NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Lebrikizumab for treating moderate to severe atopic dermatitis in people 12 years and over

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of lebrikizumab within its marketing authorisation for treating moderate to severe atopic dermatitis in people 12 years and over.

Background

Atopic dermatitis (also known as atopic eczema) is a long-term condition that affects the skin. It is characterised by a red blotchy rash, dry, itchy and inflamed skin. The skin can also ooze and weep. Constant scratching can cause the skin to split and bleed, which can cause skin infections. Severe dermatitis can be physically disabling or incapacitating and can cause anxiety or depression.

Estimates of the prevalence of atopic dermatitis vary. It is more common in childhood (affecting 1 in 5 children in the UK) and affects 1 in 10 adults in the UK.[1] Of the people who need treatment for atopic dermatitis, 7% will have moderate to severe disease and around 60% of these people will need a systemic treatment rather than an ointment.[2]

Atopic dermatitis is usually managed in primary care. Treatment strategies include advice on the avoidance of factors that can provoke dermatitis, such as soap, and the use of emollients to moisturise and relieve symptoms. For flares, or dermatitis that does not respond to these measures, topical corticosteroids are normally prescribed once or twice daily in conjunction with continued use of emollients as recommended in Technology Appraisal 81.

Two calcineurin inhibitors (tacrolimus and pimecrolimus) are recommended as second-line treatment options when the disease has not been adequately controlled by the use of topical steroids at the maximum strength and potency or where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy (TA82). Tacrolimus ointment is recommended for treating moderate to severe atopic dermatitis in people aged 2 years and older, while pimecrolimus cream is recommended for treating moderate disease on the face and neck in children aged 2 to 16 years (TA82). Alitretinoin is recommended as a possible treatment for adults with severe chronic hand dermatitis affecting their quality of life and not responding to potent topical corticosteroids (TA177). In addition, phototherapy and photochemotherapy (psoralen–ultraviolet A; PUVA) can be used to manage moderate to severe atopic dermatitis in selected adults and older children.[3]

People with moderate or severe dermatitis not responding to topical treatments may be referred to secondary care and treated with stronger oral medications such as oral

steroids, systemic immunosuppressants (azathioprine, ciclosporin, mycophenolate mofetil and methotrexate).[4]

Abrocitinib (TA814), tralokinumab (TA814), upadacitinib (TA814) and dupilumab (TA534) are recommended as options for treating moderate to severe atopic dermatitis in adults and young people 12 years and over whose disease has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated.

Baricitinib is recommended as an option for treating moderate to severe atopic dermatitis in adults whose disease has not responded to at least 1 other systemic therapy (TA681).

The technology

Lebrikizumab (brand name unknown, Almirall) does not currently have a marketing authorisation for atopic dermatitis. It has been studied in a range of phase III clinical trials in people with moderare to severe atopic dermatitis, aged from 6 months to 18 years and over.

Intervention(s)	Lebrikizumab
Population(s)	People with moderate to severe atopic dermatitis
Subgroups	If the evidence allows the following subgroups will be considered: • people with atopic dermatitis affecting the hands; • people for whom systemic therapies have been inadequately effective, not tolerated or contraindicated; • skin colour subgroups.

Comparators	Established clinical management (combination of emollients, low to mid potency topical corticosteroids, and rescue therapy including higher potency topical or oral corticosteroids or topical calcineurin inhibitors) as well as: • Phototherapy including with ultraviolet (UVB) radiation or psoralen-ultraviolet A (PUVA) • Immunosuppressive therapies (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil) • Alitretinoin (in people with atopic dermatitis affecting the hands) • Abrocitinib • Tralokinumab • Upadacitinib • Dupilumab • Baricitinib
Outcomes	The outcome measures to be considered include: • measures of disease severity • measures of symptom control • 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. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. 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:** 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. Review date 2024. Dupilumab for treating moderate to severe atopic dermatitis (2018) NICE Technology Appraisal 534. Review date: 2021. Alitretinoin for the treatment of severe chronic hand eczema (2009) NICE technology appraisal guidance 177. On static list. Tacrolimus and pimecrolimus for atopic eczema (2004) NICE technology appraisal guidance 82. On static list. Frequency of application of topical corticosteroids for atopic eczema (2004) NICE technology appraisal guidance 81. On static list.

	Related technology appraisals in development: Nemolizumab for treating moderate to severe atopic dermatitis in people aged 12 and over or prurigo nodularis in adults. NICE technology appraisal guidance [ID10515]. Publication date to be confirmed. **Related NICE guidelines:** Atopic eczema in under 12s: diagnosis and management (2007) NICE guideline CG57. Secondary infection of common skin conditions including eczema: antimicrobial prescribing. NICE guideline NG190. **Related NICE guidelines in development:** Atopic Dermatitis (Eczema). NICE guideline. Publication date to be confirmed. **Related interventional procedures:** Grenz rays therapy for inflammatory skin conditions (2007) NICE interventional procedures guidance 236. **Related quality standards:** Atopic eczema in under 12s (2013). NICE quality standard 44.
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2018) NHS manual for prescribed specialist services (2018/2019) Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2,4,5 NHS England (2013) 2013/14 NHS standard contract for specialised allergy services (all ages). Service specification No: B09/S/b NHS England (2013) 2013/14 NHS standard contract for specialised dermatology services (all ages). Service specification No: A12/S/a NHS England (2017) Commissioning medicines for children in specialised services policy

Questions for consultation

Where do you consider lebrikizumab will fit into the existing care pathway for moderate to severe atopic dermatitis?

What is the impact of the safety update issued by the MHRA regarding JAK inhibitors on the treatment pathway for moderate to severe atopic dermatitis?

For a person needing systemic therapy to treat their atopic dermatitis would lebrikizumab be used as a first systemic treatment or after immunosuppressive therapies (such as ciclosporin, methotrexate, azathioprine)?

Is lebrikizumab likely to be used in combination with topical corticosteroids or as a monotherapy in clinical practice?

Have all relevant comparators for lebrikizumab been included in the scope?

Which treatments are considered to be established clinical practice in the NHS for moderate to severe atopic dermatitis in people aged 12 years and over? Do the treatments considered to be established clinical practice differ between people aged 12-17 and adults?

How should established clinical management be defined?

Are the outcomes listed appropriate?

Are the subgroups suggested appropriate? Are there any other subgroups of people in whom lebrikizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Would lebrikizumab be a candidate for managed access?

Do you consider that the use of lebrikizumab 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 lebrikizumab 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-tehnology-appraisal-guidance/changes-to-health-technology-evaluation).

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?
- Overall in the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

References

1. National Eczema Society. Our skin and eczema. Accessed April 2023
2. National Institute for Health and Care Excellence (2022) Resource impact report: Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis (TA814) . Accessed April 2023.
3. Simpson EL, Bruin-Weller M, Flohr C, Ardern-Jones MR, Barbarot S et al. 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.
4. British Association of Dermatologists (2022) Atopic eczema. Accessed April 2023.