EE454

Budget Impact Analysis of Bimekizumab for the Treatment of Axial Spondyloarthritis (axSpA) in Greece

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Objectives

To assess the budgetary impact of integrating bimekizumab, into treatment options for adult patients with axial spondyloarthritis (axSpA) in Greece, alongside existing biologic therapies and small molecules.

Background

- Axial spondyloarthritis (AxSpA) is a chronic inflammatory disease primarily affecting the spine and sacroiliac joints[1,2,3], causing severe back pain, fatigue, and stiffness, which can lead to irreversible structural damage, spinal fractures and injury. AxSpA is often accompanied by peripheral and extramusculoskeletal manifestations, such as enthesitis, peripheral arthritis, inflammatory bowel disease, uveitis, and psoriasis. AxSpA is divided into non-radiographic (nr-axSpA) and radiographic (r-axSpA or ankylosing spondylitis) forms, depending on whether structural changes are visible on radiographs[4].
- The primary treatment goal, as outlined by Assessment of SpondyloArthritis international Society (ASAS)-EULAR[5] and the Greek Ministry of Health[6], is to enhance long-term health-related quality of life (HRQoL) by controlling symptoms, reducing inflammation, preventing structural damage, and maintaining function and social participation. Treatment typically begins with non-steroidal anti-inflammatory drugs (NSAIDs) and may progress to biologic or targeted synthetic disease-modifying antirheumatic drugs (bDMARDs or tsDMARDs) [5,7,8]. Although guidelines recommend switching to another bDMARD following first-line therapy failure, 50%-65% of patients do not achieve an ASAS40 response (40% improvement in ASAS criteria) with tumor necrosis factor inhibitors (TNFi), and 58%-64% do not respond to interleukin-17 inhibitors (IL-17Ai)[9-12].
- Bimekizumab is the first humanized immunoglobulin G1 (IgG1)/κ monoclonal antibody designed to selectively inhibit IL-17F in addition to IL-17A by targeting all three dimers (IL-17A/A, IL-17A/F, and IL-17F/F)[13]. Bimekizumab received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on April 26, 2023, recommending its approval for the treatment of axSpA[14].

Methods

Budget Impact Model Structure

- A budget impact model was locally adapted to delineate the financial implications of introducing bimekizumab for the treatment of axSpA in Greece, alongside currently available therapies, from the Greek national payer (EOPPY) perspective, over the next 5 years (2025–2029).
- The target population was adult patients with axSpA and the model framework is presented in Figure 1.
- Local market share information were used for the distribution of patients between comparators.
- Direct reimbursement costs of each treatment (including drug acquisition, administration, monitoring, disease management and adverse events) were included in the analysis (Table 1).
- The model outcome was the financial impact, measured as incremental cost and total budget impact of bimekizumab in the Greek market.

Model Inputs

- The modelled population was aligned with the eligibility criteria of the BE AGILE I and II clinical trials[15,16] including adults who are b/ts DMARD pure naïve and b/ts DMARD pure experienced. A top-down approach beginning with the total adult population of Greece was used (Table 2).
- All biologics (original/biosimilars) and small molecules, such Janus kinase (JAK) inhibitors that were marketed and recommended for patients with axSpA in Greece at the time of the analysis, were included.
- Local market share estimates with and without bimekizumab were based on market insights of UCB and a recent market research in Greece (Greek Physician Market Research 2023) (Table 3).
- Efficacy inputs were based on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI 50), using data from a published network meta-analysis[17]. BASDAI50 represents an improvement of ≥50% of the BASDAI score from baseline[18,19].
- Unit cost of each treatment was calculated based on their ex-factory prices as they were published in the latest drug price bulletin issued by the Greek ministry of health[20], after applying the relevant discounts provided in the corresponding legislation (official government gazette, law 115/7.8.2017).

Sensitivity Analysis

- A deterministic sensitivity analysis (DSA) was performed by adjusting multiple parameters from their initial estimates to evaluate the stability of the base case findings.
- Scenario analyses were additionally carried out, omitting monitoring and adverse event costs, and altering the time horizon from 1 to 4 years.

Results

Base-Case Analysis

- The eligible population was projected to grow from 6,738 patients in the first year to 7,053 by the fifth year, with the number of axSpA patients receiving bimekizumab in the new market scenario rising from 131 in 2025 to 427 in 2029.
- Adding bimekizumab to the axSpA market resulted in an estimated average cost of €267 per patient over five years, leading to an increase in public healthcare expenditure with an average annual total budget impact of €1,851,487 (Figure 2).

Sensitivity Analyses

Results of sensitivity analyses revealed no significant deviations from the base case results.

Conclusions

Introducing bimekizumab to the Greek axSpA market is expected to improve clinical outcomes. The modest incremental cost of €267 per patient over five years results in an average annual budget impact of €1.85M, demonstrating that bimekizumab offers clinical benefits without imposing significant financial strain on the healthcare system.

Summary

Analysis Population:
Greek adults with axial spondyloarthritis

Analysis Comparator:
Biologic therapies and small molecules, such a Janus kinase inhibitors (JAKs), currently available in the Greek market

Analysis year:
2023

Analysis results:
An average total budget impact of €1,851,487 per year

Figure 1 Budget Impact Model Framework for AxSpA

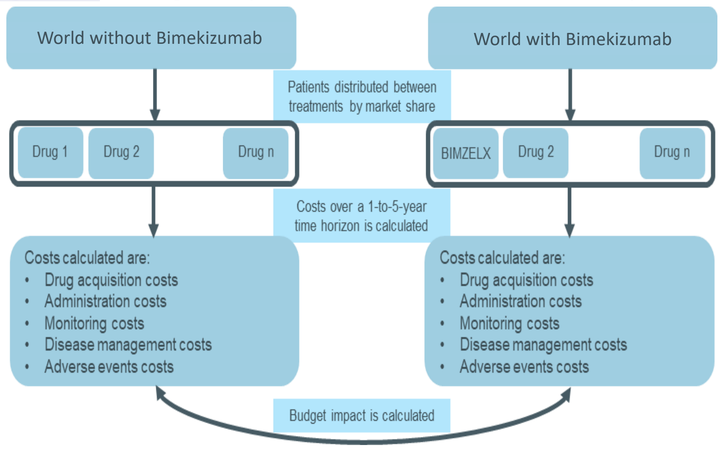

Figure 2 Total annual incremental costs and cumulative costs (5-years period)

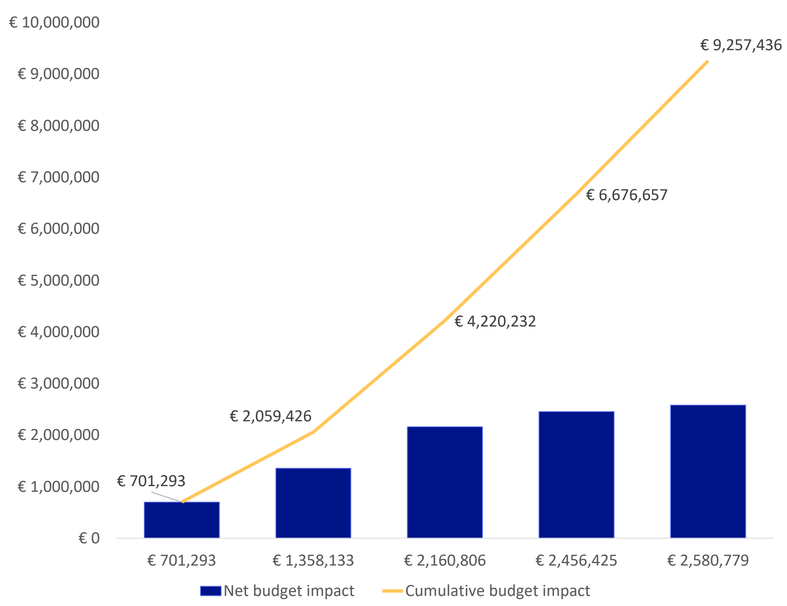

Table 1 Costs used in the analysis

Drug acquisition costs for the different treatments[1]

Treatment	Pack size	Dose (mg) per vial/ syringe/ tablet	Cost per pack (Ex-Factory price)
Bimekizumab	2	160	€ 2,147.55
Adalimumab	1	40	€ 252.83
Adalimumab (Biosimilar)	2	40	€ 300.15
Certolizumab pegol	2	200	€ 566.06
Etanercept	4	50	€ 471.77
Etanercept (Biosimilar)	4	50	€ 420.55
Golimumab	50	1	€ 609.32
Infliximab IV	1	100	€ 265.95
Infliximab (Biosimilar) SC	2	120	€ 689.69
Ixekizumab	2	80	€ 1,701.87
Risankizumab	2	75	€ 2,530.70
Secukinumab 150mg	1	150	€ 429.28
Secukinumab 300mg	2	150	€ 852.15
Upadacitinib	28	15	€ 673.82

Treatment monitoring[2]

Service	Unit cost per service
Rheumatologist	€ 10.00
Full blood count	€ 1.69
Erythrocyte Sedimentation Rate	€ 1.00
Liver Function Test	€ 5.92
C-reactive Protein	€ 1.92
Urea and Electrolytes Test	€ 4.30
TB Heaf Test	€ 1.50
Antinuclear antibody	€ 7.35
Double-stranded DNA test	€ 12.75
MRI	€ 115.01
Chest Radiograph	€ 3.44

Disease Management costs[3]	Mean
Intercept	€1,239.58

Adverse event costs[4]	Cost per event
Serious infection	€1,563.00

Sources: [1] Drug price bulletin issued by the Greek ministry of health[20]; [2] Unit costs derived from Government Gazette (FEK 1181B'/8-5-2014) and EOPYY official website[21]; [3] TA383[22], £ 1,284.19 in year 2016 inflated to 2023 GBP (£) values (ONS. Consumer Prices Index, Special Aggregate: 06 Health 2016-2023 = 1.210) and converted to Greek euros (€) based on economic database of Organization for Economic Co-operation and Development[23] (using the latest available Purchasing Power Parities [PPP] ratio in US dollars for health indicator: US$ = €0.528 for Greece and US$ = £0.664 for UK); [4] Data associated with the inpatient management, were retrieved from both local clinical experts and the list of DRG issued by the Greek Ministry of Health[24]. Costs related to the outpatient management, were calculated by combining healthcare resource consumption, according to local clinical expert estimates and unit costs. Unit costs associated with each input extracted from Government Gazette (FEK 1181B'/8-5-2014) and EOPYY official website[21].

Table 2 Overview of eligible axSpA patient population inputs

Population inputs	Greek Patients[a]	Source
Prevalence of axSpA (0.24%)	22,059	Andrianakos. A., et al. 2003[25]; Trontzas et al. 2005[26]; Local clinical experts' estimates
Incidence of axSpA (0.005%)	440	Alamanos et al. 2021[27]; Local clinical experts' estimates
Population with nr-axSpA (7%)	1,544	Greek Physician Market Research Oct-Nov 2022; Local clinical experts' estimates
Population with r-axSpA (93%)	20,514	Greek Physician Market Research Oct-Nov 2022; Local clinical experts' estimates
Percentage of patients with axSpA eligible to receive treatment with b/tsDMARDs (30%)	6,738	Greek Physician Market Research Oct-Nov 2022; Local clinical experts' estimates

Note: [a] Data apply to each year (2025-2029)

Table 3 Market shares in the world without & with bimekizumab

	Current scenario (current treatment mix)					Future scenario (New treatment mix)				
Treatment	**2025**	**2026**	**2027**	**2028**	**2029**	**2025**	**2026**	**2027**	**2028**	**2029**
Bimekizumab	0%	0%	0%	0%	0%	1.80%	2.40%	4.60%	6.70%	8.20%
Adalimumab	10.00%	9.00%	8.40%	8.00%	8.00%	10.00%	9.00%	8.00%	8.00%	8.00%
Adalimumab (Biosimilar)	15.00%	14.20%	14.00%	14.00%	14.00%	15.00%	14.20%	14.00%	14.00%	14.00%
Certolizumab pegol	8.00%	8.00%	7.00%	6.00%	6.00%	8.00%	8.00%	7.00%	6.00%	5.40%
Etanercept	6.00%	5.50%	5.50%	5.50%	5.50%	5.50%	5.50%	5.50%	5.50%	5.00%
Etanercept (Biosimilar)	7.00%	6.50%	6.50%	6.00%	5.50%	7.00%	6.30%	6.00%	6.00%	5.00%
Golimumab	3.00%	3.00%	3.00%	3.00%	3.00%	3.00%	3.00%	3.00%	2.00%	2.00%
Infliximab	5.00%	5.00%	4.50%	4.50%	4.00%	5.00%	5.00%	4.50%	4.50%	4.30%
Infliximab (Biosimilar)	4.00%	5.00%	6.00%	6.00%	7.00%	4.00%	5.00%	6.00%	6.00%	6.30%
Ixekizumab	2.50%	2.30%	2.50%	2.50%	2.50%	2.50%	2.30%	2.50%	2.50%	2.50%
Secukinumab[a]	3.10%	3.10%	3.10%	3.10%	3.10%	3.10%	3.10%	3.10%	3.10%	3.10%
Upadacitinib	3.20%	4.00%	4.00%	5.00%	5.00%	3.00%	3.80%	3.80%	4.00%	4.50%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**

Note: [a] In nr-axSpA only the 150mg Secukinumab is licensed, and 60% of the r-axSpA Secukinumab patients goes to the high dose

ASAS: Assessment of Spondylarthritis international Society; axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; b/tsDMARDs: biologic/targeted synthetic disease-modifying antirheumatic drugs; cDMARDs: conventional disease-modifying antirheumatic drugs; CHMP: Committee for Medicinal Products for Human Use; DSA: deterministic sensitivity analyses; health-related quality of life; EMA: European Medicines Agency; HRQoL: health-related quality of life; IgG1: immunoglobulin G1; IL: Interleukin; JAKs: Janus kinase inhibitors; nr-axSpA: non-radiographic axSpA; NSAIDs: non-steroidal anti-inflammatory drugs; r-axSpA: radiographic axSpA; TNFi: tumor necrosis factor-alpha inhibitors

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Clinical and experimental rheumatology. 2021 May-Jun;39(3):660-667. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **KM, RS, KV, FM**; Drafting of the publication, or revising it critically for important intellectual content: **KM, RS, DD, DT, PC, SP, KV, FM, KG, LN, WD**; Medical writing: **RS**; Final approval of the publication: **DD, DT, PC, SP, KV, FM, KG, WD**. **Author Disclosures: MK, RS:** employees of ECONCARE LP which had contracts with UCB, Abbvie, Leo, BMS. **DT:** no conflict of interest. **SP:** Research grants and/or consultant's fees from Abbvie, Boehringer, Pfizer, UCB, Eli-Lilly, BIANEΣ, ELPEN, Genesis, Sobi, Demo, Yansen. **VK, FM:** employee of UCB, Greece. **GK:** Payments from Aristotle University, Thessaloniki. Contract with Pfizer via University of the Peloponnese. Contracts with UCB, Abbvie, Leo, BMS via consulting firm. **LN:** employee of UCB, UK. **DW:** employee of UCB, Belgium. **Acknowledgements:** This study was funded by UCB. The authors acknowledge Frederik Fierensand, Sergei Kalynych and Martina Hazlingerova, UCB for publication coordination and Charlotte Frall, Costello Medical, Bristol, UK and Shimaila Siddiqui, Costello Medical, Manchester, UK for editorial assistance. All costs associated with development of this poster were funded by UCB.

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Poster ID: EE454

Link expiration: November 20, 2024