NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Deuruxolitinib for treating severe alopecia areata ID6597

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of deuruxolitinib within its marketing authorisation for treating severe alopecia areata in adults.

Background

Alopecia areata is a chronic, inflammatory, autoimmune condition affecting the hair follicles leading to a sudden onset of hair loss. It does not cause scarring or permanent damage to the hair follicles. It can affect any hair-bearing skin such as the beard, eyebrows, eyelashes, body and limbs. The most common presentation of alopecia areata is small, round or oval patches of baldness on the scalp. Rarely, it may affect the whole scalp (alopecia totalis) or even the entire body and scalp (alopecia universalis). For some people, patchy hair loss may continue over a long period of time, referred to as persistent patchy or chronic alopecia areata. Other types of alopecia areata are characterised by different patterns of hair loss. For example, diffuse alopecia areata is characterised by sudden thinning of the hair all over the scalp, rather than in patches. Alopecia areata ophiasis refers to hair loss from the sides and lower back of the scalp, alopecia areata sisaipho refers to hair loss from the front of the scalp, forehead and rarely the eyebrows while alopecia barbae refers to hair loss in the beard and moustache area.[1,2]

Alopecia areata occurs when hair follicles change from the growth (anagen) phase to the loss (telogen) phase prematurely, but the exact cause is unknown. While there is a genetic predisposition, it can occur at any age, affecting both males and females equally.[1,2] It is suggested that there may be higher incidence in children and young adults[3] and there may also be a link to social deprivation.[4] In the UK, it is estimated that approximately 0.58% of adults have alopecia areata[4], of which 7% to 10% may have the severe form[3,5] and 10 to 50% may have nail involvement.[3,5] Alopecia areata is also associated with higher rates of atopic and other autoimmune conditions.[4,6]

Alopecia areata is typically diagnosed clinically based on presenting features such as patterns of hair loss, exclamation mark hairs (short, broken hairs tapering proximally) and a positive pull test.[3] In some cases, identifying whitening of the hairs can also aid diagnosis. Prognosis is unpredictable and varies, depending on severity and duration of the condition. Spontaneous remission within one year is seen in up to 80% of people with limited patches of hair loss of less than one year duration.[1] However, hair pattern regrowth is variable and unpredictable and when hair loss becomes extensive, spontaneous re-growth is rare.[1,2] Evidence also suggests that there is a correlation between alopecia areata and depression and anxiety.[7]

Clinical management depends on the severity of hair loss. If there is evidence of hair regrowth or there is less than 50% hair loss, management may include advice on cosmetic options to camouflage hair loss and watchful waiting. If there is no hair regrowth and more than 50% hair loss, treatment options in primary care may include topical corticosteroids, one of the few treatments currently licensed for use in alopecia areata. If hair loss does not respond to treatment, people may be referred to

a dermatologist. Specialist management depends on disease duration, activity, location, extent, and the person's age and individual preference. NICE technology appraisal guidance 958 recommends ritlecitinib as an option for treating severe alopecia areata in people 12 years and over. Other options include local steroid injections or oral corticosteroids, dithranol, contact sensitisation treatment (contact immunotherapy), psoralen plus ultraviolet A light therapy (PUVA), minoxidil, immunosuppressive drugs such as oral azathioprine, ciclosporin, methotrexate and sulfasalazine and prostaglandin analogues such as bimatoprost and latanoprost.[1,2,8]

The technology

Deuruxolitinib (Leqselvi, Sun Pharma) does not currently have a marketing authorisation in the UK for alopecia areata. It has been compared with placebo in a clinical trial in adults with severe alopecia areata defined as at least 50% scalp hair loss with no other cause.

Intervention(s)	Deuruxolitinib
Population(s)	Adults with severe alopecia areata
Comparators	Established clinical management without deuruxolitinib, which may include • ritlecitinib
Outcomes	The outcome measures to be considered include: • severity of alopecia areata • percentage of area affected by hair loss • 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 availability and cost of biosimilar and generic products should be taken into account. 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:** Ritlecitinib for treating severe alopecia areata in people 12 years and over (2024) NICE technology appraisal guidance TA958. Baricitinib for treating severe alopecia areata (2023) NICE technology appraisal guidance TA926.
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan. NHS England (2018) NHS manual for prescribed specialist services (2018/2019). Chapter 61.

Questions for consultation

Where do you consider deuruxolitinib will fit into the existing care pathway for alopecia areata? Which types of alopecia areata would deuruxolitinib be considered for?

Would deuruxolitinib be a candidate for managed access?

Please select from the following, will deuruxolitinib be:
A. Prescribed in secondary care with routine follow-up in secondary care
B. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Do you consider that the use of deuruxolitinib 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 deuruxolitinib is 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.

References

1. NICE 2024 Clinical Knowledge Summaries Alopecia Areata. Accessed August 2025.

2. British Association of Dermatologists 2024 Patient Information Leaflet Alopecia Areata. Accessed August 2025.

3. BMJ Best Practice 2025 Alopecia areata. Accessed August 2025.

4. Harries M et al. (2022) The epidemiology of alopecia areata: a population-based cohort study in UK primary care. Br J Dermatol 186(2):257-265.

5. Madani S, Shapiro J. 2000 Alopecia areata update. J Am Acad Dermatol 42(4):549-66.

6. National Alopecia Areata Foundation. "Alopecia areata: related conditions." Accessed August 2025.

7. Macbeth A et al. 2022. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. British Journal of Dermatology 187(1):73-81.

8. Alopecia UK "Treatments for Alopecia Areata." Accessed August 2025.