Real-World Outcomes of Bimekizumab in Hidradenitis Suppurativa: A Systematic Literature Review and Meta-Analysis

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Objective

To address the lack of synthesized real-world evidence by providing the first quantitative synthesis of clinical outcomes associated with **bimekizumab** (BKZ) in **hidradenitis suppurativa** (HS) through a systematic review and meta-analysis

Background

- **BKZ**, a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated **clinically meaningful efficacy** in patients with **HS** in **phase III clinical trials** [1]
- Nevertheless, **real-world evidence** on BKZ in HS remains limited and has not yet been **systematically synthesized**. Data on disease activity outcomes assessed by the International Hidradenitis Suppurativa Score System (**IHS4**) and responder endpoints such as **IHS4-55** and Hidradenitis Suppurativa Clinical Response (**HiSCR-50**) are still emerging

Methods

- A systematic literature search was conducted in **PubMed** and **EMBASE**. Relevant conference abstracts were screened manually
- Eligible studies were prospective or retrospective observational cohorts including **≥ 9 HS patients** treated with **BKZ** and reporting **Week 16 effectiveness outcomes**. Where overlapping study populations were identified, only the study with the largest sample size was retained
- Analysis of disease activity outcomes:
  - Mean change in **IHS4** from baseline to week 16 was pooled using single-arm random-effects meta-analysis assuming paired measurements
  - Between-study variance was estimated using **restricted maximum likelihood** (REML)
  - Corresponding 95% confidence intervals (CIs) were computed using the **Hartung-Knapp-Sidik-Jonkman method**
  - Missing standard deviations (SDs) were **imputed** using pooled estimates from studies with available data
  - **Sensitivity analyses** assessed assumptions regarding paired measurements and handling of missing SDs
- Analysis of responder outcomes:
  - **IHS4-55** and **HiSCR-50** response rates at Week 16 were pooled as proportions using logit-transformed random-effects generalized linear mixed models

Results

Study characteristics

- The literature search identified **59 records**, of which **five publications** [2-6] met the inclusion criteria
- Baseline disease severity was comparable across studies, with mean IHS4 values ranging from approximately 19 to 25
- Overall, **195** patients contributed to the pooled analysis of IHS4 change from baseline to Week 16

Disease activity outcomes

- BKZ treatment was associated with **improvements** in disease activity, measured by absolute change in IHS4 from baseline to Week 16
- Pooled mean improvement in **IHS4** at Week 16 was **9.58 points** (95% CI: 7.37-11.80), with no detected heterogeneity ($I^2 \approx 0\%$)
- In sensitivity analyses excluding the study requiring SD imputation, the pooled IHS4 improvement remained consistent at **9.21 points** (95% CI: 7.17-11.24)
- Across sensitivity analyses assessing assumptions regarding paired measurements and the handling of missing SDs, **pooled estimates remained consistent** (≈ 9.19- 9.21 points)

Responder outcomes

- Only three studies [3,5-6] reported **IHS4-55** response rates at Week 16, ranging from 46.2% to 53.3%
- The pooled **IHS4-55 responder proportion** was **47.5%** (95% CI: 38.0-57.2; $I^2 \approx 0\%$)
- Only three studies [4-6] reported **HiSCR-50** response rates at Week 16, ranging from 54.0% to 66.7%
- The pooled **HiSCR-50 responder proportion** was **56.9%** (95% CI: 47.6-65.7; $I^2 \approx 0\%$)

Limitations

- Results should be interpreted cautiously given the **observational nature** of the included studies
- The evidence base remains limited, with **only a few eligible publications** and **small patient numbers**

Conclusions

Real-world evidence indicates that BKZ treatment is associated with improvements in HS disease activity and responder outcomes at Week 16

As the first quantitative synthesis of real-world evidence on BKZ in HS, this meta-analysis demonstrates consistent findings across studies, while highlighting the need for larger studies with longer follow-up

INCLUDED STUDIES

Spain
- Mansilla Polo 2025 (n= 78)
- Urena Paniego 2024 (n= 15)
- Molina Leyva 2024 (n= 15)

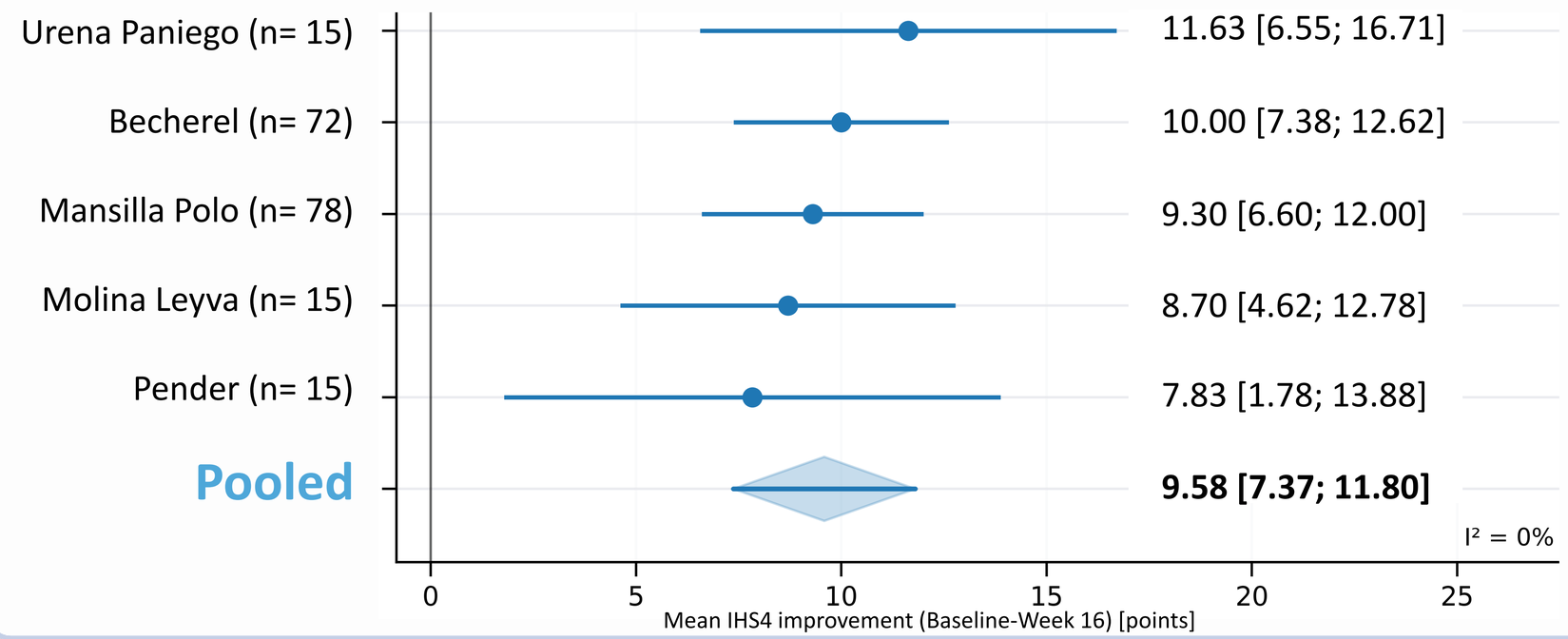
France
- Becherel 2023 (n= 72)

Ireland
- Pender 2026 (n= 15)

Total patients

N= 195

ABSOLUTE IHS4 IMPROVEMENT FROM BASELINE TO WEEK 16



RESPONDER OUTCOMES AT WEEK 16

IHS4-55 RESPONDER RATE

47.5%

0% 50% 100%

k= 3 studies; n= 101

HiSCR-50 RESPONDER RATE

56.9%

0% 50% 100%

k= 3 studies; n= 114

KEY FINDINGS AND RESULTS

First quantitative synthesis of real-world BKZ evidence in HS

BKZ was associated with improvements in disease activity and response

Findings remained robust across sensitivity analyses

IHS4 IMPROVEMENT

~10 points

reduction at Week 16

IHS4-55 RESPONDER RATE

~50% of patients

responded at Week 16

HiSCR-50 RESPONDER RATE

~60% of patients

responded at Week 16

Abbreviations: **BKZ:** Bimekizumab; **HS:** Hidradenitis Suppurativa; **IHS4:** International Hidradenitis Suppurativa Score System; **HiSCR-50:** Hidradenitis Suppurativa Clinical Response; **REML:** Restricted maximum likelihood

References: [1]Fachinformation Bimzelx® 160 mg / - 320 mg Injektionslösung in einer Fertigspritze/im Fertigpen; aktueller Stand. [2]Becherel et al, 2023: BKZ in severe resistant HS: a real-world cohort. [3]Mansilla-Polo et al, 2025: BKZ shows high long-term efficacy in the treatment of patients with moderate to severe HS in real-world clinical conditions. [4]Urena-Paniego et al, 2024: Efficacy and safety of BKZ in patients with moderate to severe HS . [5]Molina-Leyva et al, 2024: Effectiveness and safety of BKZ in the treatment of patients with moderate to severe HS. [6]Pender et al, 2026: BKZ for treatment of moderate to severe HS. Images created in BioRender. Alaeddin, N. (2026) https://BioRender.com/hk60rs4

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