NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Baricitinib for treating severe alopecia areata

Draft scope

Draft remit/appraisal objective

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

Background

Alopecia areata is a chronic, inflammatory 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 (alopecia areata incognita) 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] In the UK, it is estimated to affect 15 in 10,000 people, of which 7% to 10% may have the severe form[4] and 10 to 50% may have nail involvement.[5]

Alopecia areata is typically diagnosed clinically based on presenting features such as exclamation mark hairs (short, broken hairs tapering proximally) and a positive pull test.[3] Prognosis is unpredictable, with spontaneous remission within one year seen in up to 80% of people with limited patches of hair loss of less than one year duration.[1]

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. 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 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

Baricitinib (Olumiant, Eli Lilly and Company) is a Janus Kinase (JAK) inhibitor, specifically inhibiting the activities of JAK1, JAK2, Tyrosine Kinase 2 and JAK3. 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, including alopecia totalis and alopecia universalis
Comparators	Established clinical management without baricitinib
Outcomes	The outcome measures to be considered include: • disease severity e.g. Severity of Alopecia Tool (SALT) • improvement in hair loss e.g. Scalp Hair Assessment Score, Measure for Eyebrow Hair Loss, Measure for Eyelash 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.
Other considerations	If evidence allows, subgroups based on severity will be considered. The availability and cost of biosimilar and generic products should be taken into account. 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.

and NICE Pathways	
• **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

How is alopecia areata diagnosed in clinical practice?

How is severity of alopecia areata determined in clinical practice?

How is alopecia areata treated in clinical practice and by whom?

- Are treatments the same for the different types of alopecia areata, for example, alopecia totalis, alopecia universalis, alopecia areata incognita, alopecia areata ophiasis, alopecia areata sisaipho and alopecia barbae?

How and when is treatment effectiveness evaluated in clinical practice?

Have all relevant comparators for baricitinib been included in the scope? Which treatments are considered to be established clinical practice in the NHS for severe alopecia areata?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom baricitinib is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider baricitinib will fit in current treatment pathway?

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 baricitinib 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.

Do you consider baricitinib 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 baricitinib can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. NICE 2018 Clinical Knowledge Summaries Alopecia Areata. Accessed 25/11/2021.

2. British Association of Dermatologists 2020 Patient Information Leaflet Alopecia Areata. Accessed 25/11/2021.

3. BMJ Best Practice 2021 Alopecia areata. Accessed 25/11/2021.

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

5. Alopecia UK "What is Alopecia Areata?" Accessed 25/11/2021.

6. Alopecia UK "Treatments for Alopecia Areata" Accessed 25/11/2021.