NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Ritlecitinib for treating moderate to severe alopecia areata in people 12 years and over

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of ritlecitinib within its marketing authorisation for moderate to severe alopecia areata in people 12 years and over.

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.[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 0.6% of adults have alopecia areata, of which 7% to 10% may have the severe form[5] and 10 to 50% may have nail involvement.[5] Alopecia areata is also associated with higher rates of atopic and other autoimmune conditions.[4]

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] 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] When hair loss becomes extensive, spontaneous re-growth is rare.

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, the only treatment 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,

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location, extent, and the person's age and individual preference. It may 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.[1,2,6]

The technology

Ritlecitinib (Pfizer, brand name unknown) does not currently have a marketing authorisation in the UK for alopecia areata. It has been studied in clinical trials in people aged 12 years and older with alopecia areata with no other cause of hair loss.

Intervention(s)	Ritlecitinib
Population(s)	People aged 12 years and over with moderate to severe alopecia areata
Subgroup(s)	If evidence allows, subgroups based on severity and type of alopecia areata will be considered
Comparators	Established clinical management without ritlecitinib
Outcomes	The outcome measures to be considered include: • disease severity • improvement in 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.
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:**

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	None. **Related appraisals in development:** 'Baricitinib for treating severe alopecia areata'. Proposed Technology Appraisal Guidance [ID3979]. Publication date to be confirmed. **Related Guidelines:** None. **Guidelines in development:** None. **Related Interventional Procedures:** None. **Related Public Health Guidance/Guidelines:** None. **Related Quality Standards:** None.
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): Chapter 61. • Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2-5.

Questions for consultation

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

Would ritlecitinib be a candidate for managed access?

Do you consider ritlecitinib 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 ritlecitinib 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:

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- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which ritlecitinib 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. NICE 2018 Clinical Knowledge Summaries Alopecia Areata. Accessed April 2022.

2. British Association of Dermatologists 2020 Patient Information Leaflet Alopecia Areata. Accessed April 2022.

3. BMJ Best Practice 2021 Alopecia areata. Accessed April 2022.

4. Harries M, Macbeth AE, Holmes S, Chiu WS, Gallardo WR, Nijher M, de Lusignan S, Tziotzios C, Messenger AG (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. Alopecia UK "What is Alopecia Areata?" Accessed April 2022.

7. Alopecia UK "Treatments for Alopecia Areata" Accessed April 2022.

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