NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Topical tapinarof for treating atopic dermatitis in people 2 years and over ID6713

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of topical tapinarof within its marketing authorisation for treating atopic dermatitis in people 2 years and over.

Background

Atopic dermatitis (also known as atopic eczema) is a chronic inflammatory skin condition characterised by itchy and inflamed skin, often associated with background dryness. The skin may also ooze, crust or become weepy. Symptoms may present differently in people with different skin tones. Persistent scratching can cause the skin to split and bleed, increasing the risk of skin infection. Atopic dermatitis can affect any part of the body, but in adults it commonly affects the hands, face, neck and flexural areas.[1]

Estimates of the prevalence of atopic dermatitis vary. It is more common in childhood, affecting around 15% to 20% of children, and around 1% to 3% of adults in the UK.[2,3] Of people with atopic dermatitis, around 8% have moderate to severe disease, and many of these (about 62%) may require systemic treatment.[3]

Atopic dermatitis is usually managed in primary care, but uncontrolled moderate-to-severe disease may require referral to secondary care. Treatment strategies include advice on avoiding triggers, such as soaps and irritants, and regular use of emollients to moisturise the skin and relieve symptoms. For flares, or dermatitis that does not respond adequately to these measures, topical corticosteroids are commonly used (NICE technology appraisal guidance 81), with continued emollient therapy. Second-line topical options include topical calcineurin inhibitors such as pimecrolimus and tacrolimus (NICE technology appraisal guidance 82). Phototherapy and photochemotherapy (psoralen plus ultraviolet A; PUVA) may be used in selected adults and older children with moderate to severe disease.[4]

People with moderate or severe atopic dermatitis that does not respond adequately to topical treatment may be referred to secondary care and offered conventional systemic immunomodulatory medicines, including methotrexate and sometimes ciclosporin.[5]

If the condition does not respond to systemic immunosuppressants, or if these treatments are not tolerated or are unsuitable, biological medicines or Janus kinase (JAK) inhibitors may be offered for moderate to severe atopic dermatitis, in line with NICE technology appraisal guidance. These include baricitinib (TA681), dupilumab (TA534), lebrikizumab (TA986), nemolizumab (TA1077), abrocitinib, tralokinumab and upadacitinib (TA814), subject to the eligibility criteria set out in the relevant guidance.

The technology

Topical tapinarof (VTAMA, Organon Pharma) does not currently have a marketing authorisation in the UK for the treatment of atopic dermatitis. It has been studied in adults and children with moderate to severe atopic dermatitis in clinical trials comparing topical tapinarof with vehicle cream. It has also been studied in a single arm extension study in people with mild to severe atopic dermatitis.

Intervention(s)	Topical tapinarof
Population(s)	People with atopic dermatitis
Subgroups	If evidence allows the following subgroups will be considered: • Disease severity • People with atopic dermatitis affecting the hands • Skin colour subgroups
Comparators	• topical corticosteroids • topical cacineurin inhibitors (pimecrolimus, tacrolimus) • phototherapy and photochemotherapy (psoralen–ultraviolet A; PUVA) • ruxolitinib (subject to NICE evaluation) For people who have not previously had a systemic therapy: • immunosuppressive therapies (azathioprine, ciclosporin, methotrexate, mycophenolate mofetil) For people whose condition has not responded to at least 1 other systemic therapy, or these are not suitable: • biological medicines (dupilumab, lebrikizumab, nemolizumab, tralokinumab) • JAK inhibitors (abrocitinib, baricitinib, upadacitinib)
Outcomes	The outcome measures to be considered include: • measures of disease severity • measures of symptom control including improvement in itch • disease free period/maintenance of remission • time to relapse/prevention of relapse • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Delgocitinib for treating moderate to severe chronic hand eczema (2025) NICE technology appraisal guidance 1107. Nemolizumab for treating moderate to severe atopic dermatitis in people 12 years and over (2025) NICE technology appraisal guidance 1077. Lebrikizumab for treating moderate to severe atopic dermatitis in people 12 years and over (2024) NICE technology appraisal guidance 986. Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis (2022) NICE technology appraisal guidance 814. Baricitinib for treating moderate to severe atopic dermatitis (2021) NICE technology appraisal guidance 681. Dupilumab for treating moderate to severe atopic dermatitis (2018) NICE technology appraisal guidance 534. Alitretinoin for the treatment of severe chronic hand eczema (2009) NICE technology appraisal guidance 177. Tacrolimus and pimecrolimus for atopic eczema (2004) NICE technology appraisal guidance 82. Frequency of application of topical corticosteroids for atopic eczema (2004) NICE technology appraisal guidance 81. **Related technology appraisals in development:**

	Ruxolitinib for treating moderate atopic dermatitis. NICE technology appraisal guidance [ID6602] Publication date to be confirmed. **Related NICE guidelines:** Secondary infection of common skin conditions including eczema: antimicrobial prescribing (2021) NICE guideline NG190. **Related quality standards:** Atopic eczema in under 12s (2013) NICE quality standard 44.

Questions for consultation

Where do you consider topical tapinarof will fit into the existing care pathway for atopic dermatitis?

Should chronic hand eczema be considered within the scope of atopic dermatitis for the purposes of this evaluation, particularly when the hands are the primary site of condition? If so, are delgocitinib and alitretinoin relevant comparators?

Please select from the following, will topical tapinarof be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would topical tapinarof be a candidate for managed access?

Do you consider that the use of topical tapinarof can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which topical tapinarof will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. NHS (2024) Atopic eczema. Accessed May 2026.

2. BMJ Best Practice (2026) Eczema: Epidemiology. Accessed May 2026.

3. Kleyn C.E, McKenzie R, Meeks A, et al. (2023) Prevalence and treatment patterns of adult atopic dermatitis in the UK Clinical Practice Research Datalink Skin Health and Disease 10;3(4):e232.

4. Simpson EL, Bruin-Weller M, Flohr C, et al. (2017) When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. Journal of the American Academy of Dermatology 2017; 77(4):623-633.

5. British Association of Dermatologists (2025) Atopic eczema. Accessed May 2026.