NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Abrocitinib for treating moderate to severe atopic dermatitis in people aged 12 and over [ID3768]

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of abrocitinib within its marketing authorisation for moderate to severe atopic dermatitis in people aged 12 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 eczema 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 12 adults in the UK.[1] Of the people who need treatment for atopic dermatitis 7% will have moderate to severe disease and around a third of these people (27%) 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 (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).

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, methotrexate and dupilumab).[3] In addition, phototherapy and photochemotherapy (psoralen–ultraviolet A; PUVA) can be used to manage chronic severe atopic dermatitis; however, this option is not usually recommended for children.[3]

Dupilumab 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, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil, or these are contraindicated or not tolerated (TA534). Since the publication of TA534 the marketing authorisation for dupilumab has been extended to also include people ages 12 to 17 years and dupilumab is commissioned by NHS England for this group.

The technology

Abrocitinib (brand name unknown, Pfizer) is a selective Janus Kinase (JAK) 1 inhibitor. JAKs are enzymes that mediate the transduction of intracellular signals involved in the process of inflammatory disease. Abrocitinib is administered orally.

Abrocitinib does not currently have a marketing authorisation in the UK for atopic dermatitis. It has been studied in clinical trials alone or in combination with topical therapy or optional rescue therapy compared with placebo in people aged 12 or over with moderate to severe atopic dermatitis who had inadequate response or inability to tolerate topical treatments, or who previously had systemic therapy. One trial included people regardless of their previous treatments.

Intervention(s)	Abrocitinib
Population(s)	People aged 12 years or over with moderate to severe atopic dermatitis
Comparators	• Phototherapy including with ultraviolet (UVB) radiation or psoralen-ultraviolet A (PUVA) • Immunosuppressive therapies (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil) • Oral corticosteroids • Alitretinoin (in people with atopic dermatitis affecting the hands) • Dupilumab • Baricitinib (subject to ongoing NICE appraisal) • Best supportive care (including emollients, topical corticosteroids, phototherapy, psychological support and rescue therapy [for example oral corticosteroids or topical calcineurin inhibitors])
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 of any managed access arrangement for the intervention will be taken into account.
Other considerations	If the evidence allows the following subgroups will be considered. These include: • people with moderate dermatitis and those with severe dermatitis • people with atopic dermatitis affecting the hands • people who require rescue treatment due to flares • skin colour subgroups. The availability and cost of biosimilar and generic products should be taken into account. 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:** Dupilumab for treating moderate to severe atopic dermatitis (2018) NICE technology appraisal guidance 534 Alitretinoin for the treatment of severe chronic hand eczema (2009) NICE technology appraisal guidance 177 Tacrolimus and pimecrolimus for atopic eczema (2004) NICE technology appraisal guidance 82

	Frequency of application of topical corticosteroids for atopic eczema (2004) NICE technology appraisal guidance 81 **Appraisals in development (including suspended appraisals)** Baricitinib for treating moderate to severe atopic dermatitis [ID1622]. NICE technology appraisal guidance. Publication expected March 2021. Crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older [ID1195] NICE technology appraisal guidance. Publication date to be confirmed Upadacitinib for treating moderate to severe atopic dermatitis in people aged 12 and over [ID3733] NICE technology appraisal guidance. Publication date to be confirmed Tralokinumab for treating moderate to severe atopic dermatitis [ID3734] NICE technology appraisal guidance. Publication date to be confirmed Tralokinumab for treating moderate to severe atopic dermatitis in people aged 12 and over [ID3823] NICE technology appraisal guidance. Publication date to be confirmed **Proposed appraisals currently in scoping** Adriforant for atopic dermatitis. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 10394. Status: A List – STS Dupilumab for children with severe atopic dermatitis. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 10434. Status: A List – STS Dupilumab for severe atopic dermatitis in children aged 6 to 11 years. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 9848. Status: A List – STS Dupilumab for treating moderate to severe atopic dermatitis in people aged 12-17. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 9830. Status: A List – STS Lebrikizumab for atopic dermatitis. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 10396. Status: A List – STS Nemolizumab for atopic dermatitis. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 10417. Status: A List – STS

	Risankizumab for moderate to severe atopic dermatitis. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 10373. Status: A List – STS **Related Guidelines:** Atopic eczema in under 12s: diagnosis and management (2007) NICE guideline CG57 **Guidelines in development** Secondary infection of common skin conditions including eczema: antimicrobial prescribing. Publication expected February 2021 **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 NICE Pathways:** Eczema (2018) NICE pathway
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapters 59 and 61 Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2, 4 and 5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017 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

Treatment pathway

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

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

- Would abrocitinib be used after dupilumab or vice versa?

- Would a person who is a 'candidate for systemic therapy' already have had phototherapy?

- Which treatments are considered to be established clinical practice in the NHS for moderate to severe atopic dermatitis in people aged 12-17 who are candidates for systemic therapy? Do these differ to treatments considered to be established clinical practice in the NHS for adults?

Comparators

- Have all relevant comparators for abrocitinib been included in the scope?

- How should best supportive care be defined?

Outcomes

- Are the outcomes listed appropriate?

Subgroups

- Are the subgroups suggested in 'Other considerations' appropriate?

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

Where do you consider abrocitinib will fit into the existing NICE pathway Eczema?

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 abrocitinib 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 abrocitinib 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 abrocitinib 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).

The current topic could be considered for appraisal through the Multiple Technology Appraisal (MTA) 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. Our skin and eczema. Accessed September 2020

2. National Institute for Health and Care Excellence. Resource impact report: Dupilumab for treating moderate to severe atopic dermatitis (TA534) (2018). Accessed September 2020

3. British Association of Dermatologists. Atopic Eczema (2020) Accessed September 2020.