Tralokinumab

We **recommend** tralokinumab in AE patients who are candidates for systemic treatment.	↑↑	**100%** Evidence and consensus based, see Evidence Report

tralokinumab: in licence for ≥ 12 years of age;
age 12-17: initially 600 mg s.c. day 1 followed by 300 mg Q2W
adults: initially 600 mg s.c. day 1 followed by 300 mg Q2W
At prescriber's discretion, every fourth week dosing may be considered for patients who achieve clear or almost clear skin after 16 weeks of treatment.

Certainty of evidence: Network meta-analysis from 2024[1, 2]:
Short term (up to 16 weeks) vs placebo (NMA medications used in clinical practice)

⊕⊕⊕⊕ HIGH for mean difference **POEM** -4.2 (-5, -3.4)
⊕⊕⊕○ MODERATE for mean difference **peak pruritus NRS** -1 (-1.2, -0.7); **DLQI** -2.4 (-3.1, -1.6)
⊕⊕○○ LOW for mean difference **EASI** -6.2 (-7.8, -4.7)

For tralokinumab versus other drugs, see Evidence Report

Mechanisms of action and efficacy

Tralokinumab is a fully human, high affinity IgG4 mAb, which neutralizes IL-13, and has been approved by the EMA in summer 2021.[3] In two 52-week, double-blind, placebo-controlled, phase III trials, adults with moderate-to-severe AE were randomized to subcutaneous tralokinumab 300 mg every 2 weeks or placebo.[4] Tralokinumab monotherapy was superior to placebo at 16 weeks of treatment. Co-primary endpoints were IGA score of 0 or 1 and EASI 75 at week 16. Patient achieving an IGA score of 0/1 and/or EASI 75 with tralokinumab at week 16 were re-randomized to tralokinumab Q2W or every 4 weeks or placebo for 36 weeks. The majority of week 16 tralokinumab-responders maintained response at week 52 with continued tralokinumab treatment without any rescue medication. In a randomised, double-blind, phase 3 trial 301 adolescent patients received either 300 mg or 150 mg of tralokinumab or placebo. After 16 weeks, significantly more patients in the tralokinumab arms showed an EASI 75 response (27.8%, 28.6%, 6.4%) or an IGA of 0 or 1 (17.5%, 21.4%, 4.3%). Subjects achieving a clinical response (IGA = 0, 1; or EASI75) at week 16 without use of rescue medication were re-randomized to maintenance dosing regimens. At 52 weeks, EASI-75 response ranged from 44.4% to 63.3% in the different maintenance dosing regimens.[5]

Dosage: acute flare, short term, long term

The recommended dosage is 300 mg every 2 weeks after a loading dose of 600 mg at treatment onset. At prescriber's discretion, every fourth week dosing may be considered for patients who achieve clear or almost clear skin after 16 weeks of treatment.

Phase III trials have also investigated what happens when patients who do well for 16 weeks on tralokinumab continue treatment as labelled, reduce treatment frequency, or discontinue treatment.

After 16 weeks, patients who reached EASI 75 or IGA success were re-randomized to continue treatment every two weeks, titrate down to every four weeks, or use placebo. At 52 weeks, without TCS, more than 55% of patients who continued twice-monthly treatment maintained EASI 75, as did approximately 50% of patients treated monthly. More than 51% of patients who stayed on twice-

monthly dosing maintained IGA 0 or 1, versus 39% and 45% of patients who switched to monthly dosing.

Safety

In the two studies, adverse events were reported in 76.4% and 61.5% of patients receiving tralokinumab and in 77.0% and 66.0% of patients receiving placebo in the 16-week initial period.

Notably, based on the currently available clinical trial data, tralokinumab appears to have lower rates of ocular complications than dupilumab.[4]

The combination therapy with TCS, TCI and UV light treatment is possible.

Screening and monitoring

The guideline committee considers that biochemical or instrumental investigations are not required for screening or treatment monitoring. This is consistent with the manufacturer's information.

Combination with other treatments

We recommend combining tralokinumab, as any systemic treatment, with emollients and, whenever needed, topical anti-inflammatory treatment in AE patients.

References

1. Drucker AM, Lam M, Prieto-Merino D, Malek R, Ellis AG, Yiu ZZN et al. Systemic Immunomodulatory Treatments for Atopic Dermatitis: Living Systematic Review and Network Meta-Analysis Update. *JAMA Dermatol* 2024;160(9):936–44.
2. Drucker AM. Systemic immunomodulatory treatments for atopic dermatitis: a living systematic review and network meta-analysis. 2022. Available at: https://eczematherapies.com/research/ (last accessed 12 May 2025).
3. Popovic B, Breed J, Rees DG, Gardener MJ, Vinall LM, Kemp B et al. Structural Characterisation Reveals Mechanism of IL-13-Neutralising Monoclonal Antibody Tralokinumab as Inhibition of Binding to IL-13Rα1 and IL-13Rα2. *J Mol Biol* 2017;429(2):208–19.
4. Wollenberg A, Blauvelt A, Guttman-Yassky E, Worm M, Lynde C, Lacour JP et al. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). *Br J Dermatol* 2021;184(3):437–49.
5. ClinicalTrials.gov. Tralokinumab Monotherapy for Adolescent Subjects With Moderate to Severe Atopic Dermatitis - ECZTRA 6 (ECZema TRAlokinumab Trial no. 6). 2021. Available at: https://clinicaltrials.gov/ct2/show/results/NCT03526861?term=ECZTRA+6&draw=2&rank=1 (last accessed 25.11.2022).