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ORIGINAL RESEARCH ARTICLE

A Cost Per Responder Analysis of Calcipotriol and Betamethasone Dipropionate PAD-Cream for the Treatment of Mild to Moderate Plaque Psoriasis in Italy

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Abstract

Background Calcipotriol and betamethasone dipropionate (CAL/BDP) formulations are the gold standard treatment for patients with mild to moderate plaque psoriasis. Yet, few studies have addressed the cost efficacy of these therapies in Italy. This study aims to evaluate the cost per response of CAL/BDP PAD-cream against CAL/BDP gel formulations from an Italian National Healthcare System (NHS) perspective.

Methods A cost-per-response model was built considering three clinical measures: Physician's Global Assessment (PGA) success (PGA < 2 and with a minimum of two-point decrease from baseline), a 75% reduction in the modified Psoriasis Area and Severity Index 75 (mPASI75) and quality-adjusted life years (QALY) gained. Clinical evidence was extracted from a pooled analysis including two phase III clinical trials assessing CAL/BDP PAD-cream against gel. Sensitivity analyses were performed to test the robustness of the results, and alternative scenarios were conducted to examine specific CAL/BDP gel comparators and drug use.

Results CAL/BDP PAD-cream showed lower costs per response than CAL/BDP gel formulations for PGA success and mPASI75. The incremental cost-effectiveness ratio was €3162.12 per QALY gained. Similar results were obtained for alternative scenarios considering the most commonly prescribed branded gel as the only comparator, or generic gel products as comparators. In an alternative scenario defining an equal amount of drug used per patient for both treatments, CAL/BDP PAD-cream turned dominant over gel formulations.

Conclusion CAL/BDP PAD-cream is a highly efficient alternative for managing mild to moderate plaque psoriasis compared with gel formulations for the Italian NHS.

Key Points

Treatment with CAL/BDP PAD-cream leads to lower costs per response for patients with mild to moderate plaque psoriasis compared with the group of CAL/BDP gel formulations prescribed in Italy.

The ICER for CAL/BDP PAD-cream versus CAL/BDP gel formulations is below the common willingness-to-pay threshold, and CAL/BDP PAD-cream is cost effective against the most commonly prescribed branded gel formulation in Italy.

The results generated in this study highlight CAL/BDP PAD-cream as an efficient alternative topical treatment for patients with mild to moderate psoriasis which, in addition to its demonstrated clinical superiority against CAL/BDP gel, can translate into cost savings for the Italian National Healthcare System.

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Introduction

Psoriasis is a chronic immune-mediated inflammatory skin disease with an estimated prevalence of 2–3% globally [1]. In Italy, this condition affects 1.8–3.1% of the general population with 170–230 new cases per 100,000 people/year [2, 3]. Plaque psoriasis is the most frequent clinical type, diagnosed in around 85% of patients with psoriasis in Italy [3]. This phenotype is characterized by scaly plaques that can be extremely itchy and typically appear on the scalp, trunk, and extensor surfaces of the lower and upper extremities [4, 5].

The chronic and disabling nature of plaque psoriasis has a negative impact on health-related quality of life (HRQoL) at a physical, emotional, and social level [5]. Patients with psoriasis report a high disease burden and usually suffer from psychological distress, including anxiety and depression [6–8]. Several studies have described an association between skin symptoms like pain, discomfort, itch or burning, and a negative impact on HRQoL [8]. Psoriasis patients consider itch reduction and symptom control as key treatment goals while at the same time identifying a need for better therapeutic options [6].

Plaque psoriasis also poses a significant economic burden for national healthcare systems (NHS) worldwide [8, 9]. Disease management involves large healthcare expenditures, worsened by the increased use of resources reported in patients with lower quality of life (QoL) [8–10]. In Italy, average costs of plaque psoriasis accounted for €8372 per patient/year, with 68% corresponding to direct healthcare costs, that is, costs associated with disease management and treatment [11].

Treatment strategies are primarily determined based on the severity of the disease, defined with clinical measures including modified [excluding the head] Psoriasis Area and Severity Index (mPASI), body surface area (BSA), and Physician's Global Assessment (PGA) [12]. Topical treatments represent first-line therapy in patients with mild to moderate psoriasis, while phototherapies or systemic therapies are often the choice for more severe or non-responder cases.

Fixed-dose combinations of calcipotriol (CAL) and betamethasone dipropionate (BDP) are recommended as the first option for acute treatment of relapses in mild to moderate psoriasis [4, 13]. CAL/BDP combinations have proven more effective than monotherapy, with similar safety profiles, in clinical trials and daily practice [4, 14]. This study focuses on a novel CAL/BDP cream formulation developed using the polyaphron dispersion (PAD)^{TM} technology, approved worldwide, including Italy, for the topical treatment of mild to moderate plaque psoriasis, including scalp psoriasis, in adults. CAL/BDP PAD-cream has demonstrated superior efficacy for this therapeutic indication, with favourable safety and improved QoL, against CAL/BDP gel formulations [14–16]. Further, patients reported better treatment convenience with CAL/BDP PAD-cream compared with CAL/BDP gel formulations. High satisfaction with CAL/BDP PAD-cream, together with good patient adherence, has also been identified in real-world use [17]. In economic terms, the impact of using CAL/BDP PAD-cream in daily clinical practice is yet to be assessed in Italy since no pharmacoeconomic studies comparing its performance with other formulations, like CAL/BDP gel, have been published to date.

Cost per response analyses allow the evaluation of treatment costs adjusted by the efficacy outcomes reported in clinical trials, providing a valuable tool to inform decision makers about the cost efficacy and economic value of healthcare technologies. This approach is extensively used to assess treatment options in psoriasis across Europe [18–22]. Herein, we aim to evaluate the economic value of CAL/BDP PAD-cream compared with CAL/BDP gel formulations in patients with mild to moderate plaque psoriasis from the perspective of the NHS in Italy. For this purpose, the outcomes and costs associated with these topical therapies have been analysed using a cost-per-response model.

Methods

Model Structure

A cost-per-response model to evaluate the cost efficacy of CAL/BDP PAD-cream against CAL/BDP gel formulations was developed from an Italian NHS perspective, considering the guidelines for pharmacoeconomic evaluations published by the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) [23]. This model focused on patients with mild to moderate plaque psoriasis. Regarding the time horizon of the model, an 8-week duration was considered according to the summary of product characteristics and the duration of the main clinical trials assessing CAL/BDP PAD-cream [14–16], and no cost or effect discounts were applied to the model. Costs were expressed in euros (as of October 2024). The model structure, inputs and assumptions were refined and validated by healthcare professionals from Italy with expertise in psoriasis (PG, FP, AC, and SM).

Model Inputs

To populate the model, a pragmatic literature review was first performed to identify relevant sources of information reporting clinical data for CAL/BDP PAD-cream and gel, and specific inputs related to treating mild to moderate plaque psoriasis in Italy.

Table 1 Proportion of responder patients per treatment

Clinical variable	CAL/BDP PAD-cream	CAL/BDP gel	Incremental response
PGA success	43.2%	31.9%	11.3%
mPASI75	44.3%	34.5%	9.8%

Response rates reported by Pinter et al., 2022 [14]

CAL calcipotriol, *BDP* betamethasone dipropionate, *mPASI75* modified Psoriasis Area and Severity Index 75, *PAD* polyaphron dispersion, *PGA* Physician's Global Assessment

Patient Response

Treatment response was determined by employing two efficacy parameters: PGA success and mPASI75, following the clinical evidence available in head-to-head clinical trials assessing CAL/BPD PAD-cream and CAL/BDP gel [14–16]. PGA success was defined as a "PGA score of 0 (clear) or 1 (almost clear) with a minimum of 2-point improvement from baseline" and mPASI75 as a "reduction in mPASI of at least 75% from baseline". Clinical data for these variables was extracted from a pooled analysis of two phase III, multicentre, randomized, investigator-blind, active, and vehicle-controlled clinical trials comparing the efficacy of CAL/BDP PAD-cream against CAL/BDP gel [14]. Response rates were significantly higher for CAL/BDP PAD-cream compared with CAL/BDP gel for both clinical measures after 8 weeks of treatment, as reported in the pooled analysis [14] (Table 1).

In addition, the comparative efficacy in terms of QoL was analysed via quality-adjusted life years (QALYs). For this purpose, utility values were calculated for responder and non-responder patients based on a previously published study [24], resulting in a utility of 0.88 for a responder and 0.45 for a non-responder. QALYs were then calculated considering the response rate for PGA success reported in the pooled analysis by Pinter et al. [14].

Comparators

CAL/BDP gel formulations currently reimbursed in Italy for the same indication as CAL/BDP PAD-cream—topical treatment of mild to moderate plaque psoriasis, including scalp psoriasis, in adults—were considered as comparators[1]: the most commonly prescribed branded gel and the generic gel formulations available in Italy.

[1] For reference, the trade names for the CAL/BDP topical formulations used as comparators in Italy are the following: branded CAL/BDP gel [Dovobet®, Leo Pharma A/S, Denmark], generic gel formulations [Psotriol®, Mibe Pharma Italia S.r.l., Italy] and [Aribec®, Aristo Pharma GmbH, Germany]. The trade name for CAL/BDP PAD-cream in Italy is [Wynzora®, Almirall S.A., Spain].

Table 2 Cost per response results in the base case scenario

Parameter	Cost per response (€)		
	CAL/BDP PAD-cream	CAL/BDP gel	Incremental cost per response*
PGA success	269.68	291.04	209.37
mPASI75	262.98	269.10	241.42

CAL calcipotriol, *BDP* betamethasone dipropionate, *mPASI75* modified Psoriasis Area and Severity Index 75, *PAD* polyaphron dispersion, *PGA* Physician's Global Assessment

*Calculated based on the following equation: (CAL/BDP-PAD cream costs − CAL/BDP gel costs)/(CAL/BDP-PAD cream response rates − CAL/BDP gel response rates)

Drug Use and Costs

The amount of drug used per patient was defined as 32.2 g/week for CAL/BDP PAD-cream and 22.7 g/week for CAL/BDP gel based on one of the phase III clinical trials analysing the efficacy of these treatments in Europe [15]. This amount of drug is used as a basis for cost calculations in the model.

Ex-factory costs for each treatment were collected from the Transparency Lists published by the Italian AIFA (in euros [€] as of October 2024) [25]. CAL/BDP gel weighted average cost was then calculated following the market share of these products in Italy in 2023 [26], the latest data available when conducting the study (Supplementary Table 1, see electronic supplementary material [ESM]).

Model Assumptions

According to the available literature, patient management for mild to moderate psoriasis is similar regardless of the topical treatment prescribed [27]. Thus, the model assumes that patient management is equivalent between CAL/BDP

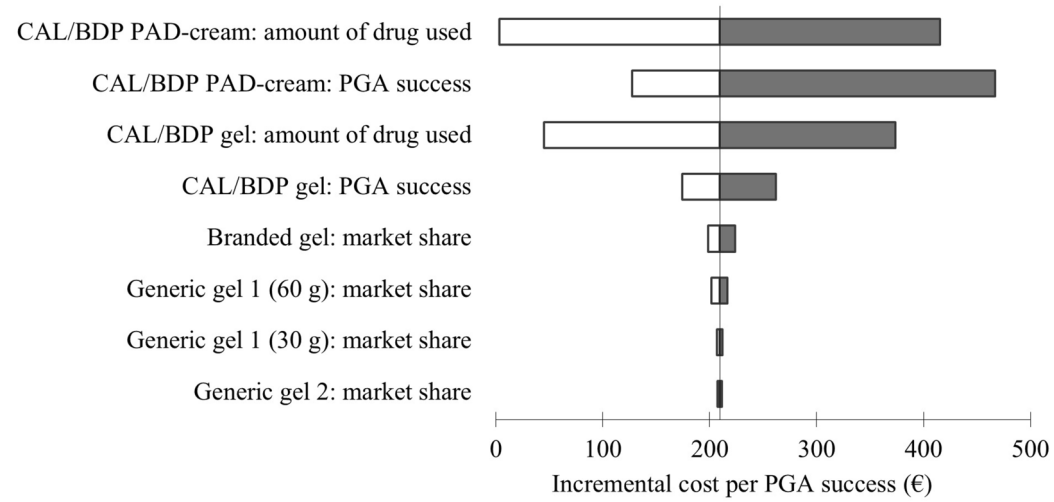
Table 3 Cost per QALY results in the base case scenario

Parameter	CAL/BDP PAD-cream	CAL/BDP gel	Incremental cost per QALY*
QALYs per responder	0.098	0.090	
Cost per QALY (€/QALY)	1190.47	1027.25	3162.12

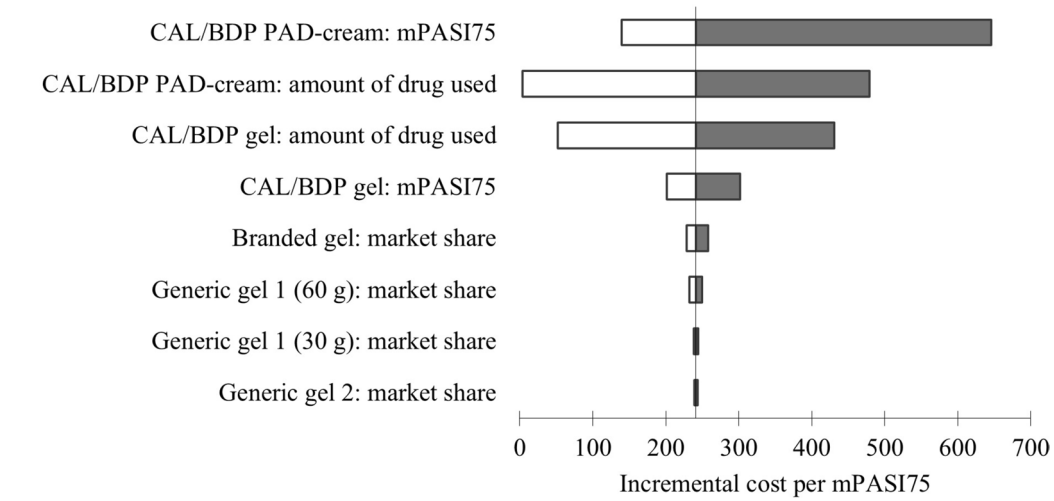
CAL calcipotriol, *BDP* betamethasone dipropionate, *ICER* incremental cost-effectiveness ratio, *mPASI75* modified Psoriasis Area and Severity Index 75, *PAD* polyaphron dispersion, *PGA* Physician's Global Assessment, *QALY* quality-adjusted life year

*Calculated based on the ICER equation: (CAL/BDP-PAD cream costs − CAL/BDP gel costs)/(CAL/BDP-PAD cream QALYs − CAL/BDP gel QALYs)

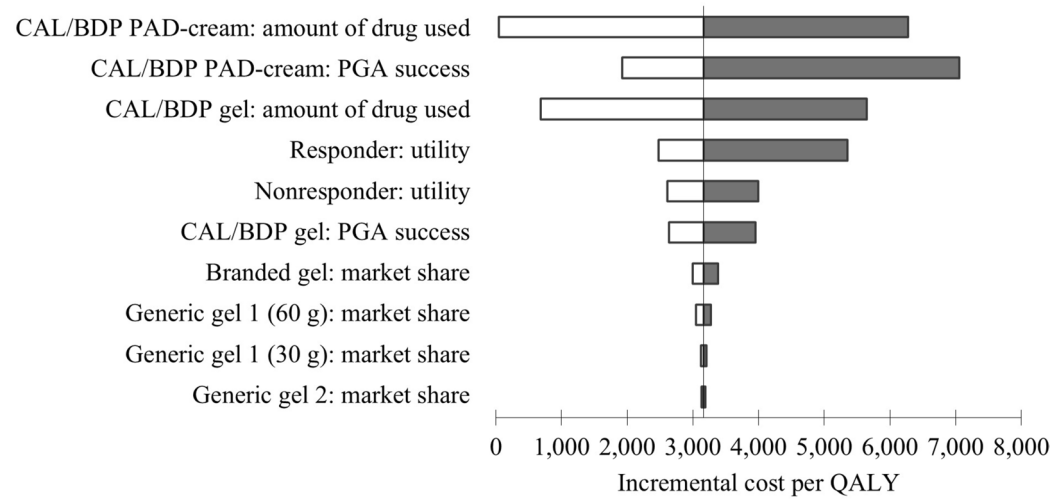
A


CAL/BDP PAD-cream: amount of drug used
CAL/BDP PAD-cream: PGA success
CAL/BDP gel: amount of drug used
CAL/BDP gel: PGA success
Branded gel: market share
Generic gel 1 (60 g): market share
Generic gel 1 (30 g): market share
Generic gel 2: market share
0
100
200
300
400
500
Incremental cost per PGA success (€)

B


CAL/BDP PAD-cream: mPASI75
CAL/BDP PAD-cream: amount of drug used
CAL/BDP gel: amount of drug used
CAL/BDP gel: mPASI75
Branded gel: market share
Generic gel 1 (60 g): market share
Generic gel 1 (30 g): market share
Generic gel 2: market share
0
100
200
300
400
500
600
700
Incremental cost per mPASI75

C


CAL/BDP PAD-cream: amount of drug used
CAL/BDP PAD-cream: PGA success
CAL/BDP gel: amount of drug used
Responder: utility
Nonresponder: utility
CAL/BDP gel: PGA success
Branded gel: market share
Generic gel 1 (60 g): market share
Generic gel 1 (30 g): market share
Generic gel 2: market share
0
1,000
2,000
3,000
4,000
5,000
6,000
7,000
8,000
Incremental cost per QALY

◂**Fig. 1** Tornado diagrams obtained from the deterministic sensitivity analysis assessing the clinical efficacy of CAL/BDP PAD-cream vs CAL/BDP gel as **A** PGA success; **B** mPASI75; and **C** QALYs. PGA success corresponds to the percentage of patients achieving a PGA score of 0 (clear) or 1 (almost clear) with a minimum 2-point improvement from baseline, and mPASI75 is the percentage of patients exhibiting a reduction in mPASI of at least 75% from baseline. *CAL* calcipotriol, *BDP* betamethasone dipropionate, *mPASI75* modified Psoriasis Area and Severity Index 75, *PAD* polyaphron dispersion, *PGA* Physician's Global Assessment, *QALY* quality-adjusted life year

PAD-cream and gel. Hence, the use of healthcare resources is considered the same for each treatment group (i.e. visits to dermatologist and primary care, and laboratory tests). Further, treatment with CAL/BDP topical combinations is considered for acute relapses of the disease, which, together with the short time horizon indicated for this type of topical therapy, translates into a comparable number of visits to the specialist independent of the responder/non-responder status of the patient, according to expert opinion (PG, FP, AC, and SM). Briefly, patients follow the treatment during the established period and their response to the corresponding therapy is evaluated once the treatment is finished, thus the management until that time is usually the same independent of the response.

In addition, the rate of adverse events in the CAL/BDP PAD-cream group was comparable to that of patients treated with CAL/BDP gel in clinical trials [14–16]. Consequently, the two treatments are assumed to have equal safety profiles.

Sensitivity Analysis

Probabilistic and deterministic sensitivity analyses (PSA and DSA, respectively) were conducted to assess the robustness of the model. DSA was performed to test the impact of the different variables collected (e.g., response rates, market share, and others) on the results. DSA results were visualized using a tornado diagram, which was selected for its ability to clearly identify the key drivers of the model's conclusions. The diagram ranks parameters by displaying the range of variation in the outcome as each input was varied across its plausible range. Consequently, the most influential parameters were positioned at the top, allowing for an intuitive understanding of which variables have the greatest impact on the outcome indicator (cost per response or cost per QALY). PSA analyses were conducted to evaluate the uncertainty of the results; 1000 iterations were run for each clinical variable (PGA success, mPASI75, and QALYs), and the results of the analyses are presented as a cost-effectiveness plane and acceptability curve. A beta distribution was assumed for the success probabilities (measured by PGA success and mPASI75), a Dirichlet distribution for the market shares of the different gel brands, a log-normal distribution for the relative risk between CAL/BDP PAD-cream versus CAL/BDP gel, a normal distribution for dosages, and a gamma distribution for utilities.

Alternative Scenarios

A set of exploratory scenarios was explored to assess the robustness of the results in plausible situations related to real-life clinical practice. Specifically, these scenarios evaluated the impact of (i) an equal amount of drug used for CAL/BDP PAD-cream and gel, considering 30 g/week per patient following expert opinion, as a proxy to account for the uncertainty derived from adherence and amount of drug used in clinical trials versus real-world settings in both CAL/BPD patient groups; (ii) one branded gel as the comparator, given that this is the predominant gel formulation prescribed in Italy according to the market share (Supplementary Table 1, see ESM); and (iii) two generic gel formulations as comparators, representing the group of gel generics available for the topical treatment of mild to moderate plaque psoriasis in Italy. These scenarios were defined by Italian clinical experts based on their healthcare context and daily practice.

Results

Base-Case Scenario

Treatment costs were higher for CAL/BDP PAD-cream (€116.50 vs a weighted average of €92.84 for CAL/BDP gel per patient at 8 weeks of treatment, respectively), but this treatment achieved better patient response rates in terms of PGA success and mPASI75 in the pooled analysis at 8 weeks of treatment [14] (Table 2). CAL/BDP PAD-cream was associated with lower costs per response for both PGA success and mPASI75 compared with CAL/BDP gel formulations at 8 weeks of treatment (Table 2).

Further, CAL/BDP PAD-cream showed superior effectiveness in terms of QALYs (0.098 vs 0.090 for CAL/BDP gel), leading to an incremental cost-effectiveness ratio (ICER, incremental cost per QALY) of €3162.12 per QALY (Table 3). CAL/BDP PAD-cream stands as a highly cost-effective alternative.

Sensitivity Analyses

DSA revealed that two key drivers of the results for the three efficacy parameters analysed are the amount of drug used and the patient response rates (Fig. 1). Additionally, the utility values calculated for responder/non-responder status appeared as an additional variable affecting the cost effectiveness per QALY (Fig. 1C).

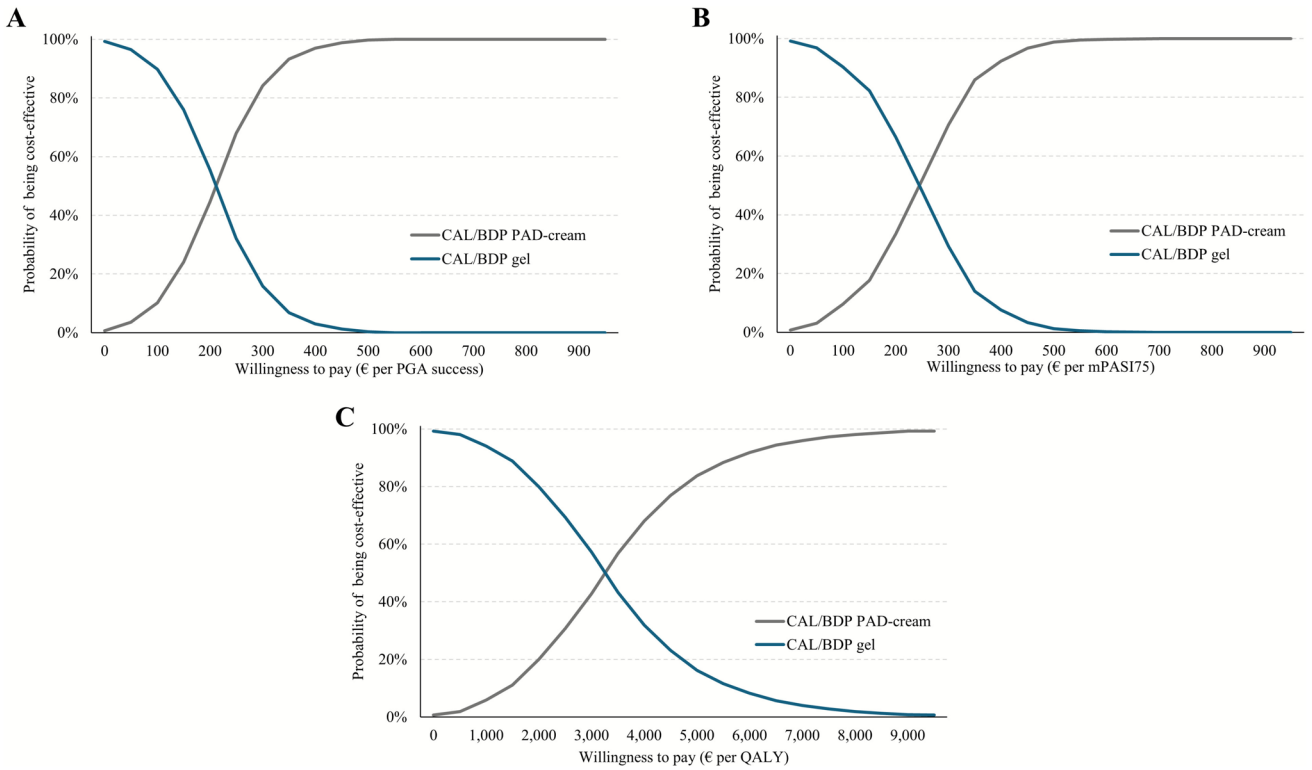


Fig. 2 Acceptability curves of CAL/BDP PAD-cream vs CAL/BDP gel. These graphs show the probability of being cost effective at different thresholds for CAL/BDP PAD-cream (grey line) and CAL/BDP gel (blue line), considering **A** PGA success; **B** mPASI75; and **C** QALYs. *CAL* calcipotriol, *BDP* betamethasone dipropionate, *mPASI75* modified Psoriasis Area and Severity Index 75, *PAD* polyaphron dispersion, *PGA* Physician's Global Assessment, *QALY* quality-adjusted life year

According to the PSA, CAL/BDP PAD-cream achieved > 50% probability of being cost effective over a willingness-to-pay threshold of €212 per PGA success and €242 per mPASI75 (Figs 2A, 2B and Supplementary Fig. 1 [see ESM]). In terms of QALYs, CAL/BDP PAD-cream was found to be cost effective at any willingness-to-pay threshold over €3150 per QALY, a value that is well below the commonly accepted threshold in Italy. Also, CAL/BDP PAD-cream showed >89% probability of being cost effective considering a willingness-to-pay threshold of €5400 per QALY (Fig. 2C and Supplementary Fig. 1 [see ESM]).

Alternative Scenarios Explored for CAL/BDP PAD-Cream in Italy

Equal Amount of Drug Used (30 g/week)

In this scenario, treatment costs per patient were similar between the two formulations, although slightly higher for CAL/BDP gel, after 8 weeks of treatment (€108.54 for CAL/BDP PAD-cream vs weighted average of €122.70 for CAL/BDP gel). The cost per response for CAL/BDP PAD-cream was marginally affected, whereas for CAL/BDP gel, the cost was higher than the base case for all clinical parameters (Table 4). CAL/BDP PAD-cream turned dominant against CAL/BDP gel for PGA success, mPASI75, and QALYs.

Branded Gel as Comparator

The branded CAL/BDP gel showed similar treatment costs to CAL/BPD PAD-cream for 8 weeks of treatment (€102.66 vs €116.50, respectively). Costs per response were lower for CAL/BDP PAD-cream, considering PGA success and mPASI75 (Table 4). Incremental costs for all clinical parameters were lower than that of the base case, including the ICER (€1849.12 per QALY). Thus, CAL/BDP PAD-cream remained a cost-effective alternative.

Generic Gel Formulations as Comparator

Treatment costs of CAL/BDP gel were much lower than that of the base case (weighted average costs for 8 weeks of treatment: €68.40 vs €92.84, respectively), leading to lower costs per response compared with CAL/BDP PAD-cream (Table 4). Despite this difference, CAL/BDP PAD-cream obtained an ICER of €6429.01 per QALY, remaining highly cost effective.

Discussion

Economic evaluations represent significant evidence for health technology assessments and are key to guiding price and reimbursement decisions on medicines. In Italy, health economic evaluations were formally integrated into the decision-making process in 2021 and are demonstrated to impact price negotiations with AIFA significantly [23, 28].

This study unveils CAL/BDP PAD-cream as an efficient alternative compared with CAL/BDP gel formulations for the topical treatment of mild to moderate plaque psoriasis in Italy. To date, this is the first cost-per-response analysis conducted evaluating CAL/BDP PAD-cream and is one of the few economic studies focusing on mild to moderate plaque psoriasis patients in Italy [3].

CAL/BDP PAD-cream has demonstrated better efficacy and higher response rates in phase III clinical trials than CAL/BDP gel. CAL/BDP PAD-cream also exhibited lower costs per response, considering two widely used clinical measures, PGA success and mPASI75. Incremental costs per response were also low for CAL/BDP PAD-cream versus gel. However, the lack of a willingness-to-pay threshold per PGA success/mPASI75 complicates their cost-efficacy interpretation.

In addition, CAL/BDP PAD-cream displayed an ICER of €3162.12 per QALY, a figure way below the willingness-to-pay threshold between €25,000 and €40,000 proposed by the Italian Health Economics Association (Associazione Italiana di Economia Sanitaria, AIES) working group [29], as well as the commonly used threshold of €30,000 considered in other economic studies in Italy [30–32]. This result remained consistent across the specific comparators analysed in the alternative scenarios (branded gel and generic gel products), with ICERs under €6500 per QALY.

Adherence to topical treatments can be suboptimal in the real world, translating into worse clinical outcomes and increased use of healthcare resources and expenditure [33]. The degree of adherence is mainly influenced by patient preferences and perception, with cosmetic issues (e.g., greasiness, stickiness, or 'messy to apply'), complex treatment regimens and low perceived effectiveness typically identified as detrimental [3, 6, 33–35]. Consequently, the amount of drug used reported in the clinical trials might not reflect the patient's reality. To account for this uncertainty conservatively, costs per response associated with an equal amount of drug used for both treatments were evaluated as an alternative scenario. CAL/BDP PAD-cream turned dominant, with lower costs per response against CAL/BDP gel, regardless of the efficacy measure analysed.

Despite the lack of comparative data assessing patient adherence across different CAL/BDP formulations, it is important to note that CAL/BDP PAD-cream has proven more convenient to use than CAL/BDP gel in clinical trials [14–16], mainly driven by its easy application and lower greasiness. These characteristics were also superior for CAL/BDP PAD-cream in an indirect treatment comparison analysis against CAL/BDP foam [36]. Further, patients have reported high adherence to CAL/BDP PAD-cream, and greater satisfaction and preference than their previous topical treatments, according to a European survey [17]. These features associated with CAL/BDP PAD-cream might ultimately impact adherence to the treatment, although the absence of studies assessing this dimension limits its analysis in this model. If new evidence on the subject is published, its impact on the cost per response should be re-evaluated employing a Markov model to better capture all the aspects related to patient management and health states.

Plaque psoriasis is a high-impact chronic disease that poses a significant burden for the Italian NHS [3, 11]. Few studies have addressed the economic implications of topical treatments in Italy, a gap deepened by the lack of clinical guidelines addressing the treatment of mild to moderate patients with topical therapies. This study provides evidence to guide therapeutic decisions for these patients, optimise healthcare resource use, and improve the topical management of the disease in Italy. In particular, CAL/BDP PAD-cream is a valuable first-line therapy for patients with mild to moderate plaque psoriasis thanks to its good clinical results and low cost per response, allowing for a more efficient use of healthcare resources.

Table 4 Cost per response and cost per QALY results in the alternative scenarios

Parameter	Cost per response or QALY		
	CAL/BDP PAD-cream (€)	CAL/BDP gel (€)	Incremental cost per response or per QALY (€)
Equal amount of drug used			
PGA success	251.25	384.63	Dominant
mPASI75	245.01	355.64	Dominant
QALYs	1109.14	1357.60	Dominant
Branded gel formulation as comparator			
PGA success	269.68	321.83	122.43
mPASI75	262.98	297.58	141.17
QALYs	1190.47	1135.95	1849.12
Generic gel formulations as comparators			
PGA success	269.68	214.41	425.68
mPASI75	262.98	198.25	490.83
QALYs	1190.47	756.80	6429.01

CAL calcipotriol, *BDP* betamethasone dipropionate, *mPASI75* modified Psoriasis Area and Severity Index 75, *PAD* polyaphron dispersion, *PGA* Physician's Global Assessment, *QALY* quality-adjusted life year

Strengths and Limitations

This study relies on clinical data from head-to-head trials comparing the efficacy of CAL/BDP PAD-cream and CAL/BDP gel, providing a robust and reliable basis to define patient outcomes. Due to this data source, the cost-per-response model is limited to an 8-week time horizon. The lack of data on longer-term outcomes limits the possibility of evaluating costs at extended times. This would be especially important in more severe patients since they suffer from additional complications, resulting in increased costs and use of healthcare resources [3, 11]. Adherence is also essential in treating mild to moderate plaque psoriasis, but no data has been generated to date that can be used to populate the model. Thus, adherence has been assumed equal for both treatments as a conservative approach. Indeed, CAL/BDP PAD-cream has demonstrated superior convenience and satisfaction compared with other formulations [14, 36], altogether suggesting that patients treated with CAL/BDP PAD-cream might be more adherent.

Cost-per-responder analysis provides surrogate evidence to help contextualise the clinical data within an economic framework and inform healthcare evaluations, whereas cost-effectiveness results expressed in cost per QALY are typically used as a basis for technology evaluation since these provide a common measure of health outcomes. Herein, QALYs were calculated based on a previous economic study conducted in Italy [24] as a first approach to assess the cost effectiveness of topical therapies in psoriasis. Nonetheless, the adequacy of the utility values employed in the model, indirectly calculated from such a study, should be further assessed if real-world evidence is published.

Conclusions

CAL/BDP PAD-cream has demonstrated its superiority against CAL/BDP gel in clinical trials, which resulted in lower costs per PGA success/mPASI75 response compared with CAL/BDP gel. CAL/BDP PAD-cream also showed an ICER considerably below the common willingness-to-pay thresholds. Additional real-world evidence assessing adherence will help to better determine the favourable profile of CAL/BDP PAD-cream against gel formulations. Nonetheless, this cost-per-response analysis combining data from clinical trials and economic modelling has provided new evidence about the cost effectiveness of CAL/BDP PAD-cream in the base-case scenario, and also in alternative scenarios, providing robust evidence for its use in Italy. This study further brings to light the importance of adapting disease management to the patient's reality, optimizing not only the clinical benefits, but potentially leading to cost savings for the Italian NHS.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40267-025-01212-x.

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Declarations

Conflict of interest FP, ACam, PG, and SM received funding from Almirall S.A. RB, ACar, and JG are employees at Almirall S.A. CC and JC are consultants of Axentiva Solutions S.L., which received consultancy fees from Almirall S.A. and, during the conduct of this study, from other pharmaceutical companies in unrelated projects.

Author contributions FP, ACam, PG, and SM participated in the review and validation of the clinical and economic inputs, structure, and assumptions for the model, as well as in the interpretation of the results and the manuscript review process. RB, ACar and JG participated in the project conceptualization, administration, supervision and manuscript review. SLH, CC and JC participated in the project conceptualization, administration, supervision, methodology, analysis, and manuscript drafting and review. All authors read and approved the final manuscript and consented to publish this study.

Availability of data and materials: The data used in this study is publicly available in the corresponding studies referenced in the article or available upon reasonable request to the corresponding author.

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Consent to participate Not applicable.

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