

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Appraisal

### Crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older

#### Final scope

#### Final remit/appraisal objective

To appraise the clinical and cost effectiveness of crisaborole within its marketing authorisation for treating mild to moderate atopic dermatitis in people aged 2 years and older.

#### Background

Atopic dermatitis (atopic eczema) is a long-term condition that affects the skin. It may start at any age but the onset is often in childhood. 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 or depression. Atopic dermatitis cannot be cured although it can improve significantly, or even clear completely, in some children and as they get older.<sup>1</sup>

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 12 adults in the UK.<sup>2</sup> In 2017-18, there were 1,130 admissions with 1,236 finished consultant episodes for atopic dermatitis in England.<sup>3</sup>

Mild to moderate atopic dermatitis is usually managed in primary care. Typical treatment first involves emollients and topical corticosteroids ([TA81](#)). When topical corticosteroids do not provide adequate control and where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy, NICE recommends the following topical calcineurin inhibitors as an option for second-line treatment:

- tacrolimus for moderate to severe atopic dermatitis in adults and children aged 2 years and older
- pimecrolimus for moderate atopic dermatitis on the face and neck in children aged 2 to 16 years ([TA82](#)).

#### The technology

Crisaborole (Staquis, Pfizer) is a nonsteroidal small molecule that inhibits the enzyme phosphodiesterase 4 (PDE4) and reduces the production of tumour necrosis factor (TNF)-alpha and other cytokines which are proteins involved in the inflammatory process and immune response. It contains a boron atom that helps penetrate the skin. It is a topical ointment.

Final scope for the appraisal of crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older

Issue Date: July 2019

Page 1 of 4

© National Institute for Health and Care Excellence 2019. All rights reserved.

Crisaborole does not have a marketing authorisation in the UK. It has been studied in phase III clinical trials in people aged 2 years and older with atopic dermatitis compared with vehicle treatment.

<b>Intervention(s)</b>	Crisaborole
<b>Population(s)</b>	People aged 2 years and older with mild to moderate atopic dermatitis
<b>Comparators</b>	<p>For mild atopic dermatitis:</p> <ul style="list-style-type: none"> <li>• Combination of emollients and mild to moderate potency topical corticosteroids</li> </ul> <p>For moderate atopic dermatitis:</p> <ul style="list-style-type: none"> <li>• High potency topical corticosteroids</li> <li>• 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><b>Other considerations</b></p>	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• adults and children</li> <li>• mild and moderate atopic dermatitis</li> <li>• people with different skin colour</li> <li>• people with atopic dermatitis affecting the hands</li> <li>• people with atopic dermatitis affecting sensitive areas (face, neck and flexures)</li> <li>• people for whom therapies have been inadequately effective, not tolerated or contraindicated.</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="#">‘Tacrolimus and pimecrolimus for atopic eczema’</a> (2004) NICE Technology Appraisal 82. Static list.</p> <p><a href="#">‘Frequency of application of topical corticosteroids for atopic eczema’</a> (2004) NICE Technology Appraisal 81. Static list.</p> <p>Related Guidelines:</p> <p><a href="#">‘Atopic eczema in under 12s: diagnosis and management’</a> (2007) NICE guideline CG57. Currently being updated.</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 Quality Standards:</p> <p><a href="#">‘Atopic eczema in under 12s’</a> (2013) NICE quality standard 44.</p> <p>Related NICE Pathways:</p> <p><a href="#">Eczema</a> (2019) NICE pathway.</p>

<p><b>Related National Policy</b></p>	<p>NHS England (2019) <a href="#">The NHS Long Term Plan</a>.</p> <p>NHS England (2018) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a> Chapter 59 (Highly specialist allergy services [adults and children]) and Chapter 61 (Highly specialist dermatology services [adults and children]).</p> <p>NHS England (2013) <a href="#">NHS standard contract for specialised dermatology services (all ages)</a>. Reference A12/S/a.</p> <p>Department of Health and Social Care (2016) <a href="#">NHS outcomes framework 2016 to 2017</a>: Domain 2.</p>
---------------------------------------	--

### References

1. NHS Choices (2016) [Atopic eczema](#). Accessed July 2019.
2. National Eczema Society. [What is Eczema?](#) Accessed July 2019.
3. NHS Digital (2018) [Hospital Admitted Patient Care Activity, 2017-18: Diagnosis](#). Accessed July 2019.