

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

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

#### Final scope

#### 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 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.<sup>1</sup> 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.<sup>2</sup>

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](#)). Since the publication of [TA82](#), the marketing authorisation for pimecrolimus cream has been extended to include people aged 3 months and older. 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.<sup>3</sup>

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

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medications such as oral steroids, systemic immunosuppressants (azathioprine, ciclosporin, mycophenolate mofetil and methotrexate).<sup>4</sup>

Abrocitinib ([TA814](#)) and upadacitinib ([TA814](#)) 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.

Dupilumab ([TA534](#)), baricitinib ([TA681](#)) and tralokinumab ([TA814](#)) are recommended as options for treating moderate to severe atopic dermatitis in adults whose disease has not responded to at least 1 other systemic therapy. Since the publication of [TA534](#) and [TA814](#) the marketing authorisations for dupilumab and tralokinumab, respectively have been extended to include people aged 12 to 17 years, and are commissioned by NHS England for this group.

### The technology

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

<b>Intervention(s)</b>	Lebrikizumab
<b>Population(s)</b>	People 12 years and over with moderate to severe atopic dermatitis who are candidates for systemic therapy
<b>Comparators</b>	<p>People for whom systemic therapy is suitable and have not previously received a systemic therapy:</p> <ul style="list-style-type: none"> <li>Immunosuppressive therapies (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil)</li> </ul> <p>People whose condition has not responded to at least 1 other systemic therapy, or these are not suitable:</p> <ul style="list-style-type: none"> <li>Abrocitinib</li> <li>Tralokinumab</li> <li>Upadacitinib</li> <li>Dupilumab</li> <li>Baricitinib</li> </ul>

<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• measures of disease severity</li> <li>• measures of symptom control</li> <li>• disease free period/maintenance of remission</li> <li>• time to relapse/prevention of relapse</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<b>Other considerations</b>	<p>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.</p>
<b>Related NICE recommendations</b>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Abrocitinib, tralokinumab or upadacitinib for treating moderate to severe atopic dermatitis.</a> (2022) NICE technology appraisal 814.</p> <p><a href="#">Baricitinib for treating moderate to severe atopic dermatitis</a> (2021) NICE Technology Appraisal 681. Review date 2024.</p> <p><a href="#">Dupilumab for treating moderate to severe atopic dermatitis</a> (2018) NICE Technology Appraisal 534. Review date: 2021.</p> <p><a href="#">Alitretinoin for the treatment of severe chronic hand eczema</a> (2009) NICE technology appraisal guidance 177. On static list.</p>

	<p><a href="#">Tacrolimus and pimecrolimus for atopic eczema</a> (2004) NICE technology appraisal guidance 82. On static list.</p> <p><a href="#">Frequency of application of topical corticosteroids for atopic eczema</a> (2004) NICE technology appraisal guidance 81. On static list.</p> <p><b>Related technology appraisals in development:</b></p> <p><a href="#">Nemolizumab for treating moderate to severe atopic dermatitis in people aged 12 and over or prurigo nodularis in adults</a>. NICE technology appraisal guidance [ID10515]. Publication date to be confirmed.</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Atopic eczema in under 12s: diagnosis and management</a> (2007) NICE guideline CG57.</p> <p><a href="#">Secondary infection of common skin conditions including eczema: antimicrobial prescribing</a>. NICE guideline NG190.</p> <p><b>Related NICE guidelines in development:</b></p> <p><a href="#">Atopic Dermatitis (Eczema)</a>. NICE guideline. Publication date to be confirmed.</p> <p><b>Related interventional procedures:</b></p> <p><a href="#">Grenz rays therapy for inflammatory skin conditions</a> (2007) NICE interventional procedures guidance 236.</p> <p><b>Related quality standards:</b></p> <p><a href="#">Atopic eczema in under 12s</a> (2013). NICE quality standard 44.</p>
<p><b>Related National Policy</b></p>	<p>The NHS Long Term Plan (2019) <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2018) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a></p> <p><a href="#">Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2,4,5</a></p> <p><a href="#">NHS England (2013) 2013/14 NHS standard contract for specialised allergy services (all ages). Service specification No: B09/S/b</a></p> <p><a href="#">NHS England (2013) 2013/14 NHS standard contract for specialised dermatology services (all ages). Service specification No: A12/S/a</a></p>

## 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.