NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Dupilumab for treating prurigo nodularis

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of dupilumab within its marketing authorisation for treating prurigo nodularis.

Background

Prurigo nodularis, also known as nodular prurigo, is a chronic inflammatory skin condition.[1] Prurigo describes the changes that appear on the skin after it has been itched and scratched for a long time due to intense itchiness (pruritus).[2] In prurigo nodularis, firm itchy bumps (nodules) form on the skin's surface caused by itching. The rash can range in severity from a few to several hundred nodules which appear most commonly on the arms, legs, upper back and abdomen. It may appear on its own or be associated with other skin diseases or underlying conditions. It may occur in episodes or be continuous. The itch associated with prurigo nodularis can interfere with sleep and affect psychological wellbeing.[1]

The cause of prurigo nodularis is unknown. However, it is associated with abnormal levels of nerve fibres and neuropeptides which may contribute to itchiness. People with prurigo nodularis also have higher levels of immune cells which produce cytokines associated with inflammatory responses that may contribute to increased itchiness.[1]

The number of people with prurigo nodularis is unclear. A study in a European population showed a prevalence of 0.1% in the general population[3]. Any age group can be affected but it is more common in older people.[3]

The treatments for prurigo nodularis aim to stop the skin itching. These include emollients, corticosteroid creams, ointments such as tacrolimus (a calcineurin inhibitor, used off-label), antihistamines, oral steroids and ultraviolet light treatment. Immunosuppressants such as azathioprine, ciclosporin or methotrexate may be used if the condition is severe and has not responded to previous treatments.[2]

The technology

Dupilumab (Dupixent, Sanofi) does not have a marketing authorisation for prurigo nodularis. It does have a marketing authorisation for the treatment of moderate to severe atopic dermatitis in people aged 12 years and older who are candidates for systemic therapy and for severe atopic dermatitis in children aged 6 to 11 years who are candidates for systemic therapy. It has been studied as an add-on treatment to topical emollients (moisturisers), corticosteroids and calcineurin inhibitors in clinical trials in comparison with placebo in adults with prurigo nodularis inadequately controlled by topical corticosteroids or when corticosteroids are not appropriate.

Intervention(s)	Dupilumab in combination with topical emollients, corticosteroids and calcineurin inhibitors
Population(s)	Adults with prurigo nodularis that had inadequate response or intolerance to existing topical treatments
Comparators	Established clinical management without dupilumab, including: • Topical emollients • Topical corticosteroids • Topical calcineurin inhibitors • Antihistamines • Oral steroids • Phototherapy including with ultraviolet (UVB) radiation • Immunosuppressive therapies (azathioprine, ciclosporin or methotrexate)
Outcomes	The outcome measures to be considered include: • measures of disease severity • measures of symptom control including improvement in itch • 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. 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.
Other considerations	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	**Related Technology Appraisals:** Dupilumab for treating severe asthma with type 2 inflammation (2021). NICE Technology appraisal guidance 751. Review date Month 2024. Dupilumab for treating moderate to severe atopic dermatitis (2018). NICE technology appraisal guidance 534. Review date to be confirmed.
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan

Questions for consultation

What is established clinical management of prurigo nodularis?

Where do you consider dupilumab will fit into the existing care pathway for prurigo nodularis?

Would dupilumab be a candidate for managed access?

Do you consider dupilumab 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 dupilumab can result in any potential 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 committee to take account of these benefits.

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 dupilumab 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-

guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. National Organization for Rare Disorders (NORD) (2021). Prurigo Nodularis. Accessed May 2022.

2. British Association for Dermatologists (2020). Nodular prurigo. Accessed May 2022.

3. IFSI-guideline on chronic prurigo including prurigo nodularis. Ständer et al. 2020.