NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Baricitinib for treating severe alopecia areata

Final scope

Final remit/evaluation objective

To appraise the clinical and cost effectiveness of baricitinib 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.[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,[4] of which 7% to 10% may have the severe form[5] and 10 to 50% may have nail involvement.[6] 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, location, extent, and the person's age and individual preference. It may include local

corticosteroid 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

Baricitinib (Olumiant, Eli Lilly and Company) is a selective and reversible inhibitor of Janus Kinase (JAK) 1 and JAK2. JAKs are enzymes that mediate the transduction of intracellular signals involved in the process of inflammatory disease. Baricitinib is administered orally.

Baricitinib does not currently have a marketing authorisation in the UK for alopecia areata. It has been studied in 2 clinical trials comparing baricitinib monotherapy with placebo in adults with severe or very severe alopecia areata. The trials included people with hair loss affecting at least 50% of the scalp, with the episode lasting for more than 6 months but less than 8 years.

Intervention(s)	Baricitinib
Population(s)	Adults with severe alopecia areata
Subgroups	If the evidence allows, the following subgroups based on severity and type of alopecia areata will be considered
Comparators	Established clinical management without baricitinib
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 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. The availability and cost of biosimilar and generic products should 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	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.

References

1. NICE (2018) Clinical Knowledge Summaries Alopecia Areata. Accessed May 2022.
2. British Association of Dermatologists (2016) Patient Information Leaflet Alopecia Areata. Accessed May 2022.
3. BMJ Best Practice (2021) Alopecia areata. Accessed May 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 May 2022.
7. Alopecia UK "Treatments for Alopecia Areata" Accessed May 2022.