**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Proposed Health Technology Appraisal**

# Baricitinib for treating moderate to severe atopic dermatitis ID1622

**Draft scope (pre-referral)**

## Draft 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).[1] In 2017-18, there were 1130 admissions, with 1,236 finished consultant episodes for atopic dermatitis in England.[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 (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 possible 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.

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.

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| **Intervention(s)** | Baricitinib with and without corticosteroids |
| **Population(s)** | Adults with moderate to severe atopic dermatitis that had inadequate response or intolerance to existing topical treatments |
| **Comparators** | • Phototherapy including ultraviolet B (UVB) radiation or psoralen-ultraviolet A (PUVA)<br>• Systemic immunosuppressive therapies (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil)<br>• Alitretinoin (in people with atopic dermatitis affecting the hands)<br>• Dupilumab<br>• Best supportive care |
| **Outcomes** | The outcome measures to be considered include:<br>• measures of disease severity<br>• measures of symptom control<br>• disease free period/maintenance of remission<br>• time to relapse/prevention of relapse<br>• adverse effects of treatment<br>• 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.<br>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.<br>Costs will be considered from an NHS and Personal Social Services perspective.<br>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. |


 

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| **Other considerations** | If the evidence allows the following subgroups will be considered. These include:<br>• skin colour subgroups, and<br>• people who are ciclosporin naïve and those who have previously received ciclosporin.<br>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 and NICE Pathways** | Related Technology Appraisals:<br>Dupilumab for treating adults with moderate to severe atopic dermatitis (2018). NICE Technology Appraisal TA534. Review date: August 2021.<br>Alitretinoin for the treatment of severe chronic hand eczema (2009). NICE Technology Appraisal TA177. Guidance on static list.<br>Tacrolimus and pimecrolimus for atopic eczema (2004). NICE Technology Appraisal TA82. Guidance on static list.<br>Frequency of application of topical corticosteroids for eczema (2004). NICE Technology Appraisal TA81. Guidance on static list.<br>Atopic eczema in under 12s: diagnosis and management (2007) NICE guideline CG57<br><br>Appraisals in development:<br>Crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older [ID1195] NICE technology Appraisal. Expected publication: June 2020.<br><br>Related Interventional Procedures:<br>Grenz rays therapy for inflammatory skin conditions (2007). NICE interventional procedures guidance 236.<br>Related NICE Pathways:<br>Treating eczema in people over 12 (2019) NICE pathway |
| **Related National Policy** | The NHS Long Term Plan, 2019. NHS Long Term Plan<br>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 61. Highly specialist dermatology services (adults and children).<br>Department of Health and Social Care (2016) NHS outcomes framework 2016 to 2017: Domain 2. |


 

**Questions for consultation**

What is established clinical practice in the NHS for patients with moderate to severe dermatitis that have an inadequate response or intolerance to existing topical treatments?

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

Should best supportive care be included as a comparator? And if so, how it should be defined?

Are the outcomes listed appropriate?

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

Where do you consider baricitinib will fit into the existing NICE pathway, Treating eczema in people over 12?

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 baricitinib 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.

Do you consider baricitinib to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of baricitinib can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.


 

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

NICE has published an addendum to its guide to the methods of technology appraisal (available at https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf), which states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost comparison methodology for this topic?
- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

**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


 