ORIGINAL REPORT

Cost-effectiveness Analysis of Dupilumab for the Treatment of Adult Patients with Severe Prurigo Nodularis in Italy

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Prurigo nodularis is characterized by intensely pruritic nodules that significantly impact patients' quality of life. This study aims to evaluate the cost-effectiveness of dupilumab compared with the best supportive care for the treatment of severe prurigo nodularis from the perspective of the Italian National Health Service. A cost-effectiveness model was developed using a decision tree followed by a Markov approach with a lifetime horizon (30 years). Baseline characteristics, efficacy, and utility data were derived from the pooled analysis of PRIME and PRIME2 trials. Direct healthcare costs based on drug acquisition, adverse event and complications management, and disease-related healthcare resource utilization were considered. Dupilumab improved health outcomes, with an incremental gain of 1.481 quality-adjusted life-years compared with best supportive care. The total cost of dupilumab treatment was €148,964, compared with €70,957 for the best supportive care arm, thus resulting in an incremental cost-effectiveness ratio of €52,661 per quality-adjusted life-year. Scenario analyses indicated that at a discount ≥ 20%, the incremental cost-effectiveness ratio was lower than €40,000/quality-adjusted life-year. Deterministic and probabilistic sensitivity analyses confirmed the robustness of the results. Dupilumab is likely to be a cost-effective treatment for severe prurigo nodularis patients eligible for systemic therapy in Italy, as it reduces disease burden and healthcare costs associated with uncontrolled prurigo nodularis.

Key words: prurigo; cost-effectiveness analysis; skin diseases; dupilumab; quality-adjusted life years.

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SIGNIFICANCE

Prurigo nodularis is a long-lasting skin condition that causes painful, itchy bumps and greatly affects quality of life. We studied dupilumab, the only treatment current reimbursed in Italy for prurigo nodularis, to see if it offers good value for money in Italy's public healthcare system. Our results show that although the treatment is more expensive, it greatly improves patients' well-being and may reduce future healthcare needs. This research helps in making informed decisions on offering better care. By showing the long-term benefits of this therapy, our work supports smarter healthcare spending and aims to improve the lives of these patients.

The term "prurigo nodularis" (PN) was coined in 1909 by James N. Hyde (1), thus being subsequently termed as "prurigo nodularis of Hyde" and referred to "multiple tumours of the skin accompanied by itching". However, up to 2018, the term "prurigo" was used to define a heterogeneous group of clinical manifestations, even those with non-nodular lesions (2). In 2018, the European Academy of Dermatology and Venereology (EADV) established that PN was the variant of "chronic prurigo" (CPG) characterized by nodular lesions (2). CPG was defined as "the presence of chronic pruritus for ≥ 6 weeks, history and/or signs of repeated scratching, and multiple localized/generalized pruriginous skin lesions" (2). CPG also includes other possible skin manifestations such as papular, plaque, umbilicated, and other prurigo manifestations (2). Nodules may be the only type of lesion of CPG, coexist with other types of lesions in the same patient, or represent a specific phase of the disease (2).

It was estimated that in Italy the prevalence of PN (in the total Italian population aged ≥ 18 years) is about 16,280 cases, including 6,073 patients with moderate-to-very severe disease, among whom around 30% are not controlled by standard treatments (3).

It was shown that the occurrence of PN in hospitalized patients in the Italian context implied increased comorbidity burden and healthcare resource consumption compared with non-PN hospitalized patients (4).

Dupilumab is a humanized IgG4 monoclonal antibody that binds the shared IL-4 receptor subunit alpha (IL-4Rα) of IL-4 and IL-13 receptor complexes, thus resulting in the inhibition of their signals (5).

Dupilumab proved to be effective in 2 randomized, double-blind, placebo-controlled phase 3 trials (6), which enrolled 151 and 160 patients, respectively, who were diagnosed with PN and had Worst-Itch Numerical Rating Scale (WI-NRS) score ≥ 7, ≥ 20 PN lesions, and Investigator's Global Assessment for PN scale (IGA-PN-S) score of 3 or 4. In particular, in the PRIME trial,

at week 24, 60.0% and 18.4% patients in dupilumab and placebo arm, respectively, achieved the primary endpoint of a ≥4-point reduction in WI-NRS. In the PRIME2 trial, at week 12, the primary endpoint was achieved in 37.2% and 22.0% patients in the dupilumab and placebo arm, respectively. In both cases, the improvement in the dupilumab arm was statistically significant (6).

As regards real-word efficacy, a recent review of the literature not involving clinical trials has shown that treatment of PN with dupilumab resulted in almost 90% clinical improvement at 16 weeks (7).

To date in Italy, dupilumab is indicated for the treatment of adults with moderate-to-severe nodular PN who are eligible for systemic therapy (8).

Dupilumab is also approved for use in atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and chronic obstructive pulmonary disease (COPD) (9). All these chronic inflammatory diseases share an aberrant type 2 immune response (10). Underpinning the dual role the IL-4/IL-13 axis plays in type 2 inflammation there are novel pathophysiological pathways of fibroproliferative regulation, epithelium development, cornification, nervous system and vasculature development, and mesenchymal differentiation (10).

This analysis aims at evaluating the cost-effectiveness of dupilumab in comparison with the best supportive care (BSC) in the treatment of PN from the perspective of the Italian National Health Service (NHS). Only the subpopulation for which the drug is reimbursed in Italy was analysed (the most severe patients), i.e., the same population included in the trials described earlier (6), but with exclusion of those with IGA-PN-S score = 3.

METHODS

Model structure and clinical data

We developed a cost-effectiveness model in MS Excel® (Microsoft Corp, Redmond, WA, USA) to evaluate the short-term and long-term clinical and economic consequences of treatment with dupilumab in addition to BSC (low-to-moderate potency topical corticosteroids and topical calcineurin inhibitors) in patients suffering from PN in Italy.

BSC alone was chosen as comparator because the model was developed starting from the pooled analysis of phase 3 PRIME and PRIME 2 trials (11), where the comparator was placebo, but BSC was permitted in both arms.

The model structure for dupilumab in PN can be divided into 2 sections. It starts with a 24-week decision tree to reflect the short-term dupilumab trials, followed by a long-term Markov model structure representing the remaining disease course (see **Fig. 1**).

As shown in the decision tree (Fig. 1A), patients with severe PN can be treated with either dupilumab + BSC or BSC alone (shown by the square decision nodes). At the first assessment point at week 24 (shown by the circle chance nodes), a clinical check is performed to determine response in both arms. Responders move to the "Response" branch of the decision tree and continue the current treatment while non-responders move to the "No response" branch and switch to BSC. Patients receiving BSC alone upon entering the model stay on BSC treatment regardless of response status.

Based on the assessment results at week 24, patients move to the long-term Markov model (Fig. 1B). Week-24 dupilumab responders enter "On Active Treatment" health state, receiving dupilumab until discontinuation for reasons such as loss of response, adverse events (AEs), patient/physician preference. After discontinuation, they move to the "On BSC" health state and switch to BSC treatment alone. Week-24 dupilumab non-responders enter "On BSC" health state and remain in that health state until death.

All patients are at equal risk of general mortality, which is not affected by PN.

The time horizon was lifetime (i.e., 30 years) as this time span best represented drug benefits. A 12-week cycle length is used in the Markov model with half-cycle correction. A 3% discount rate was applied to both costs and outcomes (12). The analysis was performed from the perspective of the NHS, thus considering direct healthcare costs updated only to 2024.

Basal characteristics of patients included in the model came from PRIME and PRIME 2 studies (6), but weight and body surface area parameters were adjusted according to the Italian Medicines Agency (Agenzia Italiana del Farmaco – AIFA) requests and Key Opinion Leaders (KOLs) suggestions (11, 12) (**Table I**).

Patients entered the analysis if they met the following criteria: WI-NRS ≥7, number of nodules ≥20 (both matching the eligibility criteria of PRIME and PRIME 2 trials [13, 14]), and IGA-PN-A = 4 (thus defining severe disease activity). Pooled data of PRIME and PRIME 2 trials showed a probability of being responders after 24 weeks in dupilumab or BSC arm of 85.0% and 33.3%, respectively, in the subset of severe patients, which globally included 123 patients). Responsiveness was defined as WI-NRS improvement ≥4 (primary endpoint of PRIME and PRIME 2 trials [6]) or IGA-PN-S reduction ≥1 (change from baseline in IGA PN-S score was assessed in both trials at weeks 4, 8, 12, and 24 [6]).

In the absence of data on the long-term (beyond 24 weeks) response in PN, data concerning atopic dermatitis (15) were used after modification and external validation by international and national KOLs (see Table I). For patients treated with dupilumab, the model included a further discontinuation rate for all causes coming from pooled data of PRIME and PRIME 2 trials (11).

Data on the Italian general population were used for survival and mortality (16), as PN and the relevant

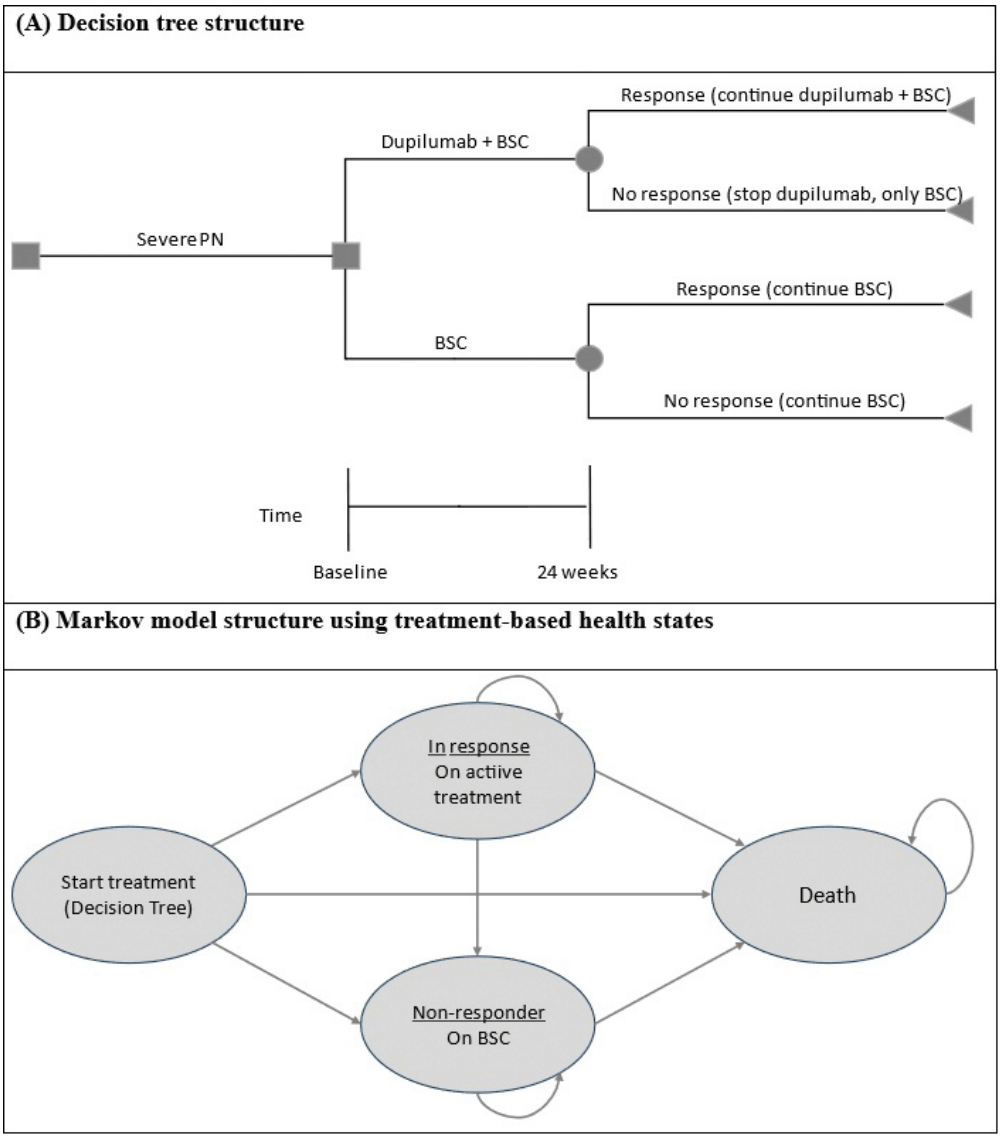

Fig. 1. Model structure for patients starting dupilumab + best supportive care (BSC) or BSC only. (A) Decision tree; (B) Markov model for both dupilumab and comparator (BSC) arms.

treatments were assumed not to affect survival. Therefore, mortality rates were considered to depend only on patients' characteristics, age, and sex.

Utility

Clinical benefits were calibrated for quality of life and calculated as quality-adjusted life-years (QALYs). According to NICE guidelines (17), EQ5D-5L values coming from PRIME and PRIME 2 trials were converted into EQ-5D-3L by using the Finch algorithm (18), which represents the best fit for the simulations. In the base case, change-from-baseline (CFB) method was used, which implies that follow-up utilities were calculated by considering the mean variation from baseline (see Table I). These values were normalized according to data concerning the Italian general population that were estimated as mean between male and female individuals (19).

Cost data used in the model

Drug costs. The resource consumption in terms of drugs and their effects was based on pooled data of PRIME and PRIME 2 trials (11).

Concerning dupilumab, in the base case analysis, the ex-factory price, net of mandatory discounts (–5%; –5%), was applied. Therefore, a 300-mg syringe was valorized as €577.60. However, as per the Italian Official Gazette, a confidential discount is in place. Consequently, the base case analysis does not reflect the true costs for the NHS. For this reason, additional scenario analyses with discounted prices (discount ranging from 10% up to 60%) were conducted to better capture the actual situation.

The cost for BSC was assumed to be zero (conservative hypothesis).

Management of adverse events. The annual probability that patients underwent one or more AEs and the fre-

Table I. Baseline characteristics of patients included in the model

Baseline characteristics	Dupilumab	BSC
Mean age at the model entry (years)	52.3±15.5	
Weight (kg)	74.3±17.6	
Women (%)	68	
Transition probabilities		
Responder at 24 weeks	85%	33.3%
Probability of a sustained response (in year 2)	98%	37%
Probability of a sustained response (in year 3)	95%	8%
Probability of a sustained response (in year 4)	93%	0%
Probability of a sustained response (in year ≥5)	92%	0%
Annual probability of discontinuing therapy (all causes)	4.28%	NA
Utilities		
Utility at baseline	0.611	0.611
Decision tree (12 weeks)	0.830	0.774
Markov model (24 weeks)	0.859	0.728[a]
Annual AE frequency		
Allergic conjunctivitis	4.04%	1.11%
Infectious conjunctivitis	3.03%	1.11%
Injection site reaction	6.06%	0%
Skin infection	1.01%	0%
Herpes (mouth)	2.02%	0%

[a]BSC and non-responders to dupilumab.
AE: adverse event; BSC: best supportive care.

quencies of rescue drugs use were extrapolated from the pooled analysis of PRIME and PRIME 2 trials (11) and stratified according to therapies (dupilumab or BSC, 7.2% and 22.8%, respectively). All the AEs were mild and transient (see Table I).

The model assumed that each AE, as mild and transient, was managed with a Specialist visit. Its cost was estimated at €25.00 as per the outpatient tariff (20). Overall, a patient/year cost of €8.75 with dupilumab and €1.20 with BSC was obtained.

Disease management. The annual cost of disease management according to the clinical response was estimated at €3,847 for non-responder patients and €711 for responder patients (4).

The costs of rescue medications were differentiated by treatment arm (dupilumab vs BSC). The estimate was made by considering the mean ex-factory prices of drugs reimbursed by the NHS (21) and the utilization frequencies recorded in the pooled analysis of the PRIME and PRIME 2 trials (11). Overall, the estimated patient/year cost for rescue medication was €2.48 and €38.49 for dupilumab and BSC, respectively.

Sensitivity analyses

Sensitivity analyses were developed to validate inputs and outputs, thus minimizing the associated uncertainty.

A deterministic sensitivity analysis (DSA) was conducted to assess the robustness of the model in light of potential deviations from the expected values of the parameters used. The DSA evaluates the effects of changes in individual input variables on the base case outcome. All variables were allowed to vary within specific value ranges.

A probabilistic sensitivity analysis (PSA) was developed to study the impact of parameter uncertainty on the model. In particular, 1,000 simulations were run with different sets of inputs sampled from distributions that represent parameter uncertainty. The analysis returned the probability as being cost-effective (PCE) defined as the probability of having an incremental cost-effectiveness ratio (ICER) below the willingness to pay (WTP) threshold of €40,000/QALY. This threshold was chosen based on the Italian Health Economics Association (AIES) suggestions (22) and KOLs opinion.

A comprehensive list of all parameters investigated in deterministic and probabilistic sensitivity analyses is reported in Table SI.

RESULTS

Base case results

Table II shows the results of the cost-utility analysis, which was conducted from the NHS perspective considering a 30-year time horizon (base case).

The use of dupilumab in the indication under examination was associated with better clinical outcomes and an increase in treatment costs, while leading to savings in other healthcare resources.

In particular, in the base case, the use of dupilumab led to an increase in both total costs of +€78,007 and QALYs (incremental gain of +1.481 QALYs). Therefore, the ICER was 52,661 €/QALY.

Scenario analyses

The ICER for each pricing scenario of dupilumab is presented in **Fig. 2.** The base case ICER is €52,661 with a PCE at a WTP threshold equal to €40,000 per QALY of 3.7%, based on the original list price of dupilumab. As discounts are applied progressively (from 10% to 60%), the ICER decreases fast for discount ≥20%; the ICER is lower than the threshold of €40,000 per QALY. Moreover, for discount ≥30%, the PCE at a WTP of €40,000 per QALY is higher than 80%.

Sensitivity analyses

Fig. 3 presents the results of the DSA conducted to explore the impact of key model parameters on the ICER of dupilumab compared with BSC. Each bar represents the range of ICER values resulting from varying 1 parameter at a time between its low and high values,

Table II. Results of the cost-utility analysis: base case (30-year horizon, i.e., lifetime)

Item	Dupilumab	BSC	Delta (dupilumab vs BSC)
Cost of the main therapy (€)	96,970	0	96,970
Adverse events and rescue medications (€)	554	736	–183
Management of the disease (€)	51,441	70,221	–18,780
Total cost (€)	148,964	70,957	78,007
QALYs	12.688	11.206	1.481
ICER (€/QALY)			52,661

BSC: best supportive care; QALYs: quality-adjusted life-years; ICER: incremental cost-effectiveness ratio.

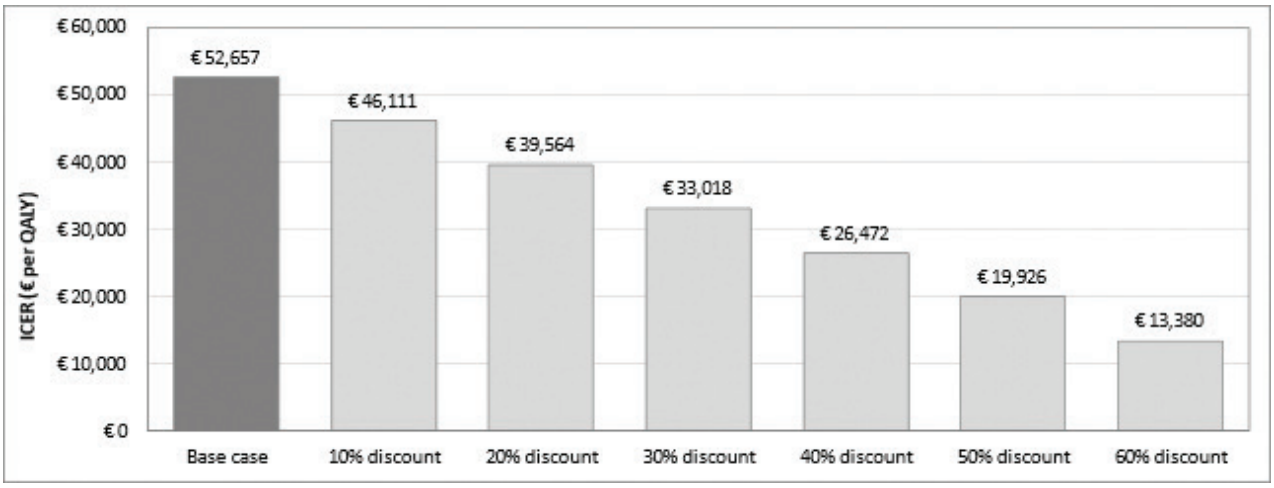

Fig. 2. Cost-effectiveness of dupilumab vs best supportive care (BSC) for different scenarios of dupilumab price. ICER: incremental cost-effectiveness ratio; PCE: probability of being cost-effective at a willingness to pay threshold equal to €40,000 per quality-adjusted life-year (QALY).

while holding all other parameters constant. The most influential parameter was the utility value assigned to patients receiving dupilumab, with ICERs ranging from €39,265 (low utility value) to €79,929 (high utility value). Other notable drivers included baseline utility, discount efficacy, discount rate applied to costs, and the acquisition cost of dupilumab. Parameters with narrower ICER ranges, such as utilities for non-responders and response rates at 24 weeks, had comparatively less impact on the ICER. This analysis highlights which parameters contribute most to the uncertainty in the cost-effectiveness estimate and identifies areas where more precise data may reduce decision uncertainty.

Results of PSA are illustrated in **Fig. 4**. In particular, the left panel illustrates the probability that dupilumab (solid line) and BSC (dashed line) are cost-effective across a range of WTP thresholds per QALY gained. As the WTP increases, the probability that dupilumab is considered cost-effective also rises, surpassing 50% at a threshold of approximately €53,000 per QALY. The right panel presents the results of the PSA on the incremental cost-effectiveness plane. Each point represents 1 of 1,000 PSA simulations, displaying the distribution of incremental costs and incremental QALYs for dupilumab compared with BSC. The black dot indicates the base-case estimate, while the ellipse encloses the 95% confidence region. All simulations fall in the north-east quadrant, indicating that dupilumab is associated with higher costs and improved health outcomes. This probabilistic analysis accounts for parameter uncertainty and confirms the robustness of the base-case results.

Results of PSA in terms of CEAC and PCE at a WTP of €40,000 per QALY gained for all pricing scenarios (discount from 10% to 60%) are reported in Figs S1–S6.

DISCUSSION

The findings of this cost-effectiveness analysis highlight the value of dupilumab as a treatment option in the Italian healthcare context. The model showed that, despite its

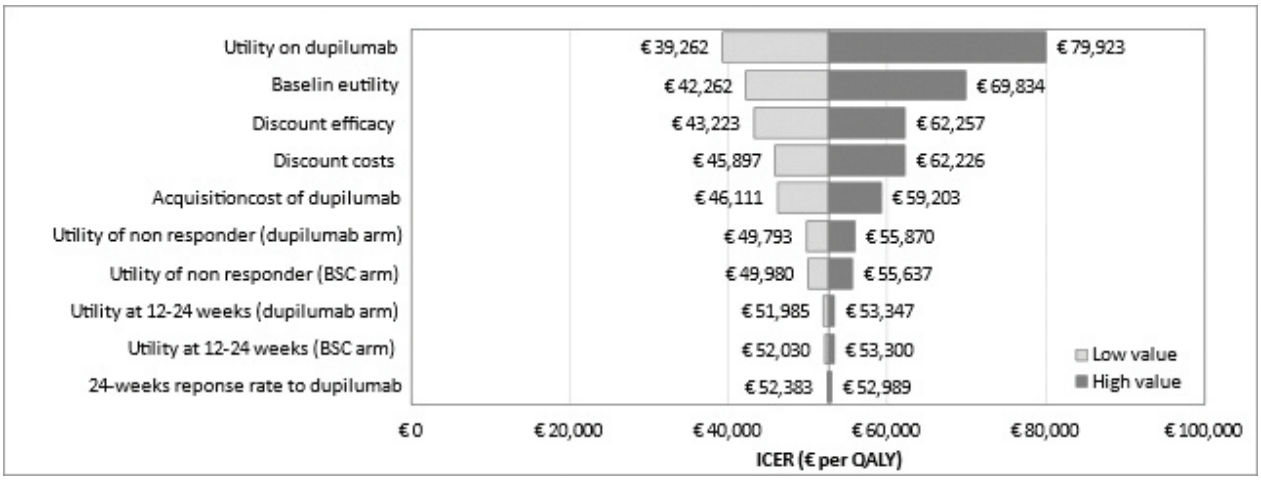

Fig. 3. Tornado diagram presenting the results of the deterministic sensitivity analysis. BSC: best supportive care; ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year.

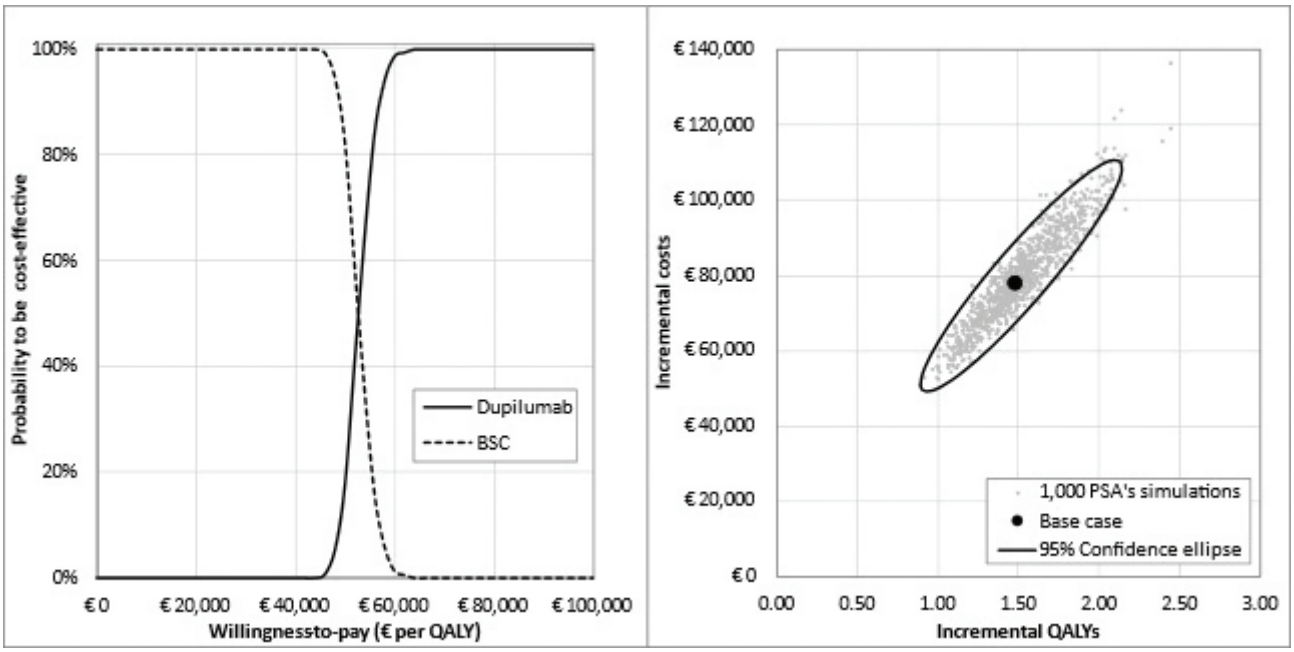

Fig. 4. Cost-effectiveness acceptability curve (left) and results of the probabilistic sensitivity analysis in the incremental cost-effectiveness plane (right). BSC: best supportive care; PCE: probability of being cost-effective at a willingness to pay threshold equal to €40,000 per QALY; PSA: probabilistic sensitivity analysis; QALY: quality-adjusted life year.

higher cost (€148,964, compared with €70,957 for the BSC arm), dupilumab provides significant health benefits by reducing pruritus severity and improving patients' quality of life (12.688 QALYs, compared with 11.206 QALYs for the BSC arm).

Patients who responded to dupilumab experienced a marked decrease in pruritus and nodule count and in frequency of exacerbation, leading to a better overall disease management experience and lower reliance on additional healthcare interventions.

BSC was chosen as comparator because the model was developed starting from the pooled analysis of phase 3 PRIME and PRIME 2 trials (6), where the comparator was placebo, but BSC (low-to-moderate potency topical corticosteroids and topical calcineurin inhibitors) was permitted. Most of these drugs are commercialized in formulations paid directly by the patient. Their costs were not taken into account in the present analysis, which considered only the direct costs sustained by the NHS. However, it should be pointed out that they would represent an additional cost. Importantly, in PRIME and PRIME2 trials, a significantly lower proportion of patients received BSC as topical rescue medications in the dupilumab arm than in the control arm (11). In a real-world setting, BSC also includes off-label systemic treatments, such as methotrexate and cyclosporin. They are also recommended by the 2020 International Forum for the Study of Itch (IFSI) guidelines as step 3 in CPG treatment, but they have to be tapered off as soon as possible upon healing of lesions, due to the relative potential toxicity of the drugs (1). In fact, they may increase the number of adverse events and visits (associated with monitoring), thereby affecting not only the patient's but also the NHS's expenses. The use of dupilumab likely reduces the need for these systemic treatments with further potential savings from the societal perspective.

Although several case series and very few retrospective cases have been published in international literature, we did not include in this analysis data from PN patients treated with dupilumab in real life (7), because the number of cases retrieved in the literature was very small (119 cases included). However, the review concluded that dupilumab demonstrated an excellent clinical response (87.5% of patients reaching clinical remission) and very good overall safety (61.3% of patients without adverse events). These figures are, as often happens, better that the figures generally reported in the registration trials, underlying that the results obtained in our analysis could be consistent with real-life treatment.

The acceptability threshold of €40,000/QALY was chosen based on the Italian Health Economics Association (AIES) suggestions (22) and KOLs opinion. It is widely used and has been considered the most appropriate in a cost-effectiveness evaluation for several years. While the ICER reported in the base case (€52,661/QALY) exceeds the conventional willingness-to-pay threshold in Italy, scenario analyses suggest that at a discounted price of 20% or greater, dupilumab becomes cost-effective. Given the confidential nature of real-world drug pricing agreements, the actual cost-effectiveness ratio is likely to be lower than the base-case estimate.

In the PRIME and PRIME2 trials, the dupilumab arm showed a significantly lower rate of anxiety and depression if compared with the control arm (6). They

were measured thanks to the Hospital Anxiety and Depression Scale (HADS). HADS-A measured anxiety and the dupilumab arm showed statistically significant differences in comparison with placebo of –1.4 and –1.5 in PRIME and PRIME 2 trials, respectively (6). HADS-D measured depression and the dupilumab arm showed statistically significant differences in comparison with placebo of –1.1 and –1.6 in PRIME and PRIME 2 trials, respectively (6). The observed reductions in HADS scores with dupilumab, although modest in absolute terms, are clinically meaningful when interpreted in the context of patient-reported outcome measures and the chronic nature of the disease. These findings suggest that the clinical benefits of dupilumab may extend beyond the direct improvement of dermatological symptoms, potentially offering significant gains in psychological well-being. We did not measure such outcomes, but we hypothesize that improvements in mental health may also contribute to enhanced adherence to therapy, better overall quality of life, and potentially lower healthcare utilization associated with psychiatric comorbidities. Moreover, although the mortality rate of patients with PN is generally comparable to that of the general population, it is important to note that these patients often present with multiple comorbidities (23), including a noteworthy prevalence of psychiatric disorders, above all anxiety and depression (24–26), which may contribute to increased mortality, particularly due to elevated suicidal risk. In particular, Kambala and colleagues, in their multicentre, longitudinal cohort study, used a health research network to identify 20,093 PN patients and matched them with the propensity score to identify a similar population of controls without PN (27). They demonstrated that there was an increased 1-year incidence and risk of suicidal ideation and suicide attempt following diagnosis of PN (27). In addition, preliminary results suggest that dupilumab or at least better management of PN severity can reduce mortality associated with common non-T2 comorbidities in these patients, something that may have wider healthcare benefits for patients and payers (28). Therefore, the broader implications of PN for healthcare resource utilization and comorbidity burden may be considered, together with the possible clinical benefits of dupilumab in reducing disease severity and the consequent additional societal and economic benefits, even though not captured by our model.

The robustness of the model was confirmed by deterministic and probabilistic sensitivity analyses, which identified baseline quality of life estimates and utility improvements as key drivers of cost-effectiveness. Moreover, the model structure was based on the same approach taken in the atopic dermatitis model, which was used and approved by the Health Technology Assessment Organs of the UK (29), France (30), Sweden (31), and by the Institute for Clinical and Economic Review (ICER) (32).

Limitations

However, certain limitations should be considered when interpreting the findings. First, long-term evidence on discontinuation rate data and long-term effectiveness concerning the use of dupilumab and BSC arms is lacking. Therefore, sustainability of treatment response with and without dupilumab was assumed to be similar between atopic dermatitis and PN. The response waning observed in patients with atopic dermatitis was judged plausible and representative of the PN evolution. In addition, the discontinuation rate used in the base case (based on the 24-weeks PRIME and PRIME2 trials [6]) is similar (or even higher) to the rate observed in the CHRONOS study (3.7% at 52 weeks [33]) for patients with moderate-to-severe atopic dermatitis. Two recent analyses on the long-term effect of dupilumab in patients with PN showed a very low discontinuation rate. Specifically, in the study of Gael et al. 2025 (34), 14 patients with prurigo (12 had PN and 2 had excoriated plaque prurigo) were treated with dupilumab for a median follow up of 14.5 months (IQR 10–26.8) and no patients discontinued treatment at the end of follow-up. As regards effectiveness, in the same study half of the patients had a partial response, and the other half had complete remission of their pruritus. In the Italian study of Paganini et al. 2024 (35), in 16 patients with PN, dupilumab proved to be successful in achieving a substantial decrease in various outcome measures (IGA-CNPG, itch & sleep NRS score, DLQI, proportion of patients with IGA≤1), as assessed by both physicians and patients at each evaluation point up to week 84. No patients interrupted the treatment during the study. Patients reaching IGA-CNPG≤1, ≥4-point amelioration itch- or sleep-NRS, increased from 72.7%/91%/82%, respectively, at week 6 up to 100% at week 84. Such long-term evidence strengthens the plausibility of data from atopic dermatitis patients used in our paper.

Moreover, such response rates were used in 3 previous analyses on PN patients developed for France (36), the USA (37), and the UK (38). The French model was also validated by the French Health Authority.

Moreover, the effect of uncertainty on discontinuation rate was investigated in the deterministic sensitivity analysis. The discontinuation rate was varied between ±10% of the base case and its influence was negligible on the results. In fact, it did not appear among the first 10 parameters that mostly influenced the ICER (see Fig. 3).

Second, disutility because of AEs was assumed to be accounted for within patient-level EQ-5D responses collected during the PRIME and PRIME 2 trials. Therefore, no additional disutility was included, to avoid double counting. Moreover, all the AEs recorded in the PRIME and PRIME 2 trials were mild and transient and probably managed with a specialistic visit; hence it seemed plausible that the impact on patients' quality of life was limited or negligible.

Conclusion

This study supports the use of dupilumab for severe PN in Italy. The treatment provides significant clinical benefits and reduces the economic burden associated with uncontrolled PN. Based on a willingness to pay of €40,000/QALY, dupilumab is likely to be cost-effective in Italy in most of the pricing scenarios. Future research should focus on collecting long-term real-world data on the durability of dupilumab response in PN, as well as its impact on psychiatric comorbidities and healthcare utilization.

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