

Optimizing the management of atopic dermatitis with a new minimal disease activity concept and criteria and consensus-based recommendations for systemic therapy

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Introduction/Background: Inconsistent criteria are used to identify patients with atopic dermatitis (AD) who are candidates for systemic therapy and assess response to systemic therapy. This may lead to undertreatment and treatment dissatisfaction. A treat-to-target (T2T) framework was previously proposed to guide systemic treatment decisions in patients with moderate-to-severe AD.¹ While patient representatives were included in the T2T consensus voting process, no patient or caregiver stakeholders were included in the development of the T2T recommendations. Additionally, a recent analysis of the cross-sectional, 28-country MEASURE-AD study suggests that the treatment targets in the T2T criteria may be insufficient to ensure optimal treatment outcomes.²

Objectives: To develop optimized and practical criteria for identifying patients who should receive systemic therapy, including definitions of treatment goals, treatment failure, and disease severity.

Methods: An executive steering committee (ESC) of 7 international experts was formed in January 2021 to provide insights and perspectives on how to optimize the identification of patients who would most benefit from systemic therapy for AD. After discussing the gaps and needs in current AD management, the ESC agreed that there was a lack of evidence on patients' treatment goals, needs, and expectations. The ESC, therefore, initiated a global, ethically, and culturally diverse patient research study (N=88) to collect these insights.

Subsequently, 9 regional sub-committees (SCs) were created to gain clinical perspectives from different regions worldwide (covering the USA and Puerto Rico, Latin America, Western Europe and Canada, Eastern Europe and Russia, the Middle East, Asia, and Australia and New Zealand). Overall, 87 experts from 44 countries contributed to the initiative, and 46 virtual ESC and SC meetings took place to discuss how to improve the lives of patients with AD. A virtual secure platform allowed discussions and contributions to continue outside these meetings.

In April 2022, all experts rated their agreement with a series of recommendations regarding the identification and monitoring of patients eligible for systemic therapy, using a 10-point Likert scale in a modified eDelphi voting process. Consensus was pre-defined as $\geq 70\%$ of all respondents rating agreement as 7 ("mildly agree"), 8 ("moderately agree"), 9 ("agree"), or 10 ("strongly agree") with a recommendation. A strong consensus was defined as $\geq 90\%$ agreement.

Results: Expert perspectives and patient insights led to the development of 34 patient-focused clinical recommendations on disease severity assessments, treatment goals and targets for clinician- and patient-reported outcomes, long-term disease control, and a novel minimal disease activity (MDA) concept. A consensus of $\geq 80\%$ was reached for all recommendations in one round of voting, with 88% of the recommendations reaching a "strong" consensus.

The MDA concept combines T2T principles with shared patient/clinician treatment decision-making principles. Patients are asked to select 1–3 feature(s) of AD which are most important to them (from itch, skin appearance/condition, sleep disturbance, mental health, skin pain, and impact on daily life). The clinician is asked to choose an objective measure of disease (from the Eczema Area and Severity Index [EASI], SCORing AD, and/or the Investigator’s Global Assessment and body surface area). Treatment targets are then chosen from a list of “moderate” and “optimal” targets based on discussions between the clinician and patient (Table 1). Optimal treatment targets include $\geq 90\%$ improvement in EASI and numeric rating scale ≤ 1 for peak pruritus, sleep, and pain. Achievement of “optimal” targets is defined as MDA.

Conclusions: This international group of AD experts developed a novel MDA concept and criteria, which builds upon existing T2T work by providing a patient-centric approach to the optimal treatment of AD. The criteria and patient-focused clinical recommendations will help to identify and monitor patients with AD who could benefit from systemic therapy.

Table 1. Recommended treatment targets for clinician-reported and patient-reported measures

Outcome measure	Moderate target ^a	Optimal target ^a
Clinician-reported measures and targets		
EASI	EASI 75 or EASI ≤ 7 (moderate to severe)	EASI 90 or EASI ≤ 3
SCORAD	SCORAD 50 or SCORAD ≤ 24 (moderate to severe)	SCORAD 75 or SCORAD ≤ 10
IGA and BSA	IGA ≤ 2 and 50% BSA improvement	IGA 0/1 and BSA $\leq 2\%$
Patient-reported measures and targets		
If itch chosen, use peak pruritus NRS	≥ 4 -point improvement (reduction)	≤ 1

If skin appearance/condition chosen, use POEM	≥4-point improvement (reduction)	≤2
If sleep disturbance chosen, use sleep NRS	≥3-point improvement (reduction)	≤1
If mental health chosen, use HADS	HADS-A <11 or HADS-D <11	HADS-A <8 and HADS-D <8
If skin pain chosen, use pain NRS	≥3-point improvement (reduction)	≤1
If impact on daily activities chosen, use DLQI (patients >16 years of age), CDLQI (patients 4–16 years of age), or IDQOL (patients <4 years of age)	≥4-point improvement (reduction)	0/1

*Targets are for all AD severities, unless otherwise specified.

CDLQI, Children’s Dermatology Life Quality Index; BSA, body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS-Anxiety; HADS-D, HADS-Depression; IDQOL, Infants’ Dermatitis Quality of Life; IGA, Investigators’ Global Assessment; NRS, numeric rating scale; POEM, Patient Oriented Eczema Measure; SCORAD, SCORing Atopic Dermatitis.

Keywords: Recommendations, consensus, moderate-severe, systemic therapy

References

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2. De Buin-Weller MS, et al. Br J Dermatol 2022;187 [abstract 185]

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