Bimekizumab budget impact analysis for the treatment of patients with moderate-to-severe hidradenitis suppurativa (HS) in Greece

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Introduction

Background

- Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease characterized by painful nodules, abscesses, tunnels, and scarring, significantly impacting patients' quality of life[1,2]. Global prevalence ranges from <1% to 4%, with women more frequently affected and onset typically after puberty[3-6]. In Greece, approximately 0.06% of the population is affected, with 61% of them demonstrating moderate-to-severe disease[7].

Current Treatments

- Management strategies include antibiotics, corticosteroids, surgical interventions, and biologics[8,9]. Adalimumab is currently approved for moderate-to-severe HS (Hurley stage II–III), and secukinumab was recommended by international institutions (NICE, 2023) for patients who failed conventional systemic therapies[10,11].

Unmet Need

- Despite available options, many patients continue to experience pain, functional impairment, and disease progression, highlighting the need for more effective and sustained treatments[12,13].

Intervention

- Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A, has shown efficacy in Phase III trials (BE HEARD I & II) and is under long-term evaluation in BE HEARD-EXT[14,15]. Bimekizumab has been included in the recently published European S2K guidelines for the treatment of moderate-to-severe HS among other biologics[16].

Aim

- This analysis aimed to assess the budgetary impact of reimbursing bimekizumab for patients with moderate-to-severe HS in Greece[17].

Methods

Budget Impact Model Structure

- An Excel-based budget impact model (BIM) was developed from the Greek National Organization for Health Services (EOPYY) perspective to estimate the economic impact of reimbursing bimekizumab for moderate-to-severe HS in Greece over five-years (2026–2030) (Figure 1).
- The eligible population included adult patients with moderate-to-severe HS.
- Two scenarios were compared: current market (without bimekizumab) vs. future market (with bimekizumab).
- Bimekizumab was compared to biologic disease-modifying anti-rheumatic drugs (bDMARDs) that are currently reimbursed in the Greek market for the treatment of moderate-to-severe HS, namely secukinumab and adalimumab.
- Only direct medical costs concerning drug acquisition, monitoring, disease management, and adverse events (AEs) were included.
- The primary model outcome was the total budget impact and incremental cost of bimekizumab.

Model Inputs

- Epidemiology and healthcare resource use were obtained from literature and validated by local clinical experts (dermatologists) (Table 1).
- Population estimates considered adult population, HS prevalence and incidence, annual mortality (0.499%)[18], and annual population growth (-1.36%)[19].
- Market shares of bimekizumab and comparators were provided by UCB (Table 2).
- Clinical efficacy inputs were derived from phase III trials (BE HEARD I & II) and supplemented by a network meta-analysis (NMA)[20]. Hidradenitis Suppurativa Clinical Response (HiSCR) was used to define treatment response, with week 16 response (50% reduction in abscess and inflammatory nodule count) from UCB NMA and week 48 response from matched adjusted indirect comparisons (MAIC)[21].
- Treatment discontinuation rates were incorporated, assuming 20.48% of patients would discontinue therapy each year based on published literature and expert consensus[22-24].
- Treatment dosing and frequency followed EMA-approved schedules[11,17,25], adjusted to reflect real-world practice in Greece as verified by local clinical experts (Table 4).
- All costs were reported in 2024 Euros (€) and adjusted for inflation using data from the Hellenic Statistical Authority (EL.STAT.)[26].
- Unit cost of each treatment was calculated based on ex-factory prices published in the latest drug price bulletin issued by the Greek ministry of health[27], after applying the relevant discounts provided in the corresponding legislation (official government gazette, law 115/7.8.2017) (Table 3).
- Healthcare resource use (HCRU) was stratified by HiSCR health states, incorporating dermatologist visits, laboratory tests, and hospitalizations. Hospitalization costs were sourced from the Greek DRG catalogue published in the Government gazette (FEK B'7262/21.12.2023), and AE costs were included for both mild-to-moderate and severe events, informed by local clinical data and published literature.
- AEs were selected based on PIONEER I & II trial, BE HEARD I & II trial, and secukinumab NICE TA [10,15,16,22,24]. Each AE has a treatment-specific annual probability, adjustable for all comparators (Table 5).
- The model outcome was the financial impact of bimekizumab defining its incremental cost and its total budget impact.

Sensitivity Analysis

- Deterministic sensitivity analysis (DSA) was conducted by varying several parameters from the original estimates to test the robustness of base case results.
- Scenario analyses were also conducted, excluding disease management and adverse event costs from the analysis, and changing the time horizon from 1 to 4 years (base case = 5 years).

Results

Base-Case Analysis

- The eligible HS population for biologic DMARD treatment ranged from 571 patients in Year 1 to 937 patients in Year 5.
- Bimekizumab was projected to achieve 5% market share in Year 1, increasing to 23% in Year 5 (Table 2).
- The budget impact analysis (BIA) estimated an incremental cost to the EOPYY budget of €342,336 in Year 1 and €2,707,559 in Year 5 (Figure 2).

Scenario and Sensitivity Analyses

- Drug unit costs and adult population size were the main drivers of the cumulative budget impact, as shown in the DSA (Figure 3).
- Scenario analysis showed no significant deviations from the base-case, indicating a limited budget impact for the Greek public payer considering the clinical benefits of bimekizumab (Table 6).

Conclusions

The introduction of bimekizumab into the Greek healthcare system is projected to result in a total budget impact of €7,852,000 over 5 years, averaging €1,570,400 per year. While this represents a measurable increase in healthcare spending, it is considered acceptable given the high unmet need and the solid therapeutic benefit of bimekizumab.

Summary

Analysis Population:
Greek adults with moderate-to-severe hidradenitis suppurativa (HS)

Analysis Comparator:
Adalimumab
Secukinumab

Analysis year:
2024

Analysis results:
An average total budget impact of €1,570,400 per year

Figure 1 Budget impact model framework

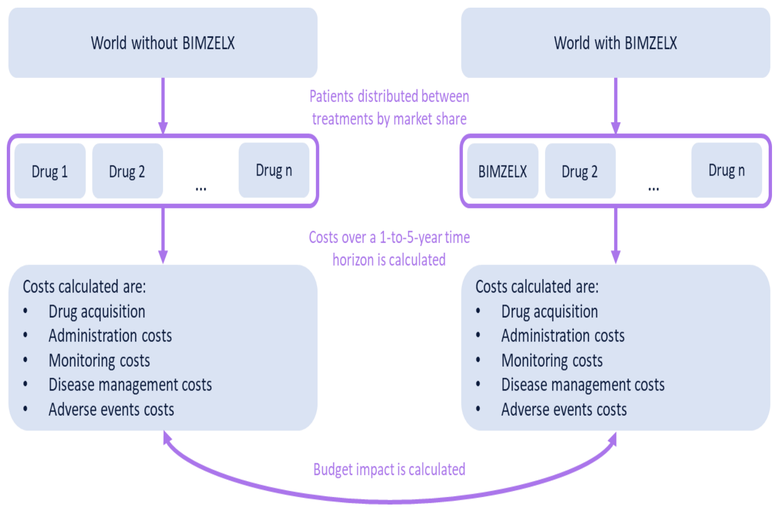

Figure 2 Total annual incremental costs and cumulative costs (5-years period)

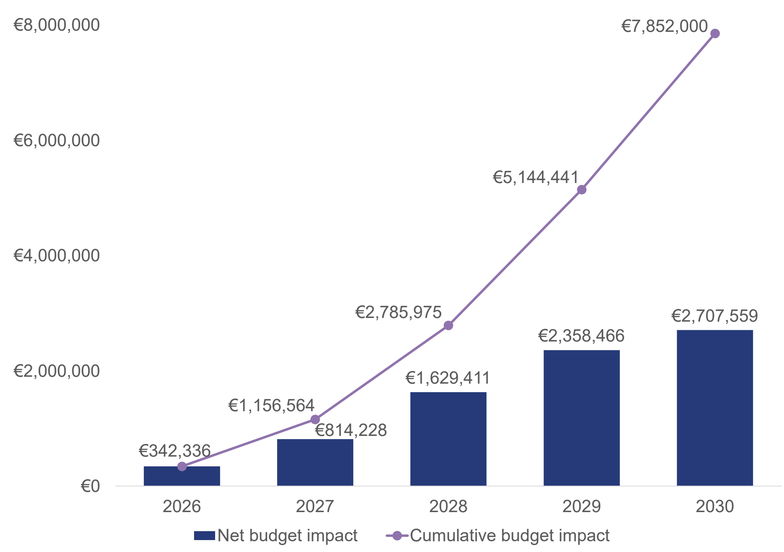

Figure 3 Tornado plot for budget impact analysis

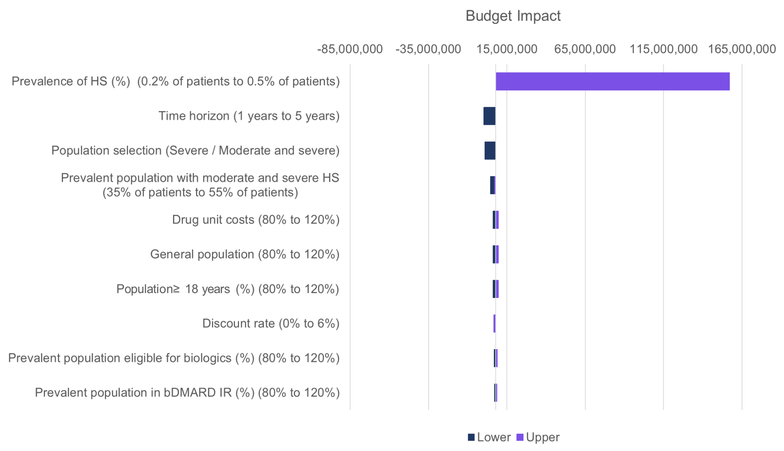

Table 1 Overview of eligible HS patient population

Population inputs	Value	Source
Adult population of Greece	8,747,417	Hellenic Statistical Authority (ELSTAT)[28]
Prevalence of adults with HS (%) [nr of patients]	0.02% [1,312]	UCB data based on EOPYYKMESS
Incidence of adults with HS (%) [nr of patients]	0.0030% [262]	UCB data based on EOPYYKMESS
Percentage of patients with moderate and severe HS (%) [nr of patients]	61% [960]	IQVIA Market Research for hidradenitis suppurativa (2023)
Percentage of treated patients eligible for bDMARDs (%) [nr of patients]	59.50% [571]	Liakou 2022[29]

Table 2 Market share scenarios

	World without Bimekizumab				
	2026	2027	2028	2029	2030
Adalimumab	23.2%	19.7%	16.2%	13.6%	11.1%
Adalimumab (Biosimilar)	58.4%	54.1%	49.6%	46.1%	42.6%
Secukinumab Q4W	15.7%	19.4%	24.9%	29.1%	31.6%
Secukinumab Q4W to Q2W	2.7%	6.8%	9.3%	11.2%	14.7%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**
	World with Bimekizumab				
	2026	**2027**	**2028**	**2029**	**2030**
Bimekizumab	4.8%	9.7%	16.5%	21.5%	22.6%
Adalimumab	23.2%	19.8%	16.3%	13.7%	11.1%
Adalimumab (Biosimilar)	58.4%	54.0%	49.6%	46.1%	42.6%
Secukinumab Q4W	12.2%	12.0%	11.4%	11.9%	13.9%
Secukinumab Q4W to Q2W	1.4%	4.5%	6.2%	6.8%	9.8%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Table 3 Costs used in the analysis

Drug acquisition costs

	Units per pack	Dose (mg) per vial/ syringe	Cost per pack[27] (Ex-Factory price)
Bimekizumab	2	320 mg	€ 1,731.53
Adalimumab	1	40 mg	€ 203.85
Adalimumab (Biosimilar)[a]	2	40 mg	€ 299.35
Secukinumab Q4W/Q4W[b]	1	150 mg	€ 362.80
Secukinumab Q4W/Q2W	2	150 mg	€ 725.58

Adverse event costs

	Severe Event	Mild/Moderate Event	Source
Headache	€ 337	€ 70	Gourzoulidis et al. 2019[30]
Hidradenitis exacerbation	€ 2,046	€ 11	Local clinical experts estimates; Government gazette (FEK B' 7262/21.12.2023)
Nasopharyngitis	€ 21	€ 21	Gourzoulidis et al. 2018[31]
Upper respiratory tract infection	€ 193	€ 193	Vellopoulou et al. 2020[32]
Diarrhoea	€ 293	€ 18	Gourzoulidis et al. 2019[30]

Disease management costs

	Unit costs	Source
Hospitalisations for HS surgery	€ 7,183	Government gazette (FEK A'262/16-12-2011 and FEK B' 7262/21.12.2023)
Outpatient visits due to HS surgery	€ 10	
Hospitalisations, non-surgery related	€ 2,046	
Routine outpatient visits	€ 10	

[a]Based on input from local clinical experts, it is assumed that 85% of patients treated with adalimumab receive biosimilars; [b]Pack cost of secukinumab 150mg.

Table 4 Dosing schedules

	Population inputs
Bimekizumab	320 mg administered Q2W for 16 weeks followed by 320 mg administered Q4W
Adalimumab	160mg at day 1, 80mg at day 15 & day 29 and every 2 weeks thereafter
Secukinumab[a]	300mg at week 0, 1, 2, 3 and 4 and every 4 weeks thereafter

[a]An 25% of patients may increase the dose to 300 mg every 2 weeks, based on local clinical experts

Table 5 Annual adverse event probability

	Bimekizumab (n=291)	Adalimumab (n=633)	Secukinumab (n=361)
Headache	9.4%%	48.0%	30.0%
Hidradenitis exacerbation	20.3%	27.4%	0.0%
Nasopharyngitis	8.3%	24.7%	23.8%
Upper respiratory tract infection	6.0%	17.8%	10.0%
Diarrhoea	9.3%	16.5%	14.1%

Table 6 Budget impact scenario analysis

	Variation value	Total Budget Impact
Base case	-	€ 7,852,000
Disease management costs	Excluded	€ 8,363,577
Adverse event costs	Excluded	€ 7,661,054
Time horizon	4 years	€ 5,144,441
	3 years	€ 2,785,975
	2 years	€ 1,156,564
	1 year	€ 342,336

AEs: Adverse Events; **b/ts DMARDs:** biologic/ targeted synthetic disease-modifying anti-rheumatic drugs; **BIM:** Budget Impact Model; **DSA:** Deterministic sensitivity analysis; **EL.STAT.:** Hellenic Statistical Authority; **EOPYY:** Greek National Organization for Health Services; **HCRU:** Healthcare resource use; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HS:** Hidradenitis Suppurativa; **MAIC:** matched adjusted indirect comparisons; **NMA:** network meta-analysis; **nr:** number; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks.

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Eur J Gastroenterol Hepatol, 2021. 33(3): p. 325-333. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **KM, RS, FM**; Drafting of the publication, or revising it critically for important intellectual content: **KM, RS, LE, LAI, FM, RJ, MM, KG**; Medical writing: **RS**; Final approval of the publication: **LE, LAI, FM, RJ, MM, KG**. **Author Disclosures: MK, RS:** employees of ECONCARE LP which had contract with UCB. **LE:** Honoraria for lectures, research protocols, and consultancy from UCB. No other conflicts of interest are declared. **LAI:** has received advisory board fees from Novartis, UCB, lecture honoraria and support for attending meetings from Amgen, AbbVie, Boehringer-Ingelheim, Novartis, UCB Pharma. She is sub-investigator in clinical trials of AbbVie, Boehringer-Ingelheim, Insmed, Novartis, Sanofi and UCB. **FM, RJ:** employee of UCB, Greece. **MM:** employee of UCB Nordic AS, Copenhagen. **GK:** No conflict of interest. **Acknowledgements:** We would like to thank all the investigators and their teams who contributed to this study. The authors acknowledge Susana Lobo Berastegui, MSc, MBA, UCB for publication coordination, Stylianos Ravanidis, Econcare LP, Athens, Greece for medical writing, Claire Osgood, Costello Medical, London, UK and Grace Young, Costello Medical, Cambridge, UK for editorial assistance. All costs associated with development of this poster were funded by UCB.

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