BRITISH ASSOCIATION
OF DERMATOLOGISTS
HEALTHY SKIN FOR ALL

alopecia uk

BRITISH HAIR
& NAIL SOCIETY
Specialists in hair and nail disorders

RITLECITINIB FOR ALOPECIA AREATA

Professional guidance supplementary to NICE TA958

Version 1, July 2024

Recently, NICE published its technology appraisal guidance TA958, recommending ritlecitinib for severe alopecia areata (AA) in those aged 12 years and over:

- Ritlecitinib is recommended, within its marketing authorisation, as an option for treating severe alopecia areata in people 12 years and over. Ritlecitinib is only recommended if the company provides it according to the commercial arrangement.
- Having concluded that ritlecitinib is a cost-effective use of NHS resources (see section 3.24), the committee recommended it for **routine use in the NHS**, for treating severe alopecia areata in people 12 years and over.

Ritlecitinib should be available routinely for people with AA through general dermatology clinics. It has also been accepted by the Scottish Medicines Consortium for use in NHS Scotland.

This guidance, developed by representatives of the British Hair and Nail Society (BHNS), and British Association of Dermatologists' (BAD) Therapy & Guidelines sub-committee and guideline development group (GDG) for managing people with AA[1] and Alopecia UK, aims to supplement the above recommendation in providing additional information that would help clinicians, commissioners and drugs formulary teams with implementation.

1. SEVERITY OF AA

Severe AA is defined as having at least 50% loss of scalp hair (e.g. Severity Alopecia Tool [SALT] score of ≥50).

The AA severity definitions used in the upcoming AA living guideline[1] are based primarily on the extent of scalp hair loss, with ***limited (mild)*** hair loss representing 1-20% scalp involvement, ***moderate*** hair loss representing 21-49% scalp involvement and ***severe*** hair loss representing 50-100% scalp involvement. Unfortunately, the extent of scalp hair loss alone does not capture the wider impact of AA on an individual, particularly when psychological distress or functional impact (e.g. loss of eyelashes or nails) is prominent or when other visible body sites are involved.

Therefore, a recent expert consensus has advocated adjusting the SALT-based severity rating when other additional factors are present. Thus, people with **moderate-AA (absolute SALT score 21-49)** "may have their severity rating increased by one level to **severe** if one or more of the following are present:

- negative impact on psychological functioning resulting from AA
- noticeable involvement of eyebrows or eyelashes
- inadequate response after at least 6 months of treatment (treatments include topical or intralesional steroids or oral steroids, etc.)
- diffuse (multifocal) positive hair pull test consistent with rapidly progressive AA."

There may be other factors which could increase the severity rating.

Clinical trials have shown a lower response rate in people with a longer duration of severe disease; however, there is insufficient evidence at present to inform decision-making about access to treatment based on disease duration. Clinical experience has demonstrated hair regrowth in people with AA who would have

---

[1] Harries *et al.*, British Association of Dermatologists living guideline for managing people with alopecia areata 2024, submitted to *Br J Dermatol* for publication.

been excluded in clinical trials due to their disease duration. Therefore, we do not recommend disease duration is included in the application for ritlecitinib or when assessing the patient's eligibility for treatment. This may change in the future as more evidence becomes available.

People with severe AA already established on a Janus kinase (JAK) inhibitor privately may seek prescription for ritlecitinib via the NHS. It would be reasonable to establish an estimated absolute SALT score prior to initiating a JAK inhibitor, e.g. via images or patient description.

Key points – severity assessment

Severe disease is defined as having:

1) At least 50% loss of scalp hair, e.g. absolute SALT score ≥50

   OR

2) Absolute SALT score 21-49 *plus* at least one additional factor

1.1 Psychological/psychosocial assessment of people with AA

Psychological/psychosocial assessment of people with AA is recommended using appropriate scoring tools to demonstrate severity on initiation but is not required for continuation of treatment. We appreciate that the Dermatology Life Quality Index (DLQI) is used routinely for initiation of high-cost treatments in other dermatological conditions. However, DLQI does not always capture accurately the impact of hair loss. Demonstrating psychological/psychosocial impact of AA can be supported by using mental health patient-reported outcome measures (PROMs) or screening tools (upcoming BAD AA guideline update; Appendix O) that have psychometrically reliable cut-off points. These include:

- Patient Health Questionnaire-9 (PHQ-9)
- PHQ-9 modified for Adolescents (PHQ-A)
- General Anxiety Disorder-7 (GAD-7) or
- Mood and Feelings Questionnaire.

Key points – impact assessment

1) Undertake psychological/psychosocial assessment to understand the impact of AA on the patient, including suicide risk.
2) Significant psychological impact increases the severity of the condition.
3) There is no one recommended measure, with clinical experience suggesting some commonly used measures do not always capture the impact of the condition (e.g. DLQI/EQ5D). From appendix O in the upcoming BAD AA guideline's supporting information document:

   "Mental health patient-reported outcome measures (PROMs) questionnaires can enable healthcare professionals to assess and/or monitor the mental health of their patients. PROMs scores should never be interpreted in isolation, as they cannot be used to make a definitive mental health diagnosis."

   Thus, a holistic appraisal, supported by appropriate measures as necessary, should be applied.
4) Currently, assessing psychological outcomes is not a recommended measure of the effectiveness of treatment with ritlecitinib as there is insufficient evidence a) that it has an impact on patients' psychology and b) on the most appropriate tool to use. Additionally, there is poor correlation between psychological and objective AA severity outcome measures.
5) Provide information on relevant patient support organisations (see Appendix).

2. WHEN TO ASSESS TREATMENT RESPONSE

- At week 36, clinicians should review treatment response; the decision on continuation of treatment depends on the evidence of hair growth, recording the absolute SALT score at this point.
- Mental health PROMs scores do not need to be recorded for treatment continuation purposes, only for defining AA severity upon initiation.

3. INADEQUATE TREATMENT RESPONSE

Prior to commencing ritlecitinib, a discussion should be had with people with AA that treatment will need to be discontinued if limited hair regrowth is achieved or if there are significant adverse effects. It is likely that any regrown hair will be lost upon discontinuation and patients should be made aware of this prior to commencing.

In the phase 2b/3 clinical trial,[2] the company used an absolute SALT score of ≤20 as the primary outcome. We recommend that this endpoint is also used in clinical practice.

- At week 36, clinicians should consider the following, depending on treatment response:
    - If no response at all then ritlecitinib should be stopped at this point.[3]
    - If terminal regrowth has been noted on examination, but an absolute SALT score of ≤20 is not achieved, then consider extending treatment duration for a further 3 months. If at that extended point, an absolute SALT score of ≤20 is still not achieved, then treatment should be discontinued.
- For those with SALT scores of 21-49 *plus* additional factors categorising the AA as severe:
    - Continuation should depend on the improvement of the parameters discussed by the clinician and patient prior to commencing the treatment.

4. CONSIDERATIONS

- People with AA will still require prescriptions for wigs whilst regrowing their hair during treatment with ritlecitinib; therefore, services for wig provision and prescriptions need to be maintained.[4]
- Clinicians should consider psychological support[5] required for people with AA due to discontinuation of ritlecitinib, resulting in hair loss. People with AA experiencing hair loss all over again may find this traumatising.
- Clinicians should counsel people with AA prior to initiation of ritlecitinib on the likelihood of it being a life-long treatment
- We encourage dermatology departments to engage with an AA-related pharmacovigilance register such as GRASS-UK to help collect real-world data on treatment response and long-term safety. These data can help us gain greater understanding of the condition/treatment trajectory, and ultimately inform future clinical practice.

---

[2] King *et al.*, *The Lancet* 2023, 401, 1518-29

[3] Summary of Product Characteristics https://www.medicines.org.uk/emc/product/15257

[4] Alopecia UK Charter for Best Practice for NHS Wigs Provision https://www.bad.org.uk/alopecia-uk-charter-for-best-practice-for-nhs-wigs-provision/

[5] Alopecia UK https://www.alopecia.org.uk/; Changing Faces https://www.changingfaces.org.uk/services-support/counselling-support/; Anxiety UK https://www.anxietyuk.org.uk/; Samaritans https://www.samaritans.org/

APPENDIX

Support for people with AA

Alopecia UK is a national charity working to improve the lives of children and adults affected by alopecia through its aims of Support, Awareness and Research. The charity provides online resources and face-to-face peer support for people struggling with the psychological impact of living with a visible difference.

Alopecia UK's website is the best starting point for anyone seeking help and advice. The website includes a wealth of information, including, but not limited to:

- Guidance for living well with alopecia
- Resources for children and young people, including a Schools' Pack
- Advice for parents
- Links to peer support options for all ages, including both online and face-to-face groups, national events and personal experience blogs
- A Service Directory of businesses offering alopecia-related products and services (e.g. wigs, headwear, permanent make up)
- A sign-up form for the charity's monthly newsletter
- Research updates
- Links to other useful organisations (e.g. Samaritans, Mind, Anxiety UK)

Visit alopecia.org.uk for more information.