

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Dupilumab for treating adults with moderate to severe atopic dermatitis [ID1048]

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of dupilumab 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 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 In 2014-15, there were 895 admissions, including 604 adults for atopic dermatitis in England²

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, and methotrexate). In addition, phototherapy and photochemotherapy (psoralen–ultraviolet A; PUVA) can be used to manage chronic severe atopic dermatitis.³

The technology

Dupilumab (Dupixent, Sanofi) is a fully human monoclonal antibody directed against the IL-4 receptor alpha subunit, which blocks signalling from both IL-4 and IL-13. This blockade is believed to reduce the inflammation and other processes that manifest as atopic dermatitis. Dupilumab is administered by subcutaneous injection.

Dupilumab does not currently have a marketing authorisation in the UK for treating atopic dermatitis in adults. It has been studied in clinical trials alone or in combination with corticosteroids in patients with moderate to severe atopic dermatitis that was poorly controlled with topical agents (corticosteroids and calcineurin inhibitors).

Intervention	Dupilumab
Population	Adults with moderate to severe atopic dermatitis who are candidates for systemic therapy
Comparators	<ul style="list-style-type: none">• Phototherapy including with ultraviolet (UVB) radiation or psoralen-ultraviolet A (PUVA)• Immunosuppressive therapies (azathioprine, ciclosporin, and methotrexate)• Oral steroids• Best supportive care (combination of emollients, low to mid potency topical corticosteroids, and rescue therapy including higher potency topical or oral corticosteroids or topical calcineurin inhibitors)• Alitretinoin (in people with atopic dermatitis affecting the hands)
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none">• 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

<p>Economic analysis</p>	<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>Other considerations</p>	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> • people with atopic dermatitis affecting the hands; • people for whom therapies have been inadequately effective, not tolerated or contraindicated • skin colour subgroups. <p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>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>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No TA177, August 2009, Alitretinoin for the treatment of severe chronic hand eczema. Review data TBC</p> <p>Technology Appraisal No TA81, August 2004, Frequency of application of topical corticosteroids for eczema. On static list</p> <p>Technology Appraisal No TA82, August 2004, Tacrolimus and pimecrolimus for atopic dermatitis (eczema). On static list</p> <p>Related Interventional Procedures:</p> <p>Grenz rays therapy for inflammatory skin conditions (2007). NICE interventional procedures guidance 236. https://www.nice.org.uk/guidance/ipg236</p> <p>Related NICE Pathways:</p>

	<p>Treating eczema in people over 12 (2016) NICE pathway</p> <p>http://pathways.nice.org.uk/</p>
Related National Policy	<p>Manual for Prescribed Specialised Services 2016/2017. Chapter 61. Highly specialist dermatology services (adults and children). NHS England, May 2016. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf</p> <p>NHS Outcomes Framework 2016 to 2017. Department of Health, April 2016. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p>

References

- 1 National Eczema Society. What is Eczema? Accessed November 2016. <http://www.eczema.org/what-is-eczema>
- 2 Health & Social Care Information Centre, Hospital Episode Statistics for England. Admitted Patient Care statistics, 2014-15. Accessed November 2016. <http://content.digital.nhs.uk/catalogue/PUB19124>
- 3 British Association of Dermatologists. Atopic Eczema. Accessed November 2016. <http://www.bad.org.uk/shared/get-file.ashx?id=69&itemtype=document>.