantar involvement (93.4% [85.8–100.0] versus 98.5% [91.7–100.0];

$p < 0.001$) and obesity (96.0% [87.6–100.0] versus 98.5% [90.8–100.0]; $p = 0.020$). Higher cumulative benefit distributions were observed in patients with scalp/face involvement (99.5% [92.2–100.0] versus 96.3% [88.6–100.0]; $p < 0.001$) and genital involvement (100.0% [92.5–100.0] versus 97.0% [89.9–100.0]; $p = 0.009$). No evidence of an unadjusted difference was observed for sex, psoriatic arthritis, nail involvement, or biologic-naïve status.

Psoriasis duration showed a weak positive correlation with cumulative benefit (Spearman

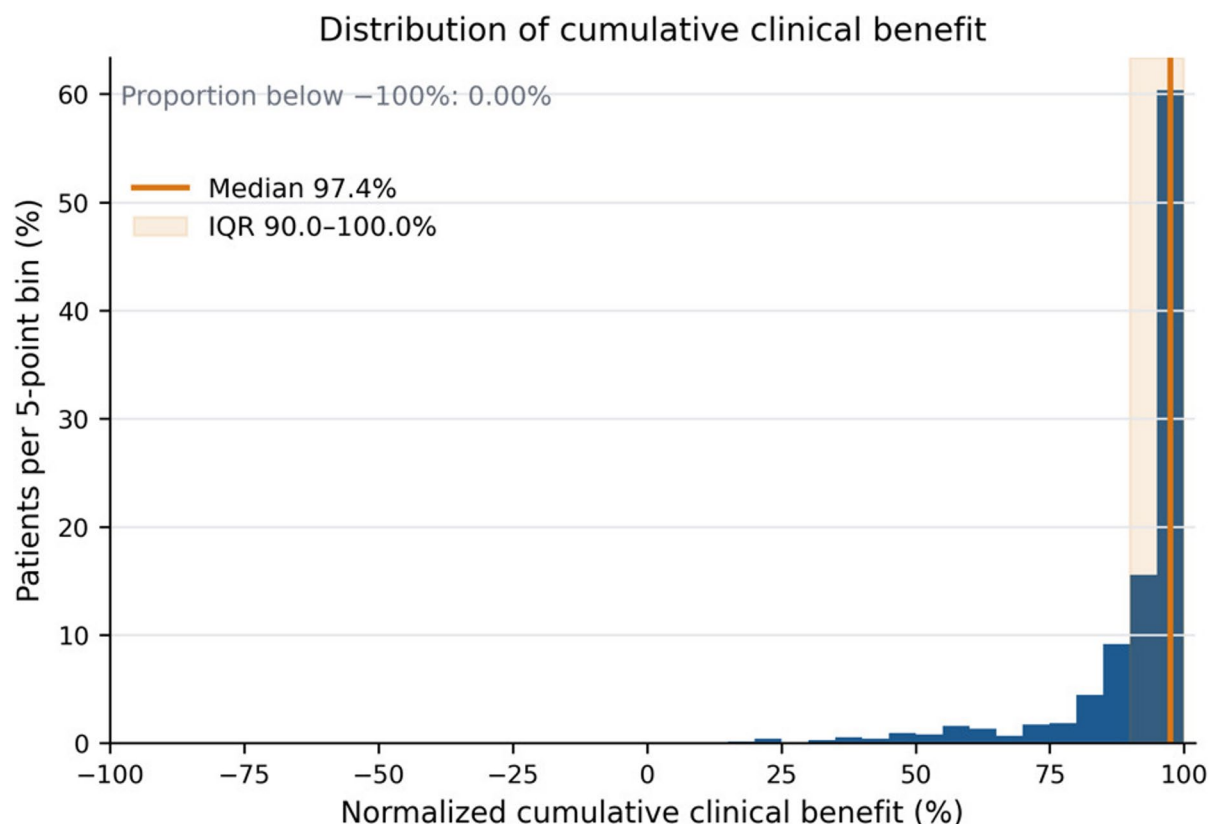


Fig. 2 Distribution of normalized cumulative clinical benefit among patients with complete PASI assessments ($n=764$). The orange line denotes the median and the

shaded area the interquartile range. *IQR*, interquartile range; *PASI*, Psoriasis Area and Severity Index

$\rho = 0.137$; 95% CI 0.065–0.206; $p < 0.001$). Neither age ($\rho = -0.011$; 95% CI -0.081 – 0.060) nor baseline PASI ($\rho = -0.004$; 95% CI -0.078 to 0.071) was associated with cumulative benefit. These unadjusted findings should be interpreted as exploratory, with the multivariable analysis providing the primary assessment of independent associations.

Multivariable Analysis

In the multivariable median regression model, palmoplantar involvement was independently associated with a 3.21-percentage-point lower median cumulative benefit (adjusted median difference -3.21 ; 95% CI -6.29 to -0.87 ; bootstrap $p = 0.010$).

Scalp/face involvement was associated with a 1.39-point higher median cumulative benefit (95% CI 0.38–3.27; bootstrap $p = 0.010$). Each additional year of psoriasis duration was associated with a 0.051-point increase in median cumulative benefit (95% CI 0.014–0.116; bootstrap $p = 0.014$).

Age, obesity, psoriatic arthritis, nail involvement, genital involvement, biologic-naïve status, and baseline PASI were not independently associated with median cumulative benefit. Full adjusted estimates are reported in Table 3 and displayed in Fig. 4.

Sensitivity Analyses

The relationship between baseline PASI and normalized cumulative clinical benefit, including

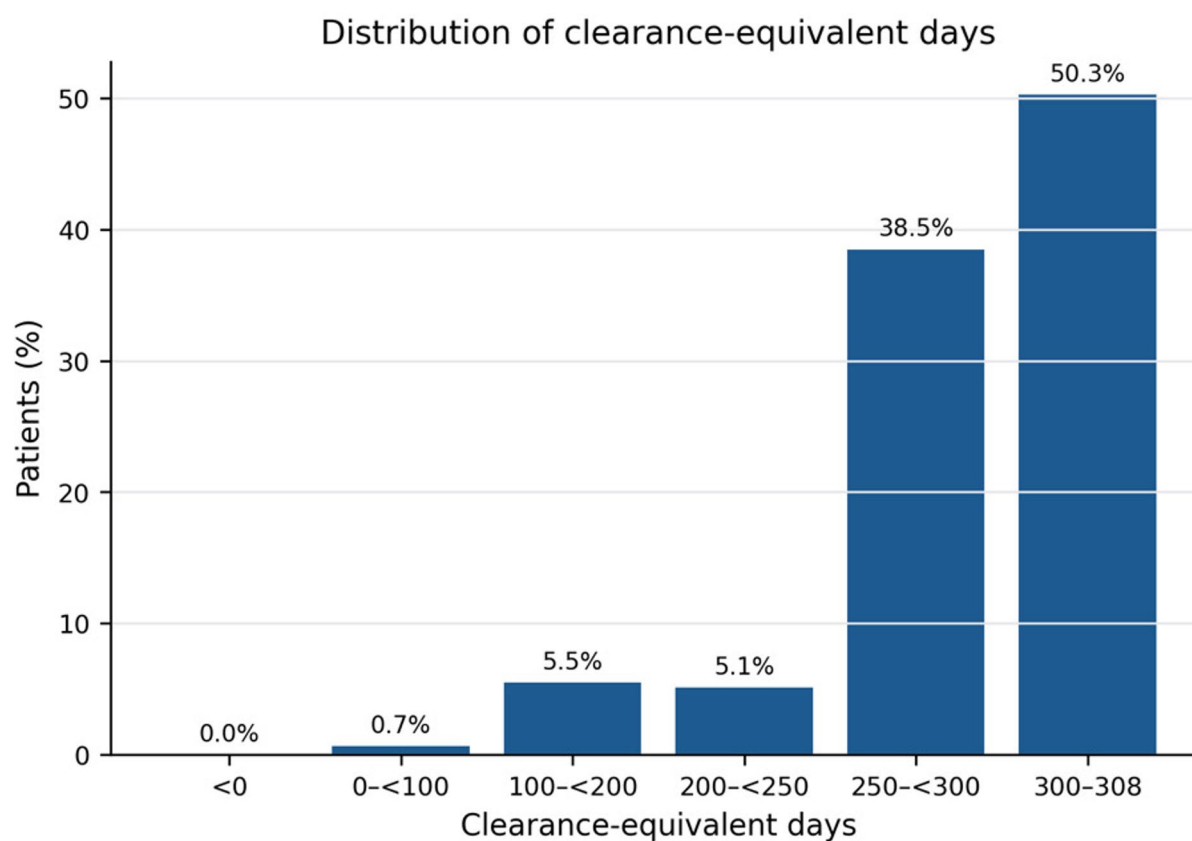


Fig. 3 Distribution of clearance-equivalent days among patients with complete PASI assessments ($n=764$). Clearance-equivalent days represent AUC/100 and should not

be interpreted as directly observed daily clearance. *IQR*, interquartile range; *PASI*, Psoriasis Area and Severity Index

Table 3 Factors associated with normalized cumulative clinical benefit: multivariable median quantile regression

Covariate	Adjusted difference	Bootstrap 95% CI	<i>p</i> -value
Age, per year	0.010	− 0.039 to 0.047	0.767
Obesity	− 2.320	− 3.442 to 0.359	0.128
Psoriasis duration, per year	0.051	0.014 to 0.116	0.014
Psoriatic arthritis	− 1.009	− 3.144 to 0.244	0.122
Palmoplantar involvement	− 3.214	− 6.292 to − 0.868	0.010
Nail involvement	− 0.595	− 2.989 to 0.629	0.368
Scalp/face involvement	1.394	0.379 to 3.274	0.010
Genital involvement	0.779	− 0.515 to 1.680	0.276
Biologic-naïve	0.838	− 0.143 to 2.392	0.122
Baseline PASI, per point	− 0.042	− 0.141 to 0.034	0.324

BMI, body mass index; *CI*, confidence interval; *PASI*, Psoriasis Area and Severity Index

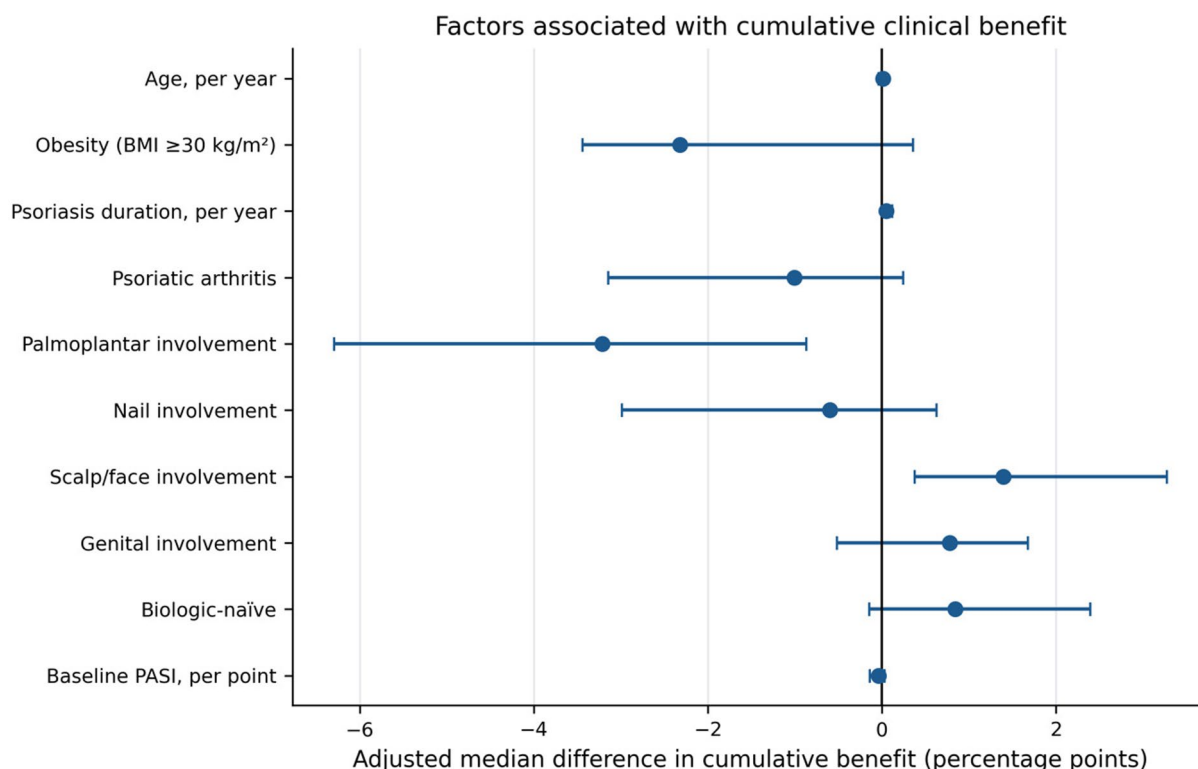


Fig. 4 Adjusted median differences in cumulative clinical benefit in patients with complete outcome and covariate data ($n = 645$). Error bars denote bootstrap 95% confidence intervals based on 1000 patient-level bootstrap samples.

BMI, body mass index; *CI*, confidence interval; *PASI*, Psoriasis Area and Severity Index

the greater variability observed at low baseline PASI values, is shown in Supplementary Figure S2. After restricting the model to patients with baseline PASI ≥ 10 ($n = 550$), palmoplantar involvement remained associated with lower benefit (-2.25 points; 95% CI -4.93 to -0.49), while scalp/face involvement remained associated with higher benefit ($+2.00$ points; 95% CI 0.56 – 3.44). Psoriasis duration also remained positively associated ($+0.075$ points per year; 95% CI 0.016 – 0.132).

The analysis based on absolute PASI AUC was concordant. Palmoplantar involvement was associated with 157.8 additional PASI-days (95% CI 29.8 – 267.3), indicating greater longitudinal disease burden. Scalp/face involvement was associated with 76.8 fewer PASI-days (95% CI -150.3 to -20.5).

In the ceiling model, palmoplantar involvement was associated with lower odds of attaining maximum benefit (adjusted OR 0.48 ; 95%

CI 0.31 – 0.73), as were obesity (OR 0.58 ; 95% CI 0.36 – 0.91) and psoriatic arthritis (OR 0.56 ; 95% CI 0.35 – 0.89). Scalp/face involvement was associated with higher odds of maximum benefit (OR 1.69 ; 95% CI 1.20 – 2.38).

DISCUSSION

In this large multicentre real-world study, brodalumab provided deep and sustained clinical improvement over 52 weeks in patients with moderate-to-severe plaque psoriasis. Among patients with complete longitudinal PASI assessments, median absolute PASI decreased from 14.7 at baseline to 0 at Week 16 and remained 0 at Weeks 32 and 52. PASI 90 response increased from 67.4% at Week 16 to 86.1% at Week 52, while PASI 100 increased from 50.7 to 70.4% . These responses translated into a median

normalized cumulative clinical benefit of 97.4% and a median of 300 clearance-equivalent days out of a theoretical maximum of 308. Overall, 50.3% of patients accumulated between 300 and 308 clearance-equivalent days, while a further 38.5% accumulated between 250 and fewer than 300 days. These findings indicate that, among patients with complete follow-up, brodalumab was associated not only with high response rates at Week 52 but also with a consistently favorable disease trajectory throughout the observation period.

The high cumulative benefit observed in our cohort is consistent with previous studies demonstrating the rapid onset and sustained efficacy of brodalumab [3, 13–17]. In a network meta-analysis evaluating cumulative clinical benefit during the first 12 weeks of treatment, brodalumab 210 mg every 2 weeks achieved median proportions of the maximum AUC of 59% for PASI 75 (95% credible interval [CrI] 57–60%), 39% for PASI 90 (95% CrI 37–40%), and 19% for PASI 100 (95% CrI 18–20%) [13]. These values were comparable to, or numerically higher than, those obtained with ixekizumab 80 mg every 2 weeks, which achieved 59%, 37%, and 17% of the maximum AUC for PASI 75, PASI 90, and PASI 100, respectively [13]. By comparison, the corresponding values were 47%, 27%, and 11% for secukinumab 300 mg; 42%, 23%, and 7% for guselkumab; and 32%, 17%, and 6% for ustekinumab [13]. These findings placed brodalumab and ixekizumab among the treatments providing the greatest early cumulative clinical benefit and emphasize how rapid response contributes substantially to the overall therapeutic effect.

Long-term cumulative benefit with brodalumab has also been evaluated in pooled analyses of the AMAGINE-2 and AMAGINE-3 trials [15]. Warren et al. reported a normalized 52-week AUC of 43.3% for PASI 100 and 61.4% for PASI 90 with brodalumab, compared with 25.6% and 43.3%, respectively, with ustekinumab [15]. This corresponded to a 69% greater cumulative PASI 100 benefit and a 42% greater cumulative PASI 90 benefit with brodalumab [15]. Patients treated with brodalumab were also more likely to achieve PASI 100 at least once and to maintain their response without rescue. These trial findings support the ability of brodalumab to

combine rapid induction of clearance with sustained response over time. The apparently higher normalized benefit observed in our study should not be interpreted as superior efficacy compared with the AMAGINE analyses, because the outcomes are methodologically different. Previous studies generally calculated the AUC of the proportion of the study population achieving a dichotomous response, such as PASI 90 or PASI 100. In contrast, our outcome was calculated for each individual patient using the continuous percentage improvement in PASI. A patient maintaining a 95% improvement therefore contributed almost the maximum possible benefit in our analysis even without formally reaching PASI 100. Consequently, our normalized cumulative benefit of 97.4% represents the average intensity and duration of improvement relative to baseline rather than the proportion of time spent in complete clearance.

Our findings can also be considered alongside the 1-year network meta-analysis conducted by Blauvelt et al. [3]. In that analysis, brodalumab ranked among the biologics with the greatest cumulative benefit and was associated with an estimated 138.0 cumulative days in PASI 100 and 235.1 days in PASI 90 over 52 weeks [3]. Brodalumab ranked numerically behind ixekizumab and risankizumab but ahead of several other biologic agents [3]. Once again, these threshold-based response days differ from the clearance-equivalent days used in our study [3]. The former represent the AUC of the proportion of patients meeting a predefined PASI threshold, whereas the latter express the full continuous PASI improvement trajectory as the mathematical equivalent of complete improvement.

Importantly, although the present cohort partially overlaps with that of Orsini et al. [14], the two studies address distinct clinical and methodological questions. The previous study was primarily a comparative analysis across eight biologic treatments and quantified cumulative benefit using the AUC of the proportion of patients achieving the dichotomous PASI 100 endpoint, translating this measure into estimated days spent in complete skin clearance. Brodalumab represented only 128 of the 1017 patients included in that analysis [14]. In contrast, the present study substantially expands the

brodalumab-treated population and calculates cumulative benefit at the individual patient level using the continuous percentage improvement in PASI across the entire 52-week trajectory. Thus, improvement below the PASI 100 threshold contributes quantitatively to the cumulative outcome rather than being classified as a non-response. In addition, the present analysis investigates demographic and clinical determinants of cumulative benefit using multivariable modelling and explores the robustness of these associations through complementary sensitivity analyses, including a ceiling-effect model, restriction to patients with baseline PASI ≥ 10 , and an absolute PASI-days approach. Therefore, the novelty of the present study lies not simply in focusing on brodalumab but also in providing a substantially larger, treatment-specific, patient-level characterization of the magnitude and persistence of clinical benefit and its associated baseline factors.

To our knowledge, this is the first large multicentre real-world study to apply a continuous patient-level cumulative PASI approach specifically to brodalumab and to investigate its demographic and clinical determinants.

Palmoplantar involvement was the factor most consistently associated with lower cumulative clinical benefit. After multivariable adjustment, it was associated with a 3.21-percentage-point reduction in median benefit, corresponding to approximately 10 fewer clearance-equivalent days, and with lower odds of attaining the theoretical maximum. These findings remained consistent after restricting the analysis to patients with baseline PASI ≥ 10 and when cumulative disease burden was assessed using absolute PASI-days. This should not be interpreted as evidence of poor brodalumab efficacy in palmoplantar psoriasis. Rather, it may reflect the therapeutic difficulty of palms and soles, where hyperkeratosis, mechanical stress, and functional impairment are common, together with the limited ability of global PASI to capture persistent site-specific disease. Palmoplantar-specific measures should therefore be considered in future cumulative benefit studies.

Scalp or facial involvement was associated with a modestly higher cumulative benefit and greater odds of attaining maximum benefit.

However, the adjusted difference was small, corresponding to approximately 4 clearance-equivalent days, and should not be interpreted as definitive evidence of a predictive effect. Residual confounding, treatment-selection patterns, and differences in baseline disease distribution may have contributed. Longer psoriasis duration was also statistically associated with greater benefit, but the effect size was minimal—approximately 0.16 clearance-equivalent days per additional year—and is unlikely to be clinically meaningful.

Biologic-naïve status was not independently associated with cumulative benefit. This is broadly consistent with post hoc analyses of AMAGINE-2 and AMAGINE-3, in which brodalumab maintained a cumulative PASI 100 advantage over ustekinumab across previous treatment subgroups, including patients with prior biologic failure [16]. In the study by Orsini et al., brodalumab was associated with 176.37 PASI 100 days in biologic-naïve patients and 162.56 days in biologic-experienced patients [14]. Differences from our findings may reflect adjustment for baseline characteristics and the use of continuous rather than binary cumulative outcomes. Moreover, a simple naïve-versus-experienced classification does not capture the number, mechanism, duration, or reason for discontinuation of previous therapies.

Baseline PASI was also not independently associated with cumulative benefit. Although Orsini et al. reported numerically more PASI 100 days in patients with baseline PASI > 10 than in those with PASI ≤ 10 —177.73 versus 157.39 days [14], percentage improvement is mathematically less stable at low baseline values. The consistency of our findings after restriction to PASI ≥ 10 and in the absolute PASI-days analysis supports their robustness.

Psoriatic arthritis and obesity were not associated with median cumulative benefit, but both were associated with lower odds of attaining the theoretical maximum. Kokolakis et al. showed that brodalumab retained a cumulative PASI 100 advantage over ustekinumab in patients with and without psoriatic arthritis (PsA), with AUC ratios of 1.84 and 1.68, respectively [17]. These findings are not contradictory, as that analysis addressed comparative

efficacy, whereas ours evaluated predictors of response among patients receiving brodalumab. Overall, PsA and obesity may modestly reduce the probability of achieving an optimal response trajectory, although these secondary findings should be interpreted cautiously.

From a clinical perspective, the present results reinforce brodalumab's ability to produce rapid, deep, and sustained disease control in routine practice. Conventional Week 52 response rates alone cannot distinguish a patient who responds early and remains almost completely clear from one who responds only late in the treatment period. The patient-level cumulative approach retains this longitudinal information and may therefore complement static PASI 75, PASI 90, and PASI 100 endpoints. It may be particularly informative for patients with difficult-to-treat manifestations, such as palmoplantar involvement, in whom modest residual disease may persist despite an apparently favorable final global PASI response.

Another consideration is the differing regulatory context for brodalumab across regions. In the US, brodalumab (SILIQ) carries a boxed warning regarding suicidal ideation and behaviour and is available only through a restricted Risk Evaluation and Mitigation Strategy (REMS) programme. Importantly, however, the current US prescribing information states that a causal association between brodalumab treatment and an increased risk of suicidal ideation and behaviour has not been established. In the European Union, brodalumab does not carry an analogous boxed warning or restricted-access programme, although the Summary of Product Characteristics includes specific precautions regarding suicidal ideation and behaviour and recommends careful assessment of the risk-benefit balance in patients with a history of depression or suicidality. These differences in regulatory framing may contribute to geographical variation in brodalumab utilization and should be considered when interpreting real-world prescribing patterns. Reassuringly, available clinical trial and long-term pharmacovigilance data have not established a causal relationship between brodalumab exposure and suicidal behaviour [11].

Strengths and Limitations

The main strengths of this study include the large multicentre real-world cohort, the use of individual longitudinal PASI trajectories, and the application of complementary sensitivity analyses to assess the robustness of the findings.

Several limitations should be acknowledged. First, the retrospective observational design precludes causal inference, and residual confounding cannot be excluded. Second, the complete case approach may have introduced selection bias by preferentially including patients with greater treatment persistence and more complete follow-up. Third, PASI was assessed only at baseline and Weeks 16, 32, and 52; therefore, the AUC calculation assumed linear change between visits and may not fully capture early response or temporary fluctuations. Clearance-equivalent days should consequently be interpreted as a mathematical transformation of cumulative PASI improvement rather than directly observed days of complete clearance. Moreover, the substantial ceiling effect limited discrimination among optimal responders, although this was explored using sensitivity analyses. The absence of an active comparator prevents conclusions regarding the relative effectiveness of brodalumab versus other biologics. Finally, site-specific severity scores, patient-reported outcomes, and centre identifiers were unavailable, limiting assessment of difficult-to-treat areas, patient-perceived benefit, and centre-level variability.

CONCLUSION

In this large multicentre real-world study, brodalumab provided deep and sustained clinical improvement over 52 weeks, with a median cumulative clinical benefit of 97.4% and 300 clearance-equivalent days. Palmoplantar involvement was associated with lower cumulative benefit, whereas scalp or facial involvement was associated with a modestly higher benefit. These findings support the use of patient-level AUC-based outcomes as a complement to conventional PASI response rates, while prospective

studies are needed to further validate their clinical relevance.

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Data Availability. Data that support the findings of this study are available from the corresponding author, upon reasonable request.

Declarations

Conflict of Interest. Luca Mastorino served as a speaker and advisory board member for Leo Pharma, Almirall, Novartis, Eli Lilly, Accord, Pierre Fabre, UCB Pharma, and Johnson & Johnson. Francesca Maria Gaiani acted as a speaker or consultant for Novartis, AbbVie, Eli Lilly, Celgene, Leo Pharma, and Almirall. Martina Maurelli has received personal fees from Almirall, Johnson & Johnson Innovative Medicine, and Leo Pharma. Luigi Gargiulo has been a consultant and/or speaker and has served as an advisory board member for AbbVie, Almirall, Amgen, Bristol Myers Squibb, Eli Lilly, Galderma, Johnson & Johnson, Incyte, LEO Pharma, Novartis, Pierre Fabre, Pfizer, Sanofi, and UCB Pharma. Carlo Giovanni Carrera declares consultancy/advisory board disease-relevant honoraria from AbbVie, Almirall, Bristol Myers Squibb, Johnson & Johnson, Eli Lilly, Novartis, and UCB Pharma. Andrea Carugno has been a speaker and/or consultant for Almirall, Amgen, AbbVie, Boehringer Ingelheim, Eli Lilly, Leo Pharma, Janssen-Cilag, Novartis, and UCB Pharma. Matteo Bianco has been a speaker for Bristol Myers Squibb. Annunziata Dattola has served as a speaker, consultant, or advisory board member for AbbVie, Almirall, Amgen, Eli Lilly, Leo Pharma, Janssen, Novartis, Boehringer Ingelheim, and UCB Pharma outside the submitted work. Maria Esposito has served as a speaker or consultant for AbbVie, Amgen, Almirall, Bristol Myers Squibb, Boehringer Ingelheim, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, UCB Pharma, and Sanofi-Regeneron. Nicola Zerbinati was Scientific Director of Matex Lab. Claudio Guarneri has served as an advisory board member and consultant, has received fees and speaker honoraria, or has participated in clinical trials for Pfizer, Janssen, Novartis, Merck Serono, Eli Lilly, Celgene, Leo Pharma, Leo Pharma Denmark, Almirall, Amgen, Sanofi-Aventis, Boehringer Ingelheim, Bristol Myers Squibb, and UCB Pharma. Francesco Loconsole served on advisory boards and/or received honoraria for lectures from AbbVie, Janssen-Cilag, Novartis, Eli Lilly, and Sanofi. Anna Campanati

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