Nemolizumab

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

nemolizumab: in licence for ≥ 12 years of age
dosage: initially 60 mg s.c. day 1 followed by 30 mg s.c. Q4W
After 16 weeks of treatment, for patients who achieve clinical response, the recommended maintenance dose is 30 Q8W

Certainty of evidence: Network meta-analysis from 2025[1]

Short term (up to 16 weeks) vs placebo (NMA medications used in clinical practice)

⊕⊕⊕◯ MODERATE for mean difference **EASI** -4.4 (-6.5, -2.4); **POEM** -3.9 (-5.1, -2.8); **DLQI** -2.4 (-3.4, -1.3); **peak pruritus NRS** -2 (-2.4, -1.6)

For nemolizumab versus other drugs, see Evidence Report

Mechanisms of action and efficacy

Nemolizumab is a humanized mAb targeting the IL-31 receptor alpha chain (IL-31RA), which was initially developed for the treatment of AE-related pruritus.

In two randomized, double-blind, placebo-controlled phase 3 trials (ARCADIA 1 and 2), a total of 1,728 adults and adolescents (aged ≥12 years) with moderate-to-severe AE and associated pruritus were enrolled. All participants had previously shown an inadequate response to TCS treatment. Patients received either 30 mg nemolizumab Q4W, with an initial loading dose of 60 mg, or placebo injections, alongside TCS and, in some cases, TCI. Randomization was conducted in a 2:1 ratio for nemolizumab versus placebo. At week 16, 44% (270/620) and 42% (220/522) of patients treated with nemolizumab achieved an EASI-75 response compared to 29% (93/321) and 30% (80/265) of patients receiving placebo. Similarly, the proportion of patients achieving IGA success (defined as an IGA score of 0 or 1 with a reduction of at least 2 points) was significantly higher in the nemolizumab groups than in the placebo groups. Significant benefits were also observed for secondary endpoints, with consistent improvements in pruritus and sleep disturbance.[2]

Patients who achieved a clinical response (IGA success or EASI-75) at week 16 were re-randomized (1:1:1) to receive nemolizumab 30 mg Q4W, nemolizumab 30 mg Q8W, or placebo for additional 32 weeks. During this period, additional topical anti-inflammatory therapy was also permitted. At week 48, a higher proportion of patients maintained IGA success in the nemolizumab Q4W (61.5%) and Q8W (60.4%) groups compared to the placebo group (49.7%). Similarly, EASI-75 response rates were higher in the nemolizumab Q4W (76.3%) and Q8W (75.7%) groups compared to placebo (63.9%).[3]

Dosage: acute flare, short term, long term

Global phase III trials investigated the nemolizumab 30 mg Q4W dose administered up to week 16 with a loading dose of 60 mg at baseline and showed positive outcomes. After week 16, clinical responders did not show a clinical difference with the Q4W and Q8W maintenance regimen.[2]

Safety

In the two mentioned phase 3 trials the frequency of adverse events was comparable between patients receiving nemolizumab and those given a placebo.[2]

The most common treatment-emergent adverse event was worsening of AE in 12% (75/616) participants in the nemolizumab group vs 11% (34/321) in the placebo group in ARCADIA 1; and 7% (37/519) vs 6% (15/263), respectively, in ARCADIA 2.

Asthma events occurred in both groups in both studies. However, it should be noted that more than 30% of all included patients reported pre-existing asthma.

In both studies, hypersensitivity reactions (urticaria) were noted. Non-serious and mild urticaria was reported in 1% and 2% patients receiving nemolizumab vs <1% patient receiving placebo in ARCADIA 1 and ARCADIA 2. Nemolizumab was not discontinued due to any of these events.[2]

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 nemolizumab, as any systemic treatment, with emollients and, whenever needed, topical anti-inflammatory treatment in AE patients.

References

1. 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).
2. Silverberg JI, Wollenberg A, Reich A, Thaçi D, Legat FJ, Papp KA et al. Nemolizumab with concomitant topical therapy in adolescents and adults with moderate-to-severe atopic dermatitis (ARCADIA 1 and ARCADIA 2): results from two replicate, double-blind, randomised controlled phase 3 trials. *Lancet* 2024;404(10451):445–60.
3. Silverberg JI, Wollenberg A, Legat FJ, Laquer VT, Armstrong AW, Herranz P et al. 667-Maintenance of efficacy and safety with nemolizumab at week 48: results from two global phase 3 pivotal studies (ARCADIA-1 and ARCADIA-2) in patients with moderate-to-severe atopic dermatitis. *British Journal of Dermatology* 2024;191(Supplement_2):ljae266. 041.