Appendix B

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Dupilumab for treating moderate to severe prurigo nodularis

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of dupilumab within its marketing authorisation for treating moderate to severe 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 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 uncertain but it is estimated that 0.03% of the population in England have the condition.[3] Any age group can be affected but it is more common in older people and affects more females than males.[3, 4]

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.

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Intervention(s)	Dupilumab in combination with topical emollients, corticosteroids and calcineurin inhibitors
Population(s)	Adults with moderate to severe 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 • Immunosuppressive therapies (azathioprine, ciclosporin, methotrexate or thalidomide) • Antidepressants including selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs)
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.

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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

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. Epidemiology of prurigo nodularis in England: a retrospective database analysis. Morgan et al. 2022
4. IFSI-guideline on chronic prurigo including prurigo nodularis. Ständer et al. 2020.