

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Baricitinib for treating moderate to severe atopic dermatitis ID1622

Final scope

**Remit/appraisal objective**

To appraise the clinical and cost effectiveness of baricitinib within its marketing authorisation for treating adults with moderate to severe atopic dermatitis.

**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 eczema can be physically disabling or incapacitating and can cause anxiety and depression.

Estimates of the prevalence of atopic dermatitis vary. In the UK, it is estimated that 1 in 12 adults have dermatitis, however it is more common in childhood (affecting 1 in 5 children).<sup>1</sup> In 2017-18, there were 1,130 admissions, with 1,236 finished consultant episodes for atopic dermatitis in England.<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 (TA81). Tacrolimus ointment (calcineurin inhibitor) is recommended when moderate to severe atopic dermatitis has not been adequately controlled by 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). Alitretinoin is recommended as a treatment for people with severe chronic hand dermatitis affecting their quality of life and not responding to potent topical corticosteroids (TA177).

Patients with dermatitis not responding to topical treatments may be referred to secondary care and treated with phototherapy and photochemotherapy (psoralen–ultraviolet A; PUVA) and systemic immunosuppressants (azathioprine, ciclosporin, mycophenolate mofetil, and methotrexate). Managing exacerbations (flares) in atopic dermatitis includes using short-term potent topical corticosteroids, oral corticosteroids and systemic therapy.

Dupilumab is recommended for adults with moderate to severe atopic dermatitis that has not responded to at least 1 other systemic therapy, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or if these treatments are contraindicated or not tolerated (TA534).

**The technology**

Baricitinib (Olumiant, Eli Lilly and Company) is a Janus kinase (JAK) inhibitor. JAKs are enzymes that mediate the transduction of intracellular signals involved in the process of inflammatory diseases. Baricitinib is delivered orally.

Final scope for the proposed appraisal of baricitinib for treating moderate to severe atopic dermatitis ID1622. Issue Date: April 2020

Baricitinib does not currently have a marketing authorisation in the UK for treating atopic dermatitis. It has been studied in clinical trials alone or in combination with corticosteroids compared with placebo in adults with moderate to severe atopic dermatitis that have had inadequate response or intolerance to existing topical treatments. One of the trials included people who previously had an inadequate response or intolerance to ciclosporin.

<b>Intervention(s)</b>	Baricitinib with and without corticosteroids
<b>Population(s)</b>	Adults with moderate to severe atopic dermatitis that had inadequate response or intolerance to existing topical treatments
<b>Comparators</b>	<ul style="list-style-type: none"> <li>• Phototherapy including ultraviolet B (UVB) radiation or psoralen-ultraviolet A (PUVA)</li> <li>• Systemic immunosuppressive therapies (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil)</li> <li>• Alitretinoin (in people with atopic dermatitis affecting the hands)</li> <li>• Dupilumab</li> <li>• Best supportive care (including emollients, topical corticosteroids, phototherapy, psychological support and rescue therapy [for example oral corticosteroids or topical calcineurin inhibitors])</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><b>Other considerations</b></p>	<p>If the evidence allows the following subgroups will be considered. These include:</p> <ul style="list-style-type: none"> <li>• skin colour subgroups,</li> <li>• people with moderate dermatitis and those with severe dermatitis, and</li> <li>• people who are ciclosporin-naive and those who have previously received ciclosporin.</li> </ul> <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>
<p><b>Related NICE recommendations and NICE Pathways</b></p>	<p>Related Technology Appraisals:</p> <p><a href="#">Dupilumab for treating adults with moderate to severe atopic dermatitis</a> (2018). NICE Technology Appraisal TA534. Review date: August 2021.</p> <p><a href="#">Alitretinoin for the treatment of severe chronic hand eczema</a> (2009). NICE Technology Appraisal TA177. Guidance on static list.</p> <p><a href="#">Tacrolimus and pimecrolimus for atopic eczema</a> (2004). NICE Technology Appraisal TA82. Guidance on static list.</p> <p><a href="#">Frequency of application of topical corticosteroids for eczema</a> (2004). NICE Technology Appraisal TA81. Guidance on static list.</p> <p><a href="#">Atopic eczema in under 12s: diagnosis and management</a> (2007) NICE guideline CG57</p> <p>Appraisals in development:</p> <p><a href="#">Crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older</a> [ID1195] NICE technology Appraisal. Expected publication: June 2020.</p> <p>Related Interventional Procedures:</p> <p><a href="#">Grenz rays therapy for inflammatory skin conditions</a> (2007). NICE interventional procedures guidance 236.</p> <p>Related NICE Pathways:</p> <p><a href="#">Treating eczema in people over 12</a> (2019) NICE pathway</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 (2018/2019) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a> Chapter 61. Highly specialist dermatology services (adults and children).</p> <p>Department of Health and Social Care (2016) <a href="#">NHS outcomes framework 2016 to 2017</a>: Domain 2.</p>

### References

- 1 National Eczema Society. [What is Eczema?](#) Accessed September 2019.
- 2 Health & Social Care Information Centre, Hospital Episode Statistics for England. Admitted Patient Care statistics, 2014-15. Accessed September 2019. <http://content.digital.nhs.uk/catalogue/PUB19124>