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ORIGINAL RESEARCH

# Current Challenges in Atopic Dermatitis: An Italian Delphi Consensus with a Special Focus on Moderate Disease

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## ABSTRACT

***Introduction***: Atopic dermatitis (AD) is a chronic, inflammatory skin disease clinically characterized by eczematous lesions and severe itch, significantly affecting the patients' quality of life. AD is classified as mild, moderate, or severe according to the extent and severity of these lesions. While therapeutic protocols for mild and severe AD are well-defined, the moderate stage represents a clinical 'gray zone' characterized by inconsistent management. It is frequently mismanaged, oscillating between undertreatment and the indiscriminate use of traditional systemic therapies. The moderate stage of AD requires a tailored approach to maximize topical treatments efficacy, avoid the side effects of systemic drugs, while remaining ready to escalate therapy if needed.

***Methods***: An Italy-based, expert-Delphi consensus was used to: (1) reach a consensus on moderate AD classification criteria; (2)

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characterize the disease-specific burden in these patients; (3) identify key elements and concerns in moderate AD treatment; and (4) identify the therapeutic and management-related unmet needs of this subset of patients.

***Results*:** Agreement was reached for 26 final statements, which included highlighting a significant disease burden also for patients with moderate AD.

***Conclusions*:** The findings underscore a misalignment between the actual disease burden of moderate AD and current regulatory reimbursement criteria. In Italy, the restricted access to innovative systemic therapies for this specific patient population represents a critical healthcare gap.

**Keywords:** Burden of disease; Cost of illness; Delphi technique; Health policy; Moderate atopic dermatitis; Unmet needs

**Key Summary Points**

*Why carry out this study?*

Atopic dermatitis (AD) is a chronic inflammatory skin disease with a significant burden on patients' quality of life

While therapeutic protocols for mild and severe AD are well-defined, moderate AD remains a clinical gray zone, frequently mismanaged and characterized by considerable unmet needs, particularly in Italy where access to innovative therapies is restricted by Italian Medicines Agency (AIFA) reimbursement criteria based on Eczema Area and Severity Index (EASI) score thresholds

This study aimed to reach an expert consensus on classification criteria, disease burden, treatment approaches, and unmet needs specifically for patients with moderate AD in Italy

*What was learned from the study?*

A two-round Delphi consensus among 48 Italian dermatologists resulted in 26 final statements, all achieving ≥ 89.6% agreement, confirming a significant multidimensional disease burden in moderate AD and highlighting a critical gap between clinical need and current reimbursement criteria

The findings provide a robust evidence base that underscores the urgent need for timely access to innovative targeted therapies for patients with moderate AD

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## INTRODUCTION

Atopic dermatitis (AD) is an inflammatory, chronic, and relapsing skin disease characterized by pruritus and eczematous lesions, with age-specific distributions. The AD etiology is complex, multifactorial, and not fully understood, involving a well-recognized interplay between skin barrier dysfunction, immune dysregulation, and environmental and genetic factors [1]. AD can be associated with other atopic diseases, such as oculorhinitis, asthma, chronic rhinosinusitis, nasal polyps, and eosinophilic esophagitis, suggesting a genetic and pathogenetic background. Furthermore, AD can be associated also with non-atopic comorbidities, including infections, anxiety, depression, and attention-deficit/hyperactivity disorders [1].

AD onset is most common in early childhood and adolescence; however, the disease can persist into or even start in adulthood, with an average prevalence of 4.4% in Europe and of 8.1% in Italy [2]. Among the affected population, the proportion of European patients with a moderate-to-severe form of the disease ranges from 46% to 66%, depending on the clinical assessment tools used [2]. AD is frequently associated with a significant burden,

deeply affecting the quality of life (QoL) and the patients' treatment choices [1].

A diagnosis of AD is clinical, based on the morphology and distribution of lesions, as well as on personal and family history [3]. In cases of late-onset AD, other conditions should be ruled out. Different sets of criteria have been developed to support the diagnosis of AD, including the widely used Hanifin and Raijka criteria, but these are currently applied mainly in clinical trials as they are not readily usable in real-world settings [1].

The most recent European guidelines for AD (EuroGuiDerm) aim for symptom management and long-term disease control through a stepped-care plan. Basic topical treatments for all forms of AD include emollients and moisturizers, combined with patient educational programs. For mild-to-moderate-to-severe AD, topical anti-inflammatory agents, such as topical corticosteroids (TCSs) and calcineurin inhibitors (TCIs), are recommended alongside psychology counseling and phototherapy. For moderate-to-severe AD, in case of failure of conventional first-line systemic traditional therapies, including short courses of corticosteroids, methotrexate, cyclosporine, and/or azathioprine (often used off-label), the next step involves advanced therapies. These include biologics that target extracellular cytokines and their receptors and Janus kinase inhibitors (JAKi) that block the JAK-STAT signaling pathway [4, 5].

Despite the high prevalence of mild-to-moderate AD [6], there are limited studies and expert consensuses specifically defining and addressing the clinical and therapeutic management of moderate AD. Here we report the results of a multi-round Delphi (MRD) process, a methodology recognized as a valuable tool for harmonizing expert opinions and translating scientific evidence into practical, real-world recommendations across complex diseases [7], that aimed to reach a consensus on a series of statements to support healthcare professionals in defining and managing moderate AD, thereby reducing the burden and addressing the unmet needs of affected patients.

# METHODS

## Study Design and Development

In this study a two-round Delphi survey was used. The survey was led and facilitated by Helaglobe S.r.l. (Florence, Italy), a team of experts specialized in consensus methodologies. Helaglobe was responsible for the literature review, organization, and coordination of the expert groups, development and analysis of the questionnaires, and drafting of the final report of the survey. The standard MRD method involves two or more rounds of questionnaires designed to collect and synthesize opinions. It is characterized by four main characteristics: anonymity, iteration, controlled feedback, and statistical aggregation of group responses.

All methods described herein were carried out in accordance with applicable guidelines and regulations. All panelists provided written informed consent to participate in this MRD study as experts. No human patients or animals were involved.

The study was organized as shown in Fig. 1 and as described in the following text.

**Step 1, Desk Analysis** The best available literature data on moderate AD indexed in the biomedical PubMed/Medline database were identified using the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) and the PICO (Patient/Population, Intervention, Comparison, Outcome) frameworks. Predefined keywords were included in the search strings for the different domains of the Delphi survey as detailed in Electronic Supplementary Material File 1. Filters applied during literature search included 10-year reference period, full-text articles, English language, and adult human subjects (≥ 18 years of age). High-quality publications with strong scientific evidence (meta-analyses, systematic reviews, clinical trials, clinical studies, guidelines, reviews, and real-world data) relevant to the topic of this MRD study were selected.

**Step 2, Meetings of the Board of Experts, Literature Review, and Statement Definition** A

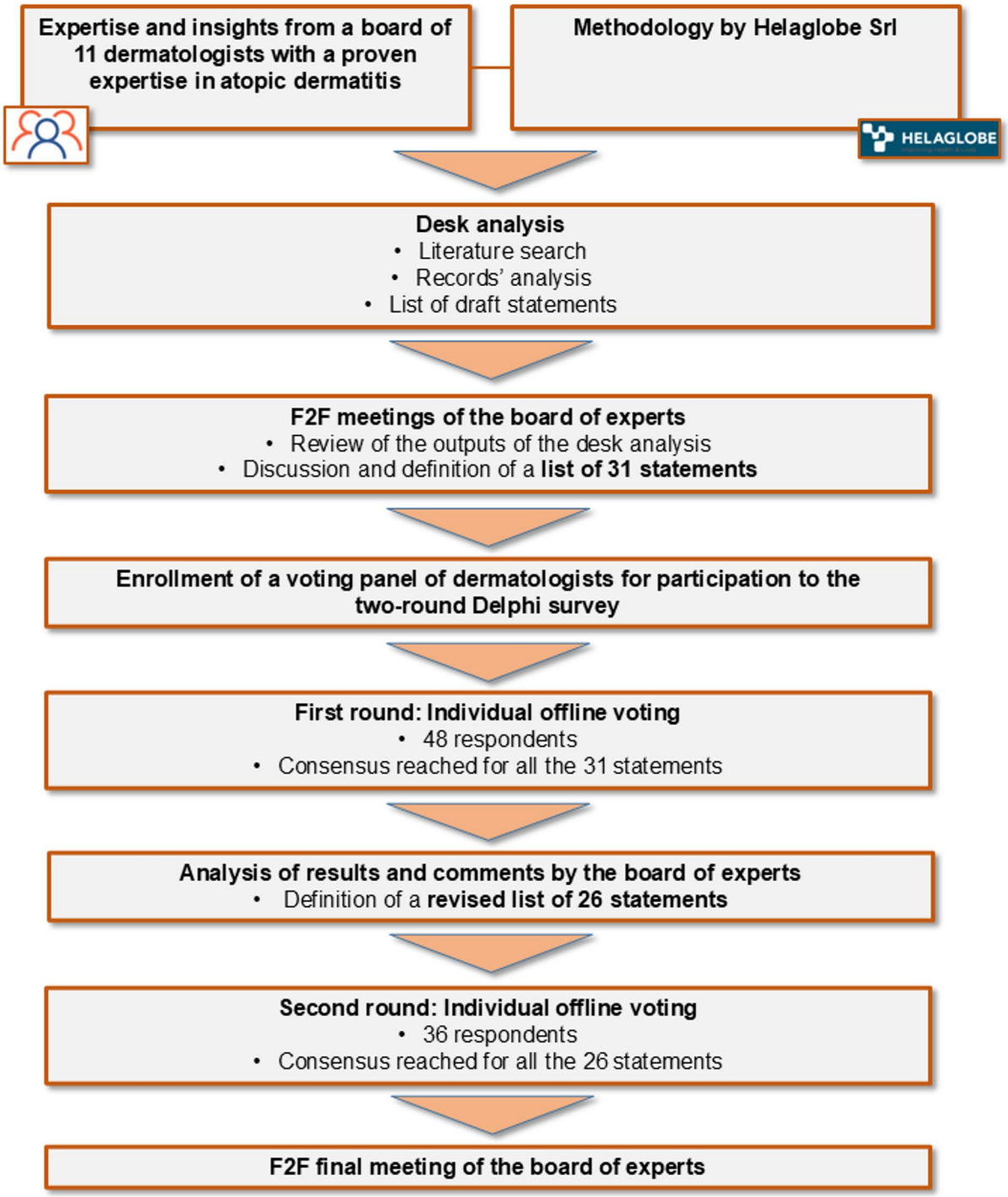


**Fig. 1** Overall design of the study. *F2F* Face-to-face

board composed of 11 dermatologists with expertise in AD reviewed, discussed, and revised the outputs of the desk analysis, including a list of draft statements, during a face-to-face (F2F) meeting. The overall process resulted in the

generation of 31 survey items grouped into four domains.

**Step 3, Delphi Panel Composition and MRD Survey** We recruited a panel of dermatologists selected among the major experts in the field of AD, representing diverse geographic areas across Italy. The aim was to capture the widest possible range of opinions regarding disease classification, treatment options, disease burden, and unmet needs in moderate AD. In total, 69 dermatologists were invited by email to participate in the MRD survey, among whom 48 (69.5%) accepted. All materials, including the survey, were in English. The 48 panel members were asked to express their judgment on the 31 statements defined during Step 2. Online voting was conducted using a 5-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree). The responses were expressed as percentages for each item. Cumulative agreement was defined as the sum of responses for scores 4 ("agree") and 5 ("strongly agree"). Consensus for each statement was reached if at least 75% of Delphi panelists scored the statement ≥ 4 on the Likert scale, as previously reported [7]. After the first round of MRD, the board of experts reviewed the comments from the Delphi voting panel and revised the statements, which were voted on offline in a second round. The final results were further discussed and approved in a F2F meeting by the board of experts (Fig. 1).

## RESULTS

This MRD study identified a series of indications and recommendations covering various domains of AD, with a focus on moderate AD management (Table 1).

Forty-eight invited panelists participated in the first round of the MRD and 36 (75.0%) took part in the second round.

In the first round of this Delphi study, 31 statements grouped into four domains (diagnosis and classification criteria; moderate AD burden of disease; treatment of moderate AD; unmet needs in moderate AD) were evaluated by the voting panelists. At the end of the first round of the MRD process, the review process was highly favorable, as all the statements reached a consensus, with an agreement > 75%. In detail, three statements achieved unanimous consensus, 20 statements reached an agreement ranging from 90% to 99%, and eight statements achieved an agreement between 80% and 89%. Following the first round of the Delphi study, the statements were reviewed based on the comments and recommendations of the voting panelists, leading to a revised list of 26 statements (Table 1). In the second round of the MRD process, the number of statements achieving unanimous consensus increased from three to ten, while 14 statements reached an agreement ranging from 90% to 99%, and only two statements achieved an agreement between 80% and 89%. The flow of the two Delphi rounds and their results are reported in Fig. 1.

## DISCUSSION

### Domain 1: Diagnosis and Classification Criteria

Atopic dermatitis varies greatly in presentation and severity. A timely classification of severity and detection of relapses, using both clinical signs and patient-reported outcomes, is essential for an effective management. AD severity can be established using the Eczema Area and Severity Index (EASI) numerical score, a well-validated and standardized tool that integrates body surface area and intensity of four clinical signs (erythema, induration/papulation, excoriation, and lichenification) into a single composite score [8]. The voting panelists reached a unanimous consensus defining moderate AD by an EASI score ranging from 7.1 to 21.0 (statement #1, domain 1, Table 1) [1, 3]. Since the EASI score does not account for disease symptoms, it should be integrated with validated patient-reported outcome (PRO) measures. The panelists unanimously supported the use of various validated tools, including the Patient-Oriented Eczema Measure (POEM), which evaluates the frequency of seven signs and symptoms

**Table 1** Statements identified in the multi-round Delphi study for domains 1 (diagnosis and classification criteria), 2 (moderate atopic dermatitis burden of disease), 3 (treatment for moderate atopic dermatitis), and 4 (unmet needs in moderate atopic dermatitis), and final degree of consensus

| Statement number | Statement | Agreement on statement(%) | References |
|---|---|---|---|
| *Domain 1: Diagnosis and classification criteria* | | | |
| 1 | Moderate AD is generally defined in the international literature as an EASI score between 7.1 and 21.0 (EASI > 7 and ≤ 21). However, EASI assessment does not take into account subjective symptoms such as pruritus, the impact on quality of life, or involvement limited to sensitive areas (such as the face, hands, and genitals) | 100 | [1, 3, 23] |
| 2 | The assessment of patient-reported outcomes in AD represents a useful complement that can be integrated with the evaluation of clinical indices. Although the DLQI is a widely used instrument, it has some limitations in terms of specificity for AD and may not fully capture the impact of the disease on quality of life. Therefore, it is recommended to also consider other validated tools, such as POEM and HADS | 100 | [9] |
| 3 | In most cases, the course of the disease is chronic and relapsing. A "flare" (exacerbation) is an acute and clinically significant worsening of the signs and symptoms of AD and should be defined not only on the basis of clinical signs but also considering patient-reported symptoms (e.g., pruritus, sleep disturbance, perceived worsening, and the need to modify therapy) | 100 | [3, 12, 24] |
| *Domain 2: Moderate atopic dermatitis burden of disease* | | | |
| 4 | Moderate AD may have a significant multidimensional impact on patients' quality of life, including pruritus and/or sleep disturbances and/or social limitations | 100 | [13, 22, 25–27] |
| 5 | Pruritus in patients with moderate AD is generally associated with an ITCH-NRS score ≥4/10. This level of pruritus may be correlated with sleep disturbances and impairment in work productivity or daily activities, affecting approximately 80% and 50% of patients with moderate AD, respectively | 100 | [13, 15, 25, 26, 28, 29] |
| 6 | Approximately half of patients with moderate AD experience clinically relevant anxiety symptoms, while depressive symptoms are present in about one third of cases. Social avoidance behaviors or limitations in daily activities are reported by approximately 20% of patients, contributing to the overall burden of the disease | 100 | [13, 25, 30, 31] |
| 7 | Dissatisfaction with prolonged topical treatments using corticosteroids and calcineurin inhibitors may negatively affect the disease burden in patients with moderate AD | 100 | [22, 31–33] |

**Table 1** continued

| Statement number | Statement | Agreement on statement(%) | References |
|---|---|---|---|
| *Domain 3: Treatment for moderate atopic dermatitis* | | | |
| 8 | Therapeutic decisions should be individualized based on disease severity (both objective and subjective), the presence of relevant comorbidities, as well as the patient's characteristics and expectations (e.g., preferences for treatment type, tolerability, and adherence) | 97.9 | [34, 35] |
| 9 | Also in patients with moderate AD, emollients/moisturizers represent the cornerstone of treatment, both as monotherapy and in combination with other therapies, depending on disease severity and clinical needs | 100 | [5–38] |
| 10 | Topical corticosteroids are among the first-line treatments for moderate AD, particularly during the acute phase or flares, especially in less extensive forms and in areas other than the face and neck. Long-term continuous use may be associated with loss of efficacy and the onset of local adverse effects, such as skin atrophy, telangiectasia, and striae rubrae | 93.7 | [5–40] |
| 11 | Systemic corticosteroids are used for short periods to treat flares and are not recommended for long-term continuous use | 97.9 | [5, 41] |
| 12 | Topical calcineurin inhibitors (tacrolimus, pimecrolimus) are recommended for the treatment of moderate AD on all skin sites, using a proactive approach to reduce the incidence of flares. In addition, they are used continuously as an alternative to TCs and as TC-sparing agents, particularly when prolonged use of TCs is contraindicated (e.g., on the face, skin folds, and hands). However, adherence may be limited by local side effects such as burning sensations, especially during the initial phases of treatment | 100 | [37, 38, 42, 43] |
| 13 | NB-UVB phototherapy is effective in AD, including moderate AD, particularly in intermittent forms characterized by prolonged periods of well-being alternating with flares, and during non-inflammatory phases. However, its use is limited by the need for frequent visits to treatment facilities, which may reduce patient adherence, as well as by accessibility issues. In addition, NB-UVB phototherapy is not indicated in acute forms of AD and may be associated with adverse effects, including an increased risk of NMSC and melanoma, especially in patients undergoing repeated treatment cycles | 89.6 | [38, 44] |

**Table 1** continued

| Statement number | Statement | Agreement on statement(%) | References |
|---|---|---|---|
| 14 | According to national and international guidelines, patients who are candidates for systemic treatment for AD are those who do not achieve a clinical response to appropriately administered topical therapy ("functional" definition), or who, despite following an adequate topical treatment regimen, are unable to participate in normal activities of daily living ("social" definition). In addition, candidates include patients with a high disease severity score, as well as those with significant involvement of sensitive areas or a relevant impact on emotional and psychological aspects | 97.9 | [5, 35, 38, 45, 46] |
| 15 | Patients with moderate AD who are not adequately controlled with topical therapy may be eligible for treatment with conventional systemic drugs; however, these therapies have drawbacks and limitations in terms of safety. In Italy, for patients who cannot continue treatment with conventional systemic therapies, there is a high unmet need, as patients with moderate AD do not meet the eligibility criteria (EASI ≥ 24) required for reimbursement of biologic treatments and JAK inhibitors | 100 | [4, 46–48] |
| 16 | Atopic dermatitis may follow a progressive worsening course. A significant proportion (estimated at around 40%) of patients with moderate disease may experience severe flares over the course of the condition, which may require treatment escalation as recommended for more extensive and severe forms of the disease | 97.9 | [49] |
| *Domain 4: Unmet needs in moderate atopic dermatitis* | | | |
| 17 | Timely access to effective and innovative therapies is perceived as an unmet need, particularly for patients with moderate AD with specific clinical characteristics (e.g., affected areas, subjective symptoms, frequency and severity of flares) who are currently not eligible for reimbursed targeted molecular therapies (biologics, small molecules) | 97.9 | [31, 50, 51] |
| 18 | In patients with moderate AD, the main needs include itch control regardless of the affected site, management of skin lesions (sometimes also painful), and improvement of quality of life | 97.9 | [31, 51, 52] |
| 19 | Patients with moderate AD report as a priority the need to improve sleep quality and reduce itch-related discomfort | 93.7 | [31, 52] |
| 20 | In patients with moderate AD, rapid relief of skin symptoms (itching, pain) may be achieved through continuous use of topical steroids and, in some cases, systemic steroids or cyclosporine, which are effective in acute symptom control. However, the main unmet need remains maintaining long-term disease control | 89.6 | [31, 51] |

**Table 1** continued

| Statement number | Statement | Agreement on statement(%) | References |
|---|---|---|---|
| 21 | Patients with moderate AD want treatments that provide sustained disease control while preventing flares | 95.9 | [31, 50, 51] |
| 22 | The long-term safety of therapies represents a central need for all patients with AD, regardless of disease severity. There is a demand for therapeutic alternatives with fewer side effects compared with traditional treatments, both among conventional and innovative options, as many patients fear adverse effects associated with both categories | 97.9 | [50, 51] |
| 23 | The high prevalence of anxiety, depression, and AD-related stigma highlights the importance of considering psychological support in patients with moderate AD, particularly in children and adolescents. These symptoms are often correlated with disease severity and tend to decrease with clinical control; therefore, the priority remains access to effective and well-tolerated therapies when indicated. The implementation of psychological support should be assessed on a case-by-case basis, taking into account the reactive nature of symptoms and the resources available in the healthcare setting | 97.9 | [31, 52, 53] |
| 24 | Patients' perception of the disease includes frustration and fear related to the unpredictable clinical course, the potential loss of therapeutic control, and difficulties in accessing certain therapies. These aspects should be acknowledged and addressed within the care pathway | 97.9 | [50, 53] |
| 25 | Many patients with moderate AD report dissatisfaction with the treatments they receive, indicating a gap between expectations and actual outcomes | 91.7 | [31, 51] |
| 26 | Patients require improved physician–patient communication, focused on shared therapeutic decision-making and the definition of realistic expectations, which are essential to optimize treatment adherence and improve care outcomes | 91.7 | [31, 51, 53] |

*AD* Atopic dermatitis, *DLQI* Dermatology Life Quality Index, *EASI* Eczema Area and Severity Index, *HADS* Hospital Anxiety and Depression Scale, *ITCH-NRS* Itch Numeric Rating Scale, *JAK* Janus kinase, *NB-UVB* narrowband ultraviolet B, *NMSC* non-melanoma skin cancer, *POEM* Patient Oriented Eczema Measure, *TCs* topical corticosteroids

over the previous week, and the Dermatology Life Quality Index (DLQI), which measures the impact of skin disease on QoL (statement #2, domain 1, Table 1). In a population-based cohort of adults, severity strata evaluation indicated a DLQI score range of 6–10 and a POEM score range of 8–16 for moderate AD. Other validated PRO tools include the Patient-Oriented Scoring Atopic Dermatitis (PO-SCORAD), which assesses lesion extent and severity alongside pruritus and sleep disturbance, with a score ranging from 25 to 50 for moderate AD [9]. Finally, the Hospital Anxiety and Depression Scale (HADS) can evaluate mental health in patients with AD. Studies show that adults with AD have higher weighted mean scores for anxiety (HADS-A) and depression (HADS-D) compared to control subjects [10]. Specifically, in that study, mean HADS,

HADS-A, and HADS-D scores in adults with moderate AD were 14.6–16.6, 7.8–9.2 and 6.8–7.4, respectively, significantly higher than in control subjects [10]. Notably, a study examining disease burden in Australian adults showed that moderate AD appears to have a greater effect on psychological wellbeing, whereas severe AD has a greater impact on physical health [11]. Since no single PRO instrument listed above comprehensively captures all AD dimensions, combining multiple tools is recommended for accurate diagnosis and severity stratification. The experts involved in this Delphi survey also agreed that AD exacerbations should be carefully evaluated considering both clinical signs and the patient's perspective (statement #3, domain 1, Table 1). Flares are a highly individualized experience, and patients may be in the best position to determine if they are experiencing one [12].

### Domain 2: Moderate AD Burden of Disease

In addition to skin signs and symptoms, AD negatively affects mental and psychological health, work productivity, sleep, and daily activities. The statements in domain 2, all of which are related to burden of moderate AD, received a 100% agreement, highlighting that a significant impact on patients' QoL is not limited to severe disease. Large-scale patient surveys have revealed that the multidimensional burden of AD is also strongly associated with time spent managing symptoms, suggesting a need for access to more effective therapies that improve symptoms and reduce this management burden [13]. Among the multiple factors affecting the QoL, the voting panelists confirmed the pivotal role of pruritus (statements #4 and #5, domain 2, Table 1), mental health issues, including anxiety, depression and social avoidance behaviors (statement #6, domain 2, Table 1), and dissatisfaction with prolonged topical treatments with TCSs and TCIs in moderate AD, due to lack of efficacy or side effects (statement #7, domain 2, Table 1).

Relentless, chronic pruritus is a hallmark symptom of AD and a primary driver of disease burden, as it impairs sleep quality and leads to social isolation, anxiety and reduced QoL. Specifically, pruritus in moderate AD has been associated with a Numeric Rating Scale (NRS) score ≥ 4/10 [14, 15]. Future AD therapeutic options should urgently include effective and targeted antipruritic therapies with fewer side effects, as well as combination strategies to achieve greater efficacy and a true reduction in disease burden [16]. Overall, consensus data regarding the burden of moderate AD are consistent with recent results from the European National Health and Wellness Survey, which also revealed that the most common comorbidities in moderate AD overlap with those experienced by patients with severe AD [17].

### Domain 3: Treatment for Moderate Atopic Dermatitis

Atopic dermatitis treatment needs to be tailored to individual phases based on clinical parameters and patients' expectations. Until recently, AD treatment was largely non-specific and, in severe disease, sometimes ineffective and/or hampered by side effects. However, the treatment landscape has shifted significantly, with multiple agents targeting specific disease pathways now available for moderate-to-severe AD [1].

Moderate AD is often underestimated and/or inadequately treated [2], requiring management approaches that sometimes necessitate more potent therapies to achieve adequate disease control. Currently, unlike mild cases managed with topicals or severe cases where systemic therapy is the clear standard, moderate AD occupies a clinical limbo [4, 18]. In Italy, as in several other countries, reimbursement for innovative therapies is governed by stringent administrative thresholds rather than clinical needs alone [19]. This regulatory barrier effectively 'strangles' the treatment options for a substantial subset of patients, particularly those with moderate disease or localized but debilitating AD (involving the face, hands, or genitals, or with intense pruritus and sleep deprivation). Consistently, in Italy and several other countries, advanced therapies, including biologics (dupilumab, tralokinumab, lebrikizumab, nemolizumab) and JAKi (upadacitinib, abrocitinib and baricitinib), are

not eligible for reimbursement for moderate AD only. Being excluded from innovative care, patients with moderate AD are often forced into an inadequate therapeutic cycle: they must choose between insufficiently effective topical regimens and traditional systemic immunosuppressants, which are often poorly tolerated and/or associated with a significant risk of cumulative adverse events. Consequently, this population faces a high disease burden, trapped in a gap where clinical severity is high but safer, more targeted therapeutic options remain administratively out of reach. The consensus achieved for statements #8–16 (domain 3, Table 1) regarding moderate AD treatment (ranging from 89.6% to 100% agreement) alongside results reported from recent studies [20] underscores the need to optimize healthcare management for patients with moderate AD in order to improve their clinical outcomes. Although associated with higher upfront expenditures, innovative therapies are expected to confer long-term economic advantages by mitigating direct medical costs related to disease progression, treatment-related adverse events (e.g., those related to long-term use of topical and systemic corticosteroids, statements #10–12, domain 3, Table 1), and the need for intensive follow-up or routine monitoring. Furthermore, they can reduce indirect costs arising from impaired health-related QoL and productivity loss. Finally, the development of novel topical agents is a rapidly advancing field that could help to optimize the management of moderate AD patients who do not yet meet the severity thresholds for systemic therapy [18].

### Domain 4: Unmet Needs in Moderate AD

Despite the increased knowledge of AD pathophysiology and the novel therapeutic strategies, unmet needs persist in management of this disease, including its moderate form. Statements included in domain 4 achieved an agreement ≥ 89.6%. They identified several unmet needs in moderate AD, including timely access to innovative and effective therapies (statements #17 and #25, domain 4, Table 1); effective itch control, skin lesions management, and QoL improvement (statement #18, domain 4, Table 1); sleep quality improvement (statement #19, domain 4, Table 1); long-term disease control (statement #20, domain 4, Table 1); sustained disease control with flare prevention (statement #21, domain 4, Table 1); long-term therapy safety (statement #22, domain 4, Table 1); access to psychological support (statement #23, domain 4, Table 1); and enhanced patient-physician communication to improve treatment adherence (statement #26, domain 4, Table 1).

It has been hypothesized that the combination of pruritus, psychological stress, social isolation, depression, and anxiety results in a vicious cycle in patients with AD [21]. The vast majority of the unmet needs listed above calls for a proactive adjustment of treatment strategies when patients with moderate AD do not achieve optimal targets. However, such adjustments are limited by strict reimbursement criteria set by the Italian Medicines Agency (AIFA), even when moderate AD symptoms, particularly pruritus, are inadequately controlled by conventional topical or systemic therapies. Therefore, the findings here presented are applicable only to the Italian healthcare and reimbursement context and should not be extrapolated to other national settings. Finally, the strong consensus achieved in this domain also highlights the need to introduce a patient-centric approach for AD assessment and management, consistently with other studies [22]. The decision-making process about AD treatment frequently prioritizes objective clinical findings and investigator-derived assessments, while overlooking PROs, such as pruritus intensity, sleep disturbance, fatigue, and psychological distress. Systematically integrating PRO measures into both clinical practice and research frameworks is critical to ensuring that therapeutic objectives align with patients' experiences, perceived disease burden and unmet needs [14].

### Limitations

This national Delphi consensus is constrained by potential expert selection bias. Its findings may have limited external validity beyond the national context and are inherently dependent on the composition of the expert panel.

Furthermore, this consensus was developed and voted exclusively by dermatologists; future iterations of this work should incorporate patient representatives in the discussion and voting process to ensure that the statements also reflect patients' lived experience and priorities.

In addition, the iterative process may have attenuated dissenting views and cannot substitute for evidence derived from prospective or real-world clinical outcomes.

## CONCLUSIONS

To the best of our knowledge, this is the first MRD study focusing specifically on moderate AD, characterized by a considerable burden and significant unmet needs. The findings of this MRD study highlight the challenges inherent in treating patients with moderate AD and represent a basis to reshape, adjust and optimize the allocation of available healthcare and financial resources. Ultimately, this will improve the care of patients with moderate AD and address their unmet needs.

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## *Declarations*

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