NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Delgocitinib for treating moderate to severe chronic hand eczema

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of delgocitinib within its marketing authorisation for treating moderate to severe chronic hand eczema.

Background

Hand eczema (also known as hand dermatitis) is an inflammatory skin condition that causes the hands to become dry, itchy and cracked. Inflamed skin may appear red or darker than the surrounding skin, and scaling, soreness, weeping and bleeding of the affected skin may also occur. Cracks in the skin from hand eczema may increase susceptibility to infection, and severe cases of hand eczema may affect mobility and use of the hands.[1]

Hand eczema may be acute or chronic depending on the cause. The condition can be classified into atopic hand eczema, caused by genetic or endogenous factors, and contact dermatitis which is caused by exposure to irritants or allergens. Hand eczema may also be caused by a combination of these elements. Hand eczema affects around 10% of the general population and up to 30% of people in high-risk occupational groups such as healthcare workers. Between one third and one half of hand eczema cases are moderate or severe.[2,3]

Treatment aims to restore normal skin, reduce symptoms and improve hand function. Current standard care for hand eczema includes regular application of emollients. Moderate to severe hand eczema is typically treated with potent topical corticosteroids or calcineurin inhibitors during an acute episode. Eczema that has not responded to topical corticosteroids may be treated with a short course of immunosuppressants (such as azathioprine, ciclosporin or methotrexate), and/or ultraviolet light therapy.

NICE technology appraisal guidance 177 recommends alitretinoin as a treatment option for adults with severe chronic hand eczema that has not responded to potent topical corticosteroids if the person has severe disease, as defined by the physician's global assessment (PGA) and a dermatology life quality index (DLQI) score of 15 or more.

The technology

Delgocitinib (brand name unknown, Leo Pharma) does not currently have a marketing authorisation in the UK. It has been studied in clinical trials comparing delgocitinib with placebo in adults with moderate to severe chronic hand eczema that has not responded to treatment with topical corticosteroids or for whom topical corticosteroids are not advisable.

Intervention(s)	Delgocitinib
Population(s)	Adults with moderate to severe chronic hand eczema that has not responded to treatment with topical corticosteroids or for whom topical corticosteroids are not advisable
Subgroups	• Primary cause of hand eczema (atopic or contact) • Moderate vs severe disease • Inadequate response to topical corticosteroids vs topical corticosteroids not advisable
Comparators	• Alitretinoin (in severe hand eczema) • Ultraviolet light therapy (PUVA) • Systemic immunosuppressive therapies (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil)
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 of any managed access arrangement for the intervention 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:** Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis. (2022) NICE technology appraisal 814. Baricitinib for treating moderate to severe atopic dermatitis (2021) NICE technology appraisal 681. Dupilumab for treating moderate to severe atopic dermatitis (2018) NICE technology appraisal 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:** Lebrikizumab for treating moderate to severe atopic dermatitis in people 12 years and over. NICE technology appraisal guidance [ID4025] Publication date to be confirmed **Related NICE guidelines:** Secondary infection of common skin conditions including eczema: antimicrobial prescribing (2021) NICE guideline NG190. **Related interventional procedures:** Grenz rays therapy for inflammatory skin conditions (2007) NICE interventional procedures guidance 236.
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2023) Manual for prescribed specialist services (2023/2024)

Questions for consultation

Where do you consider delgocitinib will fit into the existing care pathway for moderate to severe hand eczema?

Is there a difference in the way hand eczema is treated depending on the cause (atopic or contact)?

Please select from the following, will delgocitinib 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.

Are there any other potential comparators specifically for hand eczema that has not responded to treatment with topical corticosteroids, or for people with hand eczema for whom topical corticosteroids are not advisable?

Would people with moderate to severe hand eczema be eligible for treatments for moderate to severe atopic dermatitis?

Are there any differences between the relevant comparators depending on whether hand eczema is moderate or severe?

Would delgocitinib be a candidate for managed access?

Do you consider that the use of delgocitinib 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.

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 delgocitinib 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. National Eczema Society (2023) Hand eczema. Accessed May 2024.

2. Quaade AS, Simonsen AB, Halling AS et al. (2021) Prevalence, incidence, and severity of hand eczema in the general population–a systematic review and meta-analysis. Contact Dermatitis 84(6):361-74.

3. Yüksel YT, Symanzik C, Christensen MO et al. (2024) Prevalence and incidence of hand eczema in healthcare workers: A systematic review and meta-analysis. Contact Dermatitis 90:331–42.