Journal of Dermatological Treatment

ISSN: 0954-6634 (Print) 1471-1753 (Online) Journal homepage: www.tandfonline.com/journals/ijdt20

Bimekizumab as-needed dosing in patients with psoriasis: a case series

Carlota Abbad-Jaime De Aragón, Emilio Berna-Rico, Pedro Jaén, Andrew Blauvelt & Álvaro González-Cantero

To cite this article: Carlota Abbad-Jaime De Aragón, Emilio Berna-Rico, Pedro Jaén, Andrew Blauvelt & Álvaro González-Cantero (2025) Bimekizumab as-needed dosing in patients with psoriasis: a case series, Journal of Dermatological Treatment, 36:1, 2492197, DOI: 10.1080/09546634.2025.2492197

To link to this article: https://doi.org/10.1080/09546634.2025.2492197

Published online: 21 Apr 2025.

JOURNAL OF DERMATOLOGICAL TREATMENT
2025, VOL. 36, NO. 1, 2492197
https://doi.org/10.1080/09546634.2025.2492197

Taylor & Francis
Taylor & Francis Group

BRIEF REPORT

OPEN ACCESS Check for updates

Bimekizumab as-needed dosing in patients with psoriasis: a case series

Carlota Abbad-Jaime De Aragón[a,b], Emilio Berna-Rico[a,b], Pedro Jaén[a,b], Andrew Blauvelt[c] and Álvaro González-Cantero[a,b,d]

[a]Department of Dermatology, Hospital Universitario Ramón y Cajal, IRYCIS, Madrid, Spain; [b]Inflammatory Diseases and Psoriasis Unit, Grupo Pedro Jaén, Madrid, Spain; [c]Blauvelt Consulting, LLC, Annapolis, MD, USA; [d]Faculty of Medicine, Universidad Francisco de Vitoria, Madrid, Spain

ABSTRACT

Introduction: Despite significant advances in psoriasis treatment, off-label dosing studies of psoriasis biologic therapies are limited.

Materials and methods: In this retrospective case series, medical records from 28 patients with moderate-to-severe psoriasis treated with bimekizumab during 64-week period from May 2023 to October 2024 at the Psoriasis Unit of the Grupo Jaen (Madrid, Spain), were evaluated. Patients were managed with an off-label, as-needed, dosing strategy, with all patients initially receiving two 320 mg doses of bimekizumab at Weeks 0 and 4; subsequent doses were administered only if a given patient dropped below a PASI90 response. Primary outcome was the percentage of patients that achieved and maintained optimal skin control over time, defined as achieving a PASI90 response.

Results: Twenty-seven out of the 28 patients achieved a PASI90 response after the first two bimekizumab doses, and all maintained PASI90 responses with as-needed dosing over time. One patient achieved PASI90 after a single dose of bimekizumab, and voluntarily decided not to receive a second dose. No adverse events were observed.

Conclusions: Larger prospective studies comparing efficacy and safety of this off-label, as needed, bimekizumab dosing regimen with standard on-label dosing are necessary to corroborate these findings.

ARTICLE HISTORY
Received 13 February 2025
Accepted 7 April 2025

KEYWORDS
Psoriasis; bimekizumab; dose reduction; on-demand

Introduction

Psoriasis, a chronic, immune-mediated, inflammatory skin disease, affects 2-3% of the world population (1). Biologic therapies have significantly transformed the treatment of psoriasis in recent years by targeting crucial cytokines involved in the pathogenesis of the disease, such as tumor necrosis factor (TNF)-α, interleukin (IL)-12/23, IL-17, and IL-23 (2). Despite significant advancements in psoriasis treatment, however, challenges remain in treating patients in real-world clinical settings. For example, highly effective biologic therapies are associated with considerable costs, limiting access to many patients, particularly in resource-poor countries with less developed healthcare systems (3). Personalized as-needed treatment strategies could optimize individual therapeutic responses while controlling costs in these settings (4), and has demonstrated to be an acceptable treatment approach to both patients and clinicians (5). Bimekizumab, the newest approved biologic for psoriasis, is a novel IL-17A/F inhibitor with a fast onset of action and very high PASI90 or PASI100 responses (6–8), and has demonstrated favorable outcomes in real-world clinical practice (9,10). Since up to 70% of patients achieve complete clearance over time, it is possible that at least a portion of these patients could maintain clearance or near clearance of skin disease with fewer maintenance doses (11,12). Yet, to date, no studies have described clinical experience in adjusting/individualizing bimekizumab dosing in real-world clinical settings. Here, a case series of 28 patients with psoriasis managed with an off-label, as-needed, bimekizumab dosing strategy are reported.

Materials and methods

Treatment strategy

In this retrospective case series, medical records from all patients with moderate-to-severe psoriasis treated with bimekizumab from May 2023 to October 2024 at the Psoriasis Unit of the Grupo Jaen (Madrid, Spain) were evaluated. Patients were managed with an off-label, as-needed, dosing strategy, with 27 patients initially receiving two 320 mg doses of bimekizumab at Weeks 0 and 4; subsequent 320 mg doses were administered only if a given patient dropped below a PASI90 response. Of note, one patient received only a single bimekizumab dose of 320 mg at Week 0, achieved a PASI90, and voluntarily decided not to receive a second dose.

Follow-up and outcome

After the initiation of bimekizumab treatment at Week 0, patients were scheduled for a Week 4 follow-up visit to receive a second dose. Once the first two doses were administered, all patients

CONTACT Alvaro González-Cantero alvarogc261893@hotmail.com Department of Dermatology, Hospital Universitario Ramón y Cajal, M-607, km. 9, 100, 28034 Madrid, Spain; Faculty of Medicine, Universidad Francisco de Vitoria, Pozuelo de Alarcón, Madrid, Spain

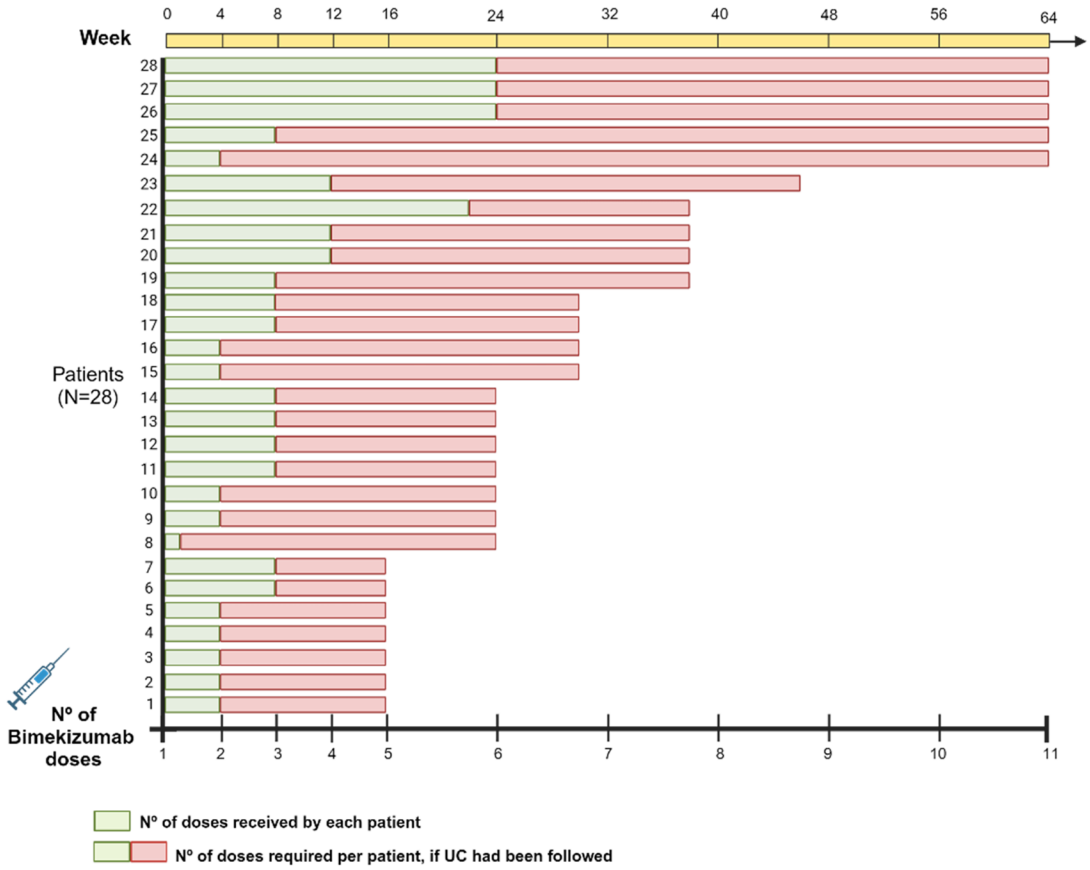

Figure 1. As-Needed dosing of moderate-to-severe psoriasis patients with bimekizumab.

underwent telephone/e-mail follow-up evaluations every 4 weeks to monitor their treatment progress. Patients agreed to contact the clinic to schedule additional injections of bimekizumab if and when psoriasis recurred. The main study outcomes were the percentage of patients that achieved and maintained optimal skin control over time, defined as achieving a PASI90 response, and safety. Adverse events were actively monitored at every visit and during each follow-up phone call.

Statistical analysis

Values are reported as mean (standard deviation [SD]) for parametric variables, median (interquartile interval [IQI]) for nonparametric variables, and *n* (%) for categorical variables. Normality was evaluated using skewness, kurtosis, and histogram plots.

Results

This case series included 28 psoriasis patients followed over a 64-weel period. In Table 1, sample's characteristics are described. Mean age was 44.9 ± 14.4 years, and the majority were male (64%). Mean disease duration before treatment was 15 (6.5 – 30.5) years, mean PASI at baseline was 8.03 ± 6.90, and 43% had previously received oral systemic or biologic treatment. Regarding cardiovascular risk factors, 57% reported dyslipidemia and 14% reported hypertension. Only one patient had psoriatic arthritis. Figure 1 shows the number of doses each patient received (green bars) over 64 weeks and the number of doses they would have received if they had received standard dosing (red + green bars).

Table 1. Baseline demographics and disease characteristics.

	Psoriasis patients (*N* = 28)
Age (years)	44.9 (14.4)
Sex, male (%)	18 (64%)
BMI (kg/m^2)	46.8 (39.6–53.0)
PASI	8.03 (6.90)
BSA	8.15 (6.13)
Dyslipidemia, n (%)	16 (57%)
Hypertension, n (%)	4 (14%)
Diabetes mellitus, n (%)	0 (0%)
Family history CVD, n (%)	3 (11%)
Psoriatic arthritis, n (%)	1 (4%)
Psoriasis duration (years)	15 (6.5–30.5)
Prior conventional systemic treatment, n (%)	12 (43%)
Prior biologic treatment, n (%)	12 (43%)
N° of doses received	3.10 (1.39)
N° of doses needed if UC had been followed	7.17 (2.12)

Data are presented as mean (SD) or median (IQR) for continuous measures, and *n* (%) for categorical measures. BMI: Body Mass Index. BSA: Body Surface Area. CVD: Cardiovascular Disease. N°: Number. PASI: Psoriasis Area Severity Index.

Twenty-seven out of the 28 patients (96.4%) achieved PASI90 after the first two doses, and all maintained treatment responses with as-needed dosing. Patients received ≤50% of bimekizumab doses over the study period without losing PASI90 (mean number of doses received [3.10 ± 1.39] vs. mean number of doses needed if labeled dosing was followed [7.17 ± 2.12]). No adverse events were observed, including no cases of oral candidiasis. Of note, one patient achieved PASI90 after receiving a single dose of bimekizumab, and voluntarily decided not to receive a second dose; this

patient maintained PASI90 during the entire study observation period and experienced no adverse events.

Discussion

In this retrospective case series, off-label, as-needed dosing of bimekizumab is reported. Remarkably, all patients achieved and sustained PASI90 over time with as-needed dosing of bimekizumab, with no cases of oral candidiasis or other adverse events reported. This experience highlights the fact that not all patients with psoriasis require on-label dosing of bimekizumab to do well. The findings also emphasize that less-than-approved dosing of bimekizumab is potentially safer for patients, at least in terms of oral candidiasis rates, and could potentially lead to marked reductions in drug costs, especially in real-world healthcare settings with limited financial resources.

A recent review has highlighted previous dose reduction studies with all types of biologics, demonstrating, for the most part, good clinical efficacy and safety along with the potential for substantial cost savings (4). Data reported here are the first to report an alternative off-label dosing strategy for bimekizumab. Dose-reduction strategies for other biologics have described extending dosing intervals between injections in a measured manner. By contrast, an as-needed, more individualized dosing strategy is reported here for bimekizumab. High levels of efficacy were maintained with as-needed dosing of bimekizumab over the course of 2 years, while minimizing the potential for safety issues (i.e. no cases of oral candidiasis were noted) and reducing overall drug costs (i.e. half the number of doses was required when compared to standard dosing). Although not studied here, it is possible that as-needed dosing of bimekizumab could promote the development of anti-drug antibodies, with associated loss of efficacy over time. In addition, the absence of a control group receiving standard bimekizumab dosing constitutes a limitation in the evaluation of efficacy for this treatment strategy. Larger and longer prospective studies comparing efficacy and safety of this off-label bimekizumab regimen vs. standard on-label dosing are necessary to corroborate these findings, which would help better inform practitioners in clinical settings where drug cost concerns limit implementation of standard bimekizumab dosing.

The sum of the red and green bars is the total number of doses that each patient would have received if on-label dosing was utilized. Green bars are the number of doses actually received.

Ethics statement

Not applicable.

Informed consent

All patients gave written informed consent for participation, for the off-label treatment approach, for data collection, and for publication of their case details.

Disclosure statement

ACG: has served as a consultant for AbbVie, Janssen, Novartis, Lilly, Almirall, UCB, BMS, Celgene and Leo Pharma receiving grants/other payments, outside the submitted work. AB: has served as a speaker (received honoraria) for Eli Lilly and Company and UCB, has served as a scientific adviser (received honoraria) for AbbVie, Almirall, Alumis, Amgen, Anaptysbio, Apogee, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Dermavant, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte, IQVIA, Janssen, Leo, Lipidio, Merck, Novartis, Oruka, Paragon, Pfizer, Regeneron, Sanofi, Spherix Global Insights, Sun Pharma, Takeda, UCB Pharma, and Union, has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly and Company, Galderma, Incyte, Janssen, Leo, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, and UCB Pharma, and owns stock in Lipidio and Oruka. The other authors declare no conflicts of interest. CAJDA, EBR, PJ have no conflicts of interest to disclose.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

ORCID

Carlota Abbad-Jaime De Aragón http://orcid.org/0000-0002-5587-1204
Emilio Berna-Rico http://orcid.org/0000-0003-0348-5421
Pedro Jaén http://orcid.org/0000-0002-7334-0044
Andrew Blauvelt http://orcid.org/0000-0002-2633-985X
Álvaro González-Cantero http://orcid.org/0000-0001-8060-4784

Data availability statement

the data underlying this article are available upon request from the corresponding author.

References

1. Parisi R, Symmons DPM, Griffiths CEM, et al. Global Epidemiology of Psoriasis: a Systematic Review of Incidence and Prevalence. J Invest Dermatol. 1 de Febrero de. 2013;133(2):377–385. doi: 10.1038/jid.2012.339.
2. Alwan W, Nestle FO. Pathogenesis and treatment of psoriasis: exploiting pathophysiological pathways for precision medicine. Clin Exp Rheumatol. 2015;33(5 Suppl 93):S2–S6.
3. Kamangar F, Isip L, Bhutani T, et al. How psoriasis patients perceive, obtain, and use biologic agents: survey from an academic medical center. J Dermatol Treat. febrero de. 2013;24(1):13–24. doi: 10.3109/09546634.2011.631979.
4. van Riel CaM, Michielsens CaJ, van Muijen ME, et al. Dose reduction of biologics in patients with plaque psoriasis: a review. Front Pharmacol. 2024;15:1505626. doi: 10.3389/fphar.2024.1369805.
5. Gleeson D, Naveed M, Moorhead L, et al. Acceptability of «as needed» biologic therapy in psoriasis: insights from a multistakeholder mixed-methods study. Br J Dermatol. 16 de Julio de. 2024;191(2):243–251. doi: 10.1093/bjd/ljae068.
6. Kimball AB, Jemec GBE, Sayed CJ, et al. Efficacy and safety of bimekizumab in patients with moderate-to-severe hidradenitis suppurativa (BE HEARD I and BE HEARD II): two 48-week, randomised, double-blind, placebo-controlled, multicentre phase 3 trials. The Lancet. 8 de Junio de. 2024;403(10443):2504–2519. doi: 10.1016/S0140-6736(24)00101-6.
7. Reich K, Papp KA, Blauvelt A, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque

psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo controlled phase 3 trial. Lancet. 2021;397(10273):487–498. doi: 10.1016/S0140-6736(21)00125-2.
8. Gordon KB, Foley P, Krueger JG, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial. Lancet. 2021;397(10273):475–486. doi: 10.1016/S0140-6736(21)00126-4.
9. Hagino T, Saeki H, Fujimoto E, et al. Effectiveness of long-term bimekizumab treatment and predictive factors for responders in moderate-to-severe psoriasis: a 52-week real-world study. J Dermatol. 2025;52(2):317–328. doi: 10.1111/1346-8138.17532.
10. Hagino T, Saeki H, Fujimoto E, et al. Real-world effectiveness and safety of bimekizumab in Japanese patients with psoriasis: a single-center retrospective study. J Dermatol. 2024;51(5):649–658. doi: 10.1111/1346-8138.17186.
11. Reich K, Warren RB, Lebwohl M, et al. Bimekizumab versus secukinumab in plaque psoriasis. N Engl J Med. 2021;385(2):142–152. doi: 10.1056/NEJMoa2102383.
12. Warren RB, Blauvelt A, Bagel J, et al. Bimekizumab versus adalimumab in plaque psoriasis. N Engl J Med. 2021;385(2):130–141. doi: 10.1056/NEJMoa2102388.