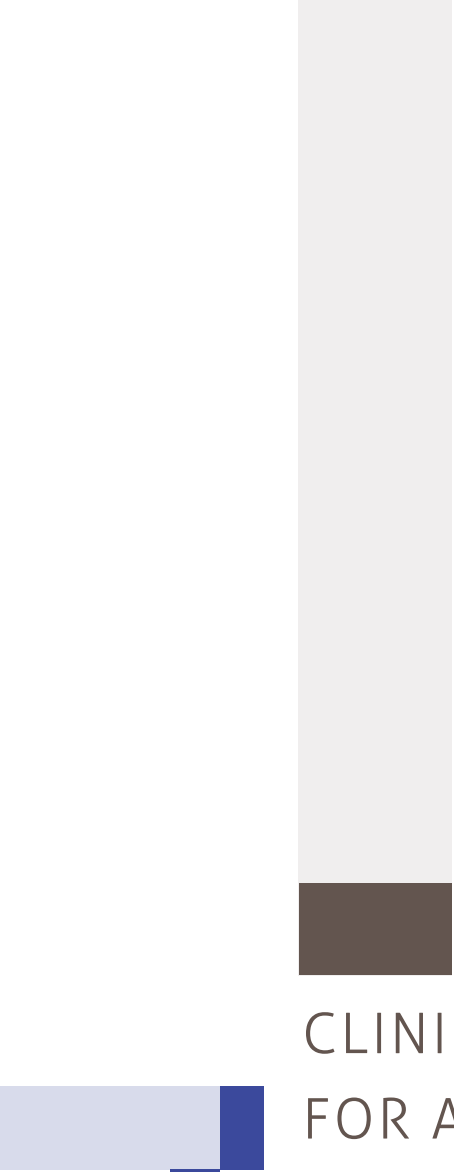


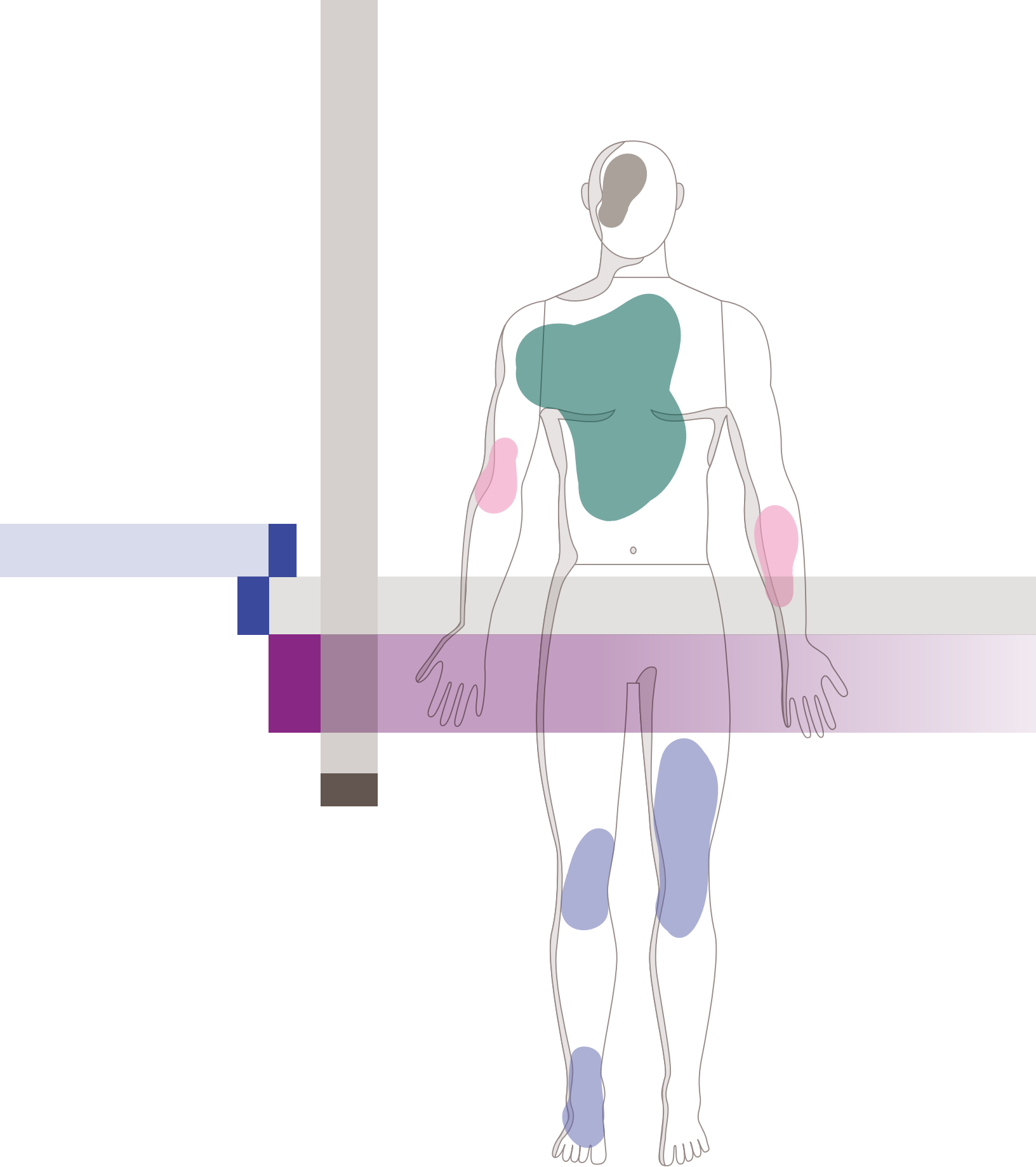


CLINICAL MEASURES AND SCALES
FOR ASSESSING



Atopic Dermatitis







Clinical Scales Used for Assessing Signs and Symptoms of Atopic Dermatitis

IGA

Investigator's Global Assessment

The IGA is a 0- to 4-point scoring system that assesses the **overall severity of the clinical signs** of atopic dermatitis.^{1,2}

The score should reflect the overall assessment (whole body area average) of the **severity of atopic dermatitis in skin lesions**.^{1,2}

The guide on the next few pages provides example photos of patients with varying levels of severity based on the clinical signs and symptoms of atopic dermatitis.

IGA

Investigator's Global Assessment



0

Clear

No inflammatory signs of atopic dermatitis



1

Almost Clear

Just perceptible erythema, and just perceptible papulation/infiltration



2

Mild Disease

Mild erythema and mild papulation/infiltration



3

Moderate Disease

Moderate erythema and moderate papulation/infiltration



4

Severe Disease

Severe erythema and severe papulation/infiltration

EASI

Eczema Area and Severity Index

The EASI scoring system uses a defined process to grade the **severity of the signs of eczema** and the **extent to which the patient is affected**.^{3,4}

1

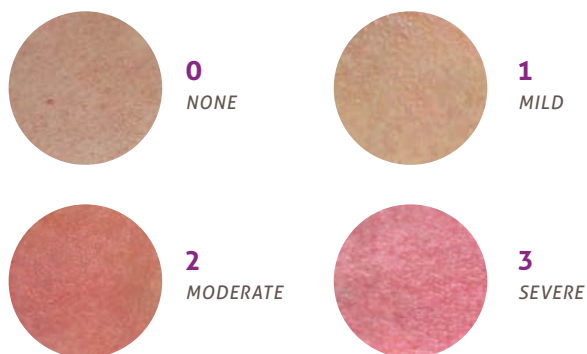
The extent of lesions in each body region is evaluated based on the percentage of involvement and given a value between 0 and 6.

Each body region value is then weighted by a corresponding multiplier; lower extremities are weighted more, and head and neck the least.

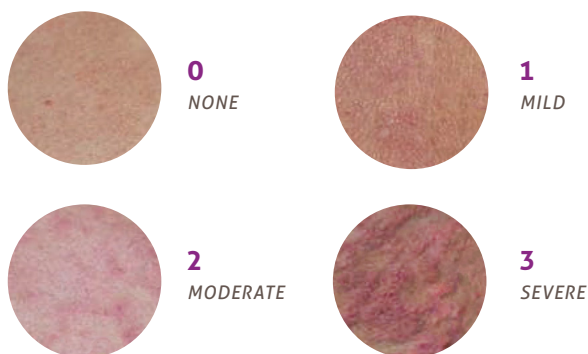
2

These are examples of the severity of each of the signs that are assessed in the chosen body region on a scale of 0 to 3. The images themselves are not part of the EASI scale.

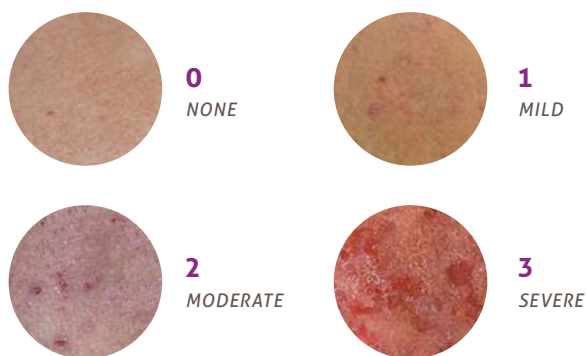
ERYTHEMA



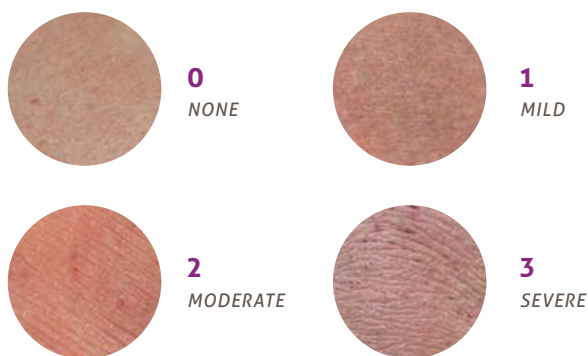
EDEMA/PAPULATION



EXCORIATION



LICHENIFICATION



3

After the extent of lesions and the severity of the signs are scored, the numbers are calculated to produce a composite score on a scale from 0 to 72.

Clear	0
Almost Clear.....	0.1-1.0
Mild	1.1-7.0
Moderate	7.1-21.0
Severe	21.1-50.0
Very Severe.....	50.1-72.0

- This is a mapping of the EASI to an IGA scale of 0 to 5.
- This is different than the IGA scale seen on the previous page.
- A scoring example is provided step-by-step on the next page.

Adapted from Leshem YA, et al. *Br J Dermatol*. 2015;172(5):1353-1357.⁵

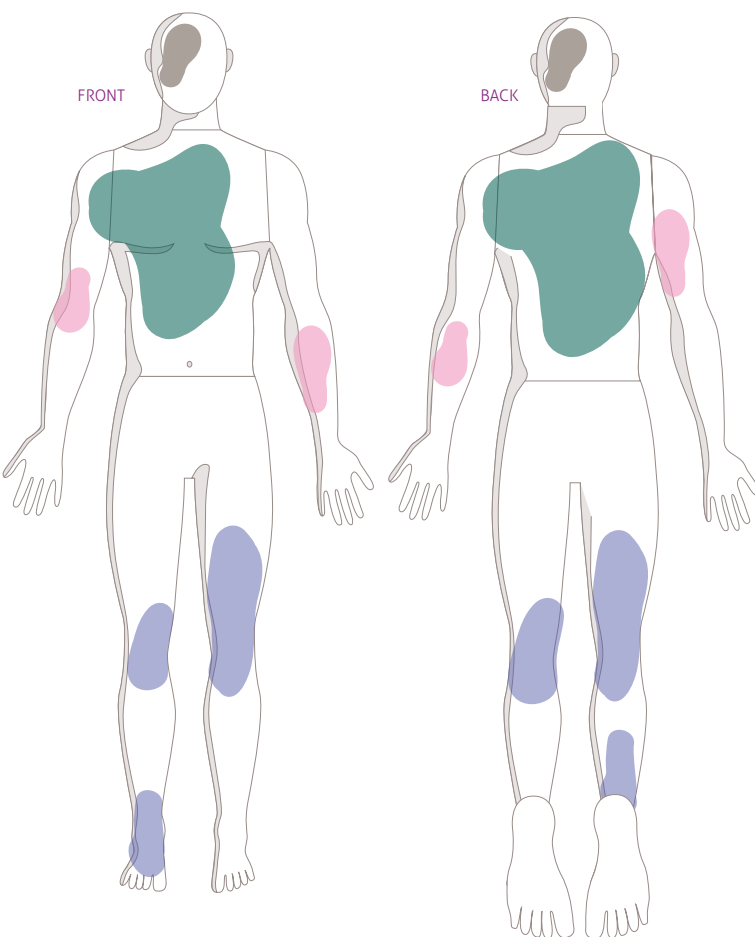
Each region then gets a total region score:

• *Severity score x Area score x Multiplier = Region score*

The final EASI score is the sum of all 4 region scores.

Scoring Example

A 29-year-old man is suffering from moderate-to-severe atopic dermatitis. The lesions cover a portion of his head and neck, as well as portions of his flexural regions on both the upper and lower extremities, while his trunk is rather red and dry.



Head and neck	
Less than 10% of the head and neck is affected	
Area score	1
Moderate erythema.....	2
Moderate edema.....	2
Severe excoriation.....	3
Moderate lichenification.....	2
Severity score	9
Upper extremities	
About 20% of the arms is affected	
Area score	2
Severe erythema.....	3
Severe edema.....	3
Severe excoriation.....	3
Mild lichenification.....	1
Severity score	10
Trunk	
About 60% of the trunk is affected	
Area score	4
Moderate erythema.....	2
Moderate edema.....	2
Moderate excoriation.....	2
Moderate lichenification.....	2
Severity score	8
Lower extremities	
About 20% of the legs is affected	
Area score	2
Severe erythema.....	3
Severe edema.....	3
Severe excoriation.....	3
Moderate lichenification.....	2
Severity score	11

Head
and neck

Upper
extremities

Trunk

Lower
extremities

$$0.9 + 4 + 9.6 + 8.8 = 23.3$$

$$9 \times 1 \times 0.1 = 0.9$$

$$10 \times 2 \times 0.2 = 4$$

$$8 \times 4 \times 0.3 = 9.6$$

$$11 \times 2 \times 0.4 = 8.8$$

Severe atopic
dermatitis

SCORAD

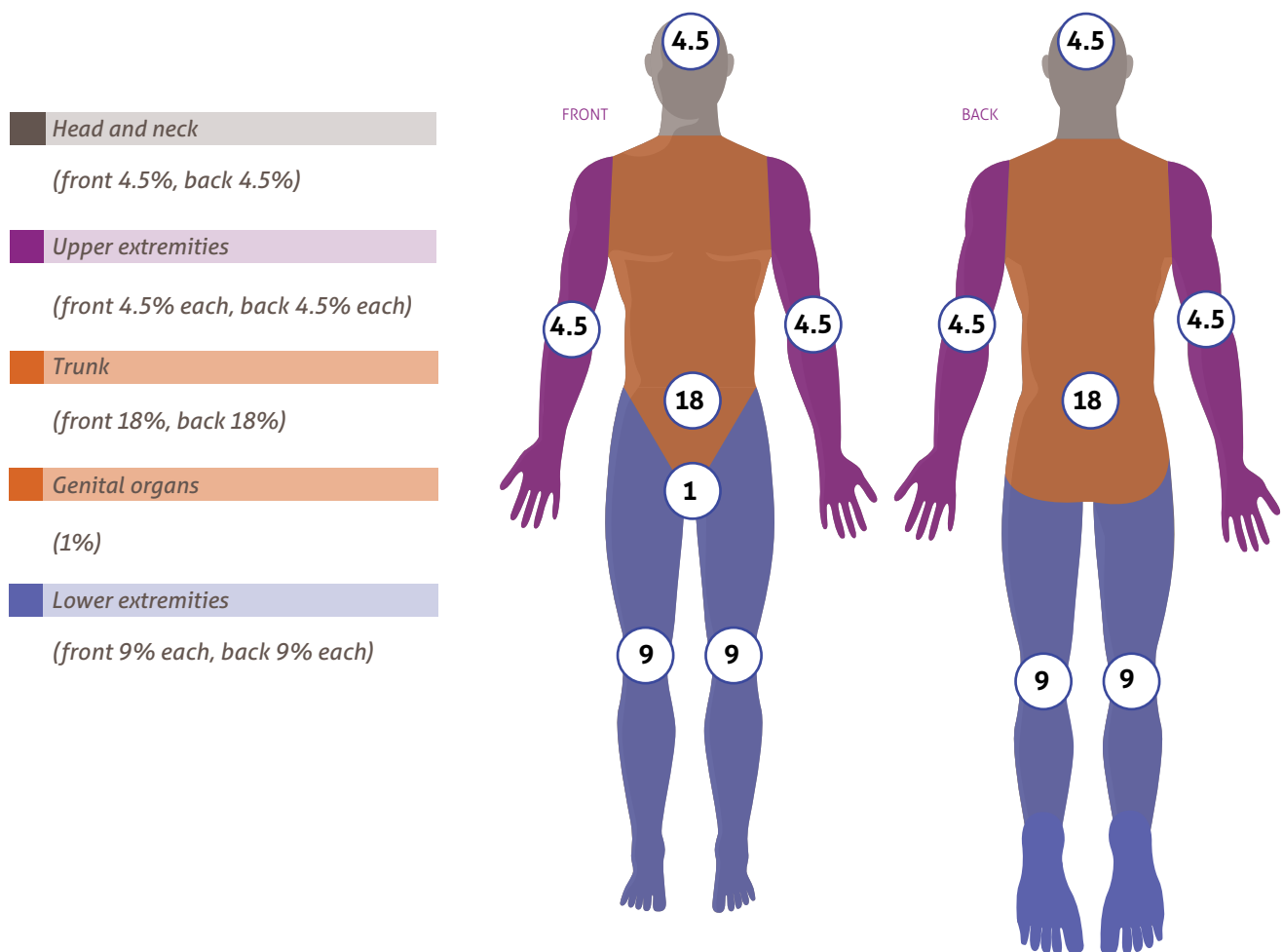
SCORing Atopic Dermatitis

SCORAD is a composite index **assessing the extent and intensity of atopic dermatitis, and the degree of subjective symptoms** (including itching and sleep disturbance). SCORAD combines both a physician's assessment and a patient self-assessment.⁶

SCORAD takes into account **3** components and their respective impact on the severity of atopic dermatitis with corresponding weighting.⁶

1 Affected surface area

The percentage of each body area affected below is assessed and then a value is calculated based on "the rule of 9," which is the percentage assigned to a body part (eg, the head and neck is 9% of the body).



The sum of all body areas is the first component of the **SCORAD** score.

2 Atopic dermatitis rating

The intensity (or severity) of lesions is scored from 0 to 3 based on the following signs:

- Erythema
- Excoriations
- Edema/papulation
- Lichenification
- Oozing/crusting
- Xerosis

*The sum of these scores is the second component of the **SCORAD** score.*

3 Subjective signs with a visual analog scale

Patients are asked to rate the intensity of their pruritus and sleep disturbance. They use a visual analog scale with 0 being none and 10 being the worst.



The final SCORAD score is then calculated using the following formula⁶:

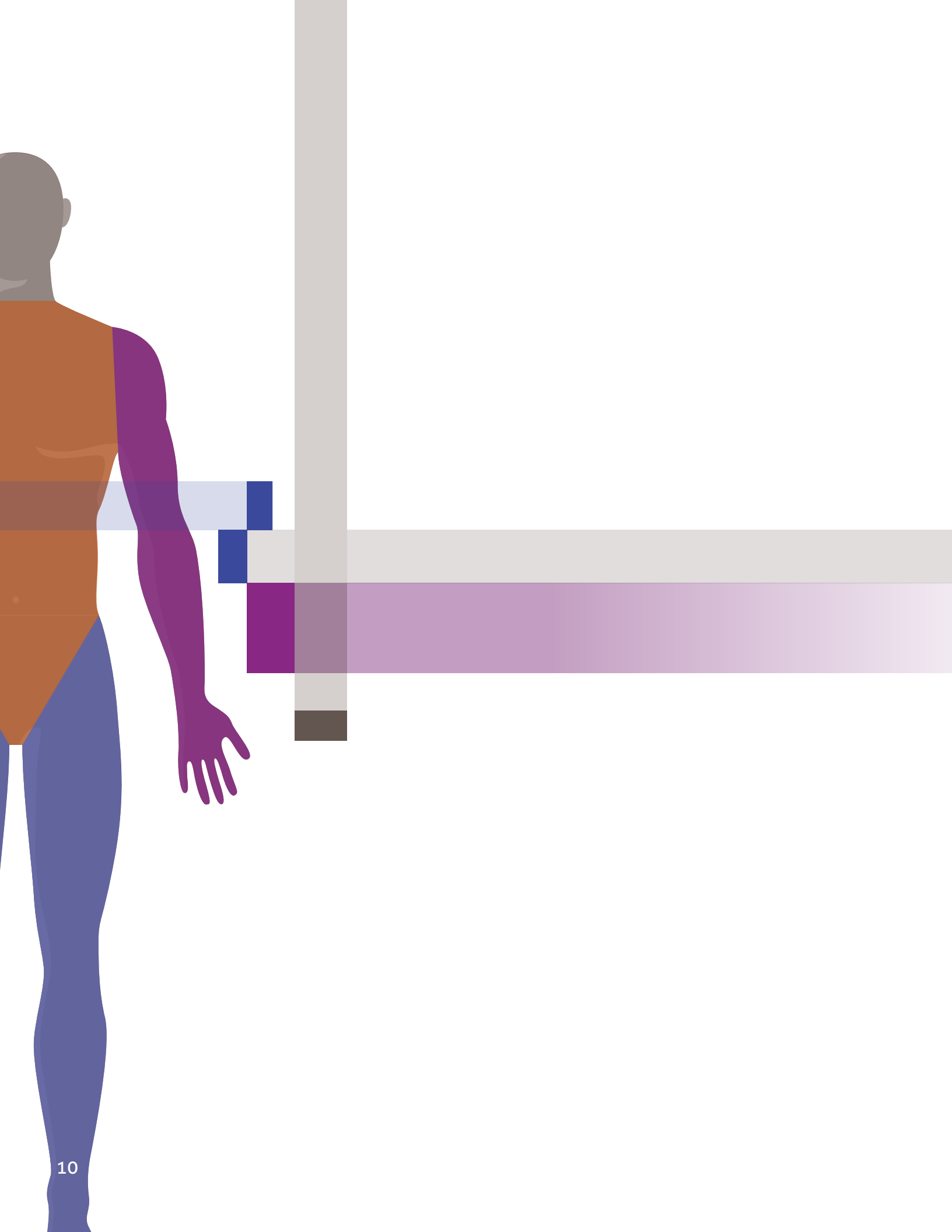
$$\frac{\text{Surface area score}}{5} + \frac{7 \text{ (Intensity score)}}{2} + \text{Subjective sign score} = \text{Final SCORAD score}$$

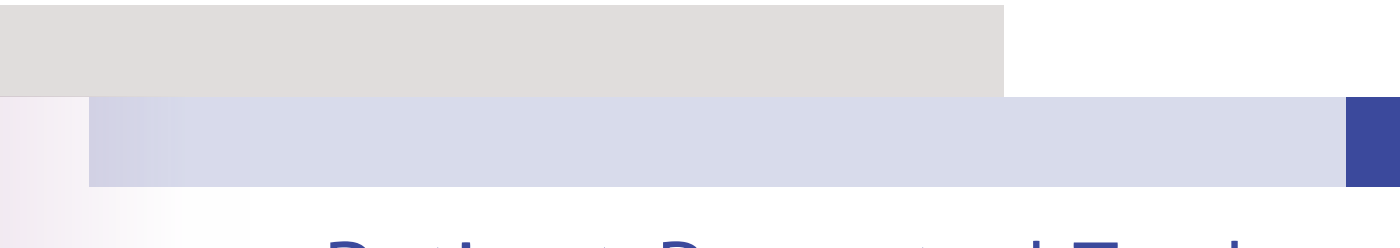
The final SCORAD score represents the patient's atopic dermatitis severity.

Mild <25

Moderate..... 25-50

Severe..... >50





Patient-Reported Tools and Scales for Assessing Atopic Dermatitis or the Burden on the Patient

ADCT

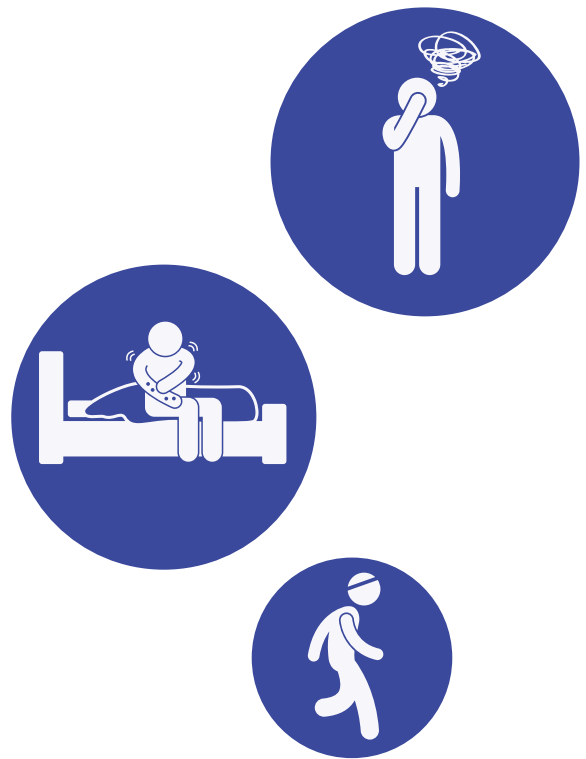
Atopic Dermatitis Control Tool

The ADCT is a patient-reported tool for measuring the **physical and emotional impact** of atopic dermatitis on patients, in order to identify the most helpful treatment plan.²

A patient is asked to fill out a 6-item questionnaire to assess their disease control over the past 7 days. Patients are given the ADCT at baseline and monitored over the following months. Questions are scored on a 5-point scale (0=none at all, and 4=extremely/every day).²

Questions are asked in relation to²:

- Overall symptom severity
- Frequency of intense itching episodes
- How bothersome the disease is
- Frequency of impact on sleep
- Severity of impact on daily activities
- Severity of impact on mood or emotions



Over the last week...

"How would you rate your eczema-related symptoms?"



0	None
1	Mild
2	Moderate
3	Severe
4	Very Severe



*"How many days did you have
intense episodes of itching
because of your eczema?"*

0	Not at all
1	1-2 days
2	3-4 days
3	5-6 days
4	Every day

Scores from each section are added up with a maximum score of 24. Higher ADCT scores indicate worse disease control, while total score-based disease control is defined as an overall score of <7 .²

PRURITUS NRS

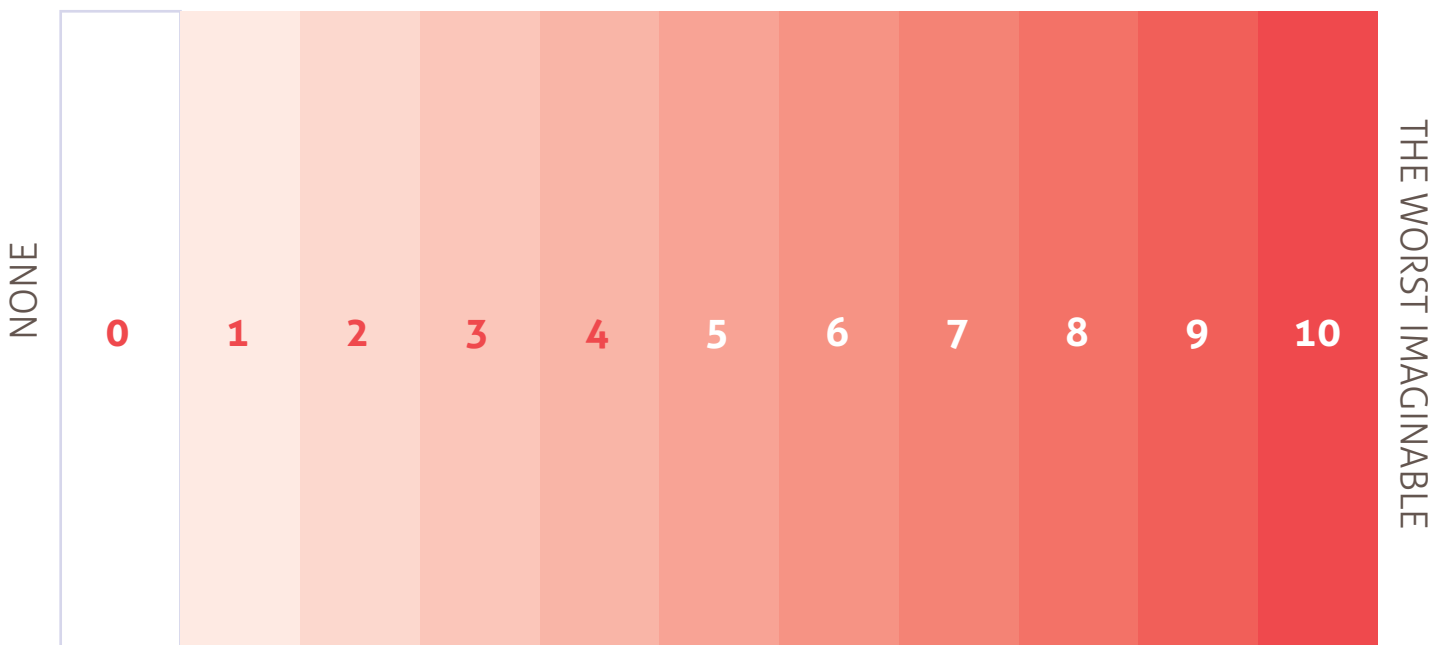
Pruritus Numerical Rating Scale

The pruritus NRS is a **patient-reported measure** that assesses average itch intensity over the previous 24 hours using a 0- to 10-point scale.⁷

Patients are asked:

“On a scale of 0 to 10, how would you rate your itch overall (on average) during the previous 24 hours?”

NUMERICAL RATING SCALE



POEM

Patient-Oriented Eczema Measure

POEM is a patient-reported tool used to **measure the intensity and monitor the frequency** of atopic dermatitis symptoms.⁸

A patient is asked 7 questions, and each question is ranked on a 5-point scale based on the number of days each week that are impacted (0=no days; 4=every day).⁹

- How many days has your skin been...
 - Itchy?
 - Bleeding?
 - Weeping?
 - Cracked?
 - Flaking off?
 - Feeling dry or rough?
- How many nights has your sleep been disturbed?



Each question carries equal weight, and the total is added up with a maximum score of 28. The score represents the patient's atopic dermatitis severity.⁹

Clear or almost clear	0-2
Mild eczema	3-7
Moderate eczema	8-16
Severe eczema	17-24
Very severe eczema	25-28

DLQI and CDLQI

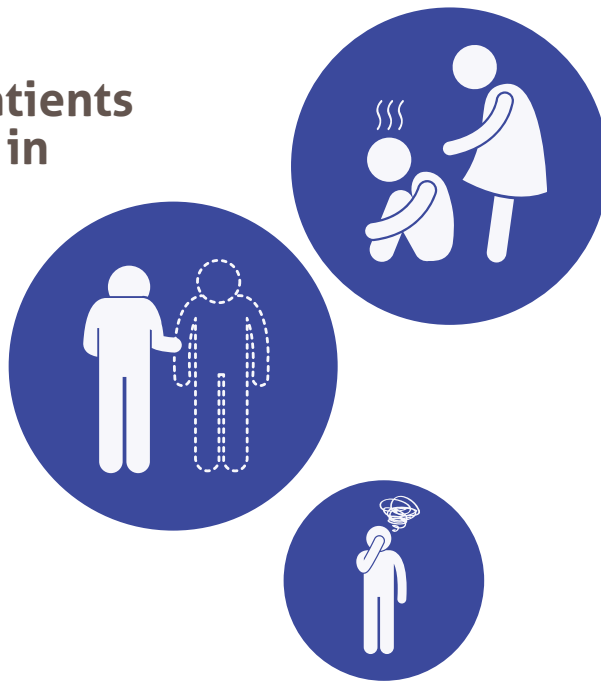
Dermatology Life Quality Index and Children's Dermatology Life Quality Index

The DLQI is a self-assessment tool for patients aged 17 years and older that **measures how skin disease (in this case, atopic dermatitis) symptoms have impacted a patient's quality of life** over a one-week period. The CDLQI was adapted from the DLQI for use in patients aged 4 to 16 years.^{10,11}

Patients are asked to fill out a questionnaire, with each question scored on a 4-point scale (For the DLQI, 0=not at all; 3=very much. For the CDLQI, 0=not at all; 3=very much/prevented school).^{10,11}

In the DLQI, adult patients are asked questions in relation to^{10,11}:

- Physical symptoms
- Social impact
- Emotional stress
- Activity limitation
- Sexual difficulties
- Isolation
- Treatment issues



In the CDLQI, patients aged 4 to 16 years are asked questions in relation to¹¹:

- School
- Sleep
- Physical symptoms
- Influence on clothing
- Activity limitation
- Treatment issues
- Emotional impact (bullying, embarrassment)



An example of a DLQI physical symptoms-based question¹⁰:

“Over the last week, how itchy, sore, painful or stinging has your skin been?”

An example of a CDLQI activity limitation-based question¹²:

“How much has your skin trouble affected going out, playing, or doing hobbies?”

0	Not at all
1	A little
2	Quite a lot
3	Very much

The CDLQI is available in either a **text** or a **cartoon** version.¹¹

For both quality of life assessment tools, once the scores are added up, the total score is interpreted based on the scale below. A higher score (maximum score is 30) indicates a greater impact on quality of life.^{10,11,13}

	DLQI	CDLQI
No effect at all.....	0-2	0-1
Small effect.....	2-5	2-6
Moderate effect.....	6-10	7-12
Very large effect.....	11-20	13-18
Extremely large effect.....	21-30	19-30

HADS

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale is a screening instrument for **clinically significant anxiety and depression**.¹⁴

Patients are asked to score a series of questions about certain physical and emotional aspects in their life. There are 2 types of questions, anxiety based and depression based, which are scored equally. The answers are scored on a 0- to 3-point scale.¹⁴

An example of an anxiety-based question¹⁴:

"I feel tense or wound up."



3	Most of the time
2	A lot of the time
1	From time to time, occasionally
0	Not at all

An example of a depression-based question¹⁴:

"I still enjoy the things I used to enjoy."



3	Hardly at all
2	Only a little
1	Not quite so much
0	Definitely as much

Anxiety and depression scores are tallied individually and represent the patient's level of anxiety/depression.¹³

Normal.....	0-7
Borderline.....	8-10
Borderline high	11-21



References: **1.** Langley GBL, Feldman SR, Nyirady J, van de Kerkhof P, Papavassilis C. The 5-point Investigator's Global Assessment (IGA) Scale: a modified tool for evaluating plaque psoriasis severity in clinical trials. *J Dermatolog Treat.* 2015;26(1):23-31. **2.** Data on file, Regeneron Pharmaceuticals, Inc. **3.** EASI User Guide. HOME—Harmonising Outcome Measures for Eczema website. <http://www.homeforeczema.org/documents/easi-user-guide-dec-2016-v2.pdf>. Accessed August 1, 2019. **4.** Hanifin JM, Thurston M, Omoto M, Cherill R, Tofte SJ, Graeber M; the EASI Evaluator Group. The eczema area and severity index (EASI): assessment of reliability in atopic dermatitis. *Exp Dermatol.* 2001;10(1):11-18. **5.** Leshem YA, Hajar T, Hanifin JM, Simpson EL. What the Eczema Area and Severity Index score tells us about the severity of atopic dermatitis: an interpretability study. *Br J Dermatol.* 2015;172(5):1353-1357. **6.** Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and Three-Item Severity score. *Curr Probl Dermatol.* 2011;41:149-155. **7.** Phan NQ, Blome C, Fritz F, et al. Assessment of pruritus intensity: prospective study on validity and reliability of the visual analogue scale, numerical rating scale and verbal rating scale in 471 patients with chronic pruritus. *Acta Derm Venereol.* 2012;92(5):449-581. **8.** Charman CR, Venn AJ, Williams HC. The patient-oriented eczema measure: development and initial validation of a new tool for measuring atopic eczema severity from the patients' perspective. *Arch Dermatol.* 2004;140(12):1513-1519. **9.** The Patient Oriented Eczema Measure (POEM) scale. Centre of Evidence Based Dermatology. University of Nottingham website. <http://www.nottingham.ac.uk/research/groups/cebd/resources/poem.aspx>. Accessed August 1, 2019. **10.** Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)—a simple practical measure for routine clinical use. *Clin Exp Dermatol.* 1994;19(3):210-216. **11.** Olsen JR, Gallacher J, Finlay AY, Piguet V, Francis NA. Quality of life impact of childhood skin conditions measured using the Children's Dermatology Life Quality Index (CDLQI): a meta-analysis. *Br J Dermatol.* 2016;174(4):853-861. **12.** Children's Dermatology Life Quality Index. Department of Dermatology at Cardiff University School of Medicine website. <https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/childrens-dermatology-life-quality-index>. Accessed August 5, 2019. **13.** DLQI Instructions for use and scoring. Department of Dermatology at Cardiff University School of Medicine website. <http://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>. Accessed August 1, 2019. **14.** Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand.* 1983;67(6):361-370.

In review, a range of clinical and patient-reported tools measure the signs and symptoms of atopic dermatitis.

Clinical Scales

- IGA (Investigator's Global Assessment)¹

Assesses the overall severity of the clinical signs of atopic dermatitis

- EASI (Eczema Area and Severity Index)³

Grades the severity of the signs of eczema and the extent to which the patient is affected

- SCORAD (SCORing Atopic Dermatitis)⁶

Assesses the extent and intensity of atopic dermatitis and degree of subjective symptoms

Patient-Reported Scales

- ADCT (Atopic Dermatitis Control Tool)²

Measures the physical and emotional impact of atopic dermatitis in adult patients to identify an appropriate treatment plan

- Pruritus NRS (Pruritus Numerical Rating Scale)⁷

Assesses average itch intensity over the previous 24 hours using a 0- to 10-point scale

- POEM (Patient-Oriented Eczema Measure)⁸

Measures intensity and monitors frequency of atopic dermatitis symptoms

- DLQI and CDLQI (Dermatology Life Quality Index and Children's Dermatology Life Quality Index)^{10,11}

Measures how skin disease symptoms have impacted a patient's (aged 17+ or 4 to 16 years) quality of life over the last week

- HADS (Hospital Anxiety and Depression Scale)¹⁴

Screens for clinically significant anxiety and depression

