National Institute for Health and Care Excellence

Health Technology Evaluation

Deuruxolitinib for treating severe alopecia areata [ID6597]

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Sun Pharma	A single technology appraisal using a cost-comparison approach is the most appropriate route for this evaluation. Deuruxolitinib meets the criteria outlined in section 2.6.1 of Health Technology Evaluations: The Manual (last updated 14 July 2025). *'At scoping consultation, questions will be asked relating to the population, treatment pathway, benefit and clinical similarity to help establish whether cost comparison is appropriate. The aim is to establish whether the intervention is clinically similar, such that it can be compared with another intervention that NICE has previously recommended in technology appraisal guidance for the same indication, using cost-comparison methods. The chosen comparator must be established in practice and have substantial use in the NHS in England for the same indication.'* The intervention (deuruxolitinib) is clinically comparable to the comparator, ritlecitinib, which has already been recommended by NICE for the treatment of severe alopecia areata (TA958). Deuruxolitinib and ritlecitinib are JAK inhibitors supported by pivotal studies which enrolled adult patients with	Thank you for your comments. The evaluation will be routed as a cost comparison.

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		severe AA (SALT≥50) and evaluated absolute SALT≤20 response at ~24 weeks. Ritlecitinib is an established treatment with widespread use across the NHS in England for the same indication. Moreover, pursuing a cost-comparison route could facilitate earlier patient access to promising new technologies while maintaining value for taxpayers.	
	British Association of Dermatologists	We support the evaluation of this topic and agree with the proposed evaluation route. Alopecia areata (AA) has a lifetime incidence of approximately 2.1%, with a point prevalence of 0.58% in the adult population. It affects both children and adults, with no gender predominance. AA has been associated with social deprivation and is more common in non-White ethnic groups. AA remains an underserved condition with limited access to robust/highly effective treatments. It is associated with severe psychosocial impact including depression/ anxiety, time off work and unemployment. Given these factors, we believe a NICE appraisal is both appropriate and necessary to ensure equitable access to emerging therapies and to support evidence-based commissioning decisions. The proposed evaluation route (e.g. single technology appraisal) is suitable, provided it allows for consideration of the broader impact, including psychosocial aspects, of AA on patients' lives.	Thank you for your comments. The evaluation will be routed as a cost comparison.
	Alopecia UK	The patient pathway for the management of alopecia areata is still very poor with many patients left untreated or treated with medications with limited proven efficacy in the context of alopecia areata. For many individuals, referral times often exceeds 12 months	Thank you for your comments.

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		With only 2 treatments with licences to treat alopecia areata, and only one of them approved by NICE, it is vital more treatments with proven efficacy in alopecia areata are assessed and approved in a timely manner.	
Wording	Sun Pharma	Considering the cost-comparison approach for this appraisal, the wording about cost effectiveness should be removed.	Thank you for your comment. The evaluation will be routed as a cost comparison. The remit remains the same.
	British Association of Dermatologists	We agree with the wording of the remit.	Thank you for your comment.
	Alopecia UK	The wording does reflect the issue. The main issue being the psychosocial impacts of hair loss. This is referenced in the Abby McBeth paper.	Thank you for your comment.
Timing issues	Sun Pharma	Current NICE scheduling timelines are appropriate. Use of a cost-comparison approach to the assessment would reduce the time and complexity of the evaluation, accelerate committee decision making, and ensure the treatment reaches patients sooner.	Thank you for your comments. This evaluation has been scheduled into the work programme. The evaluation will be routed as a cost comparison.
	British Association of Dermatologists	Currently, ritlecitinib is the only licensed and NICE-approved drug for AA, beyond topical steroids. Ritlecitinib (JAK 3/TEC inhibitor) can take a longer timeframe to achieve regrowth, including in certain cases up to 9-12 months. Also, around 40% of patients respond to ritlecitinib so there is a large group of people who will not respond. Therefore, a different targeted therapy such as deuruxolitinib (JAK1/JAK2 inhibitor) will give patients more options. The trial	Thank you for your comments. This evaluation has been scheduled into the work programme.

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		data also suggest patients demonstrated faster hair regrowth. With ritlecitinib, 23% of patients achieved 80% regrowth by week 24, versus 41.9% of patients on higher dose of deuruxolitinib. There is a significant mental health burden associated with this hair loss disorder and current treatments are messy, or painful, or unlicensed, and/or require travel to dermatology centres weekly for contact immunotherapy. Effective therapy for this group is urgently needed to minimise cumulative life course impairments resulting from being affected by AA, allowing those affected to attain their full potential in life. Duration of AA may also impact long-term prognosis, so access to effective therapy early in the disease course in this group is important.	
	Alopecia UK	There are weaknesses in the patient pathway for treatment of patients with alopecia. With limited licensed medicines and only one medicine approved by NICE. Approval and access to a new effective and safe medicine will improve wellness of people with alopecia	Thank you for your comments. This evaluation has been scheduled into the work programme.
Additional comments on the draft remit	Alopecia UK	We ask that NICE considers the BAD living guideline for alopecia areata. This is the first guideline since 2012 and gives an assessment of efficacy of other medicines available. (Harries, M.J. et al. (2025) “British Association of Dermatologists living guideline for managing people with alopecia areata 2024,” British Journal of Dermatology, 192(2), pp. 190–205. Available at: https://doi.org/10.1093/bjd/ljae385.) Availability of an effective medicine which results in hair regrowth will overcome much of the psychosocial impacts and could reduce the burden on the NHS through ongoing appointments	Thank you for your comments. Evidence to be considered should be included in any submissions.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Sun Pharma	We consider the background information accurate and complete.	Thank you for your comment.
	British Association of Dermatologists	The background section includes a recent epidemiology reference, but some aspect could be expanded, and the other references updated, as outlined below: The background section includes the recent UK epidemiological studies (Harries *et al.* https://onlinelibrary.wiley.com/doi/10.1111/bjd.20628) that estimates the current (2018) point prevalence of AA in UK adults. It should be noted that these data were derived from interrogation of a large primary care database (RCGP-RSC) and therefore rely on individuals with AA presenting to primary care. This may underestimate the total prevalence in the UK population. This paper also includes detailed information on age of onset, risk groups (e.g. more frequently in those of Asian background, and from socially deprived and urban areas), as well as referral rates. The increased prevalence in ethnic minority and deprived populations may be underestimated as these groups may be less likely to present to health services. These factors are only partially explored in the background section. Treatment of AA of less than 50% surface area with topical corticosteroids in primary and secondary care is commonplace. With single patches of hair loss, watchful waiting is likely to result in spontaneous regrowth in 80% of cases, but with increasing extent of disease, spontaneous regrowth becomes much less likely. It would be worth acknowledging the AA Priority Setting Partnership that highlights AA uncertainties important to both clinicians and patients (Macbeth *et al.* https://onlinelibrary.wiley.com/doi/10.1111/bjd.15099). The background section should include reference to the BAD living guideline for managing people with AA (Harries *et al.* https://doi.org/10.1093/bjd/ljae385; N.B. a second iteration has been	Thank you for your comments. The background section is intended to be a brief overview of the condition. We have updated the scope to reflect that the prevalence in some ethnic minority and socioeconomic groups may be underestimated. We have updated the scope to remove reference to AA only being treated with topical corticosteroids if hair loss of more than 50% is present.

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		submitted for publication). Also, the following reference outlines prescribing practices prior to ritlecitinib availability in the NHS, giving insights into the standard of care prior to the availability of JAK inhibitors https://doi.org/10.1002/jvc2.495.	
	Alopecia UK	In paragraph 4 it suggests that just patients with 50% hair loss are given options for camouflage, which we assume to be wigs. In our experience, wig wearing in those with severe forms of alopecia (more than 50% hair loss) is commonplace. Please consider that in our research approx. 65% people with alopecia areata wear wigs most of the time, with many being given NHS prescription for wigs.	Thank you for your comment. The scope has been updated to include reference to the use of wigs in patients with 50% hair loss.
Population	Sun Pharma	Yes [the population is defined appropriately].	Thank you for your comment.
	British Association of Dermatologists	Yes, the population is appropriate, as per the licence in the US. For clinical trial purposes, severe AA has been defined based on scalp hair loss of ≥50% and this has been measured using the SALT score. However, we know from treating these patients, that loss of facial hair and psychological comorbidity can have a tremendous impact which would upscale someone with scalp loss of 21-49% to severe when these additional factors are found. An example of a scale utilised to demonstrate this is Alopecia Areata Symptom Impact Scale (AASIS).	Thank you for your comments.
	Alopecia UK	We would not consider alopecia totalis as 'rare' (paragraph 1). The WHO definition of rare disease is a prevalence of 1 in 2000. In our understanding alopecia totalis affects approx. 10% of people with alopecia equating to an estimated global prevalence of 0.08-0.15% (Vu et al. 2022).	Thank you for your comments. We have removed the reference to alopecia totalis being rare.

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Subgroups	Sun Pharma	Sun Pharma do not intend to explore subgroups for this appraisal. Sun Pharma intends to seek reimbursement in line with the MHRA licence wording.	Thank you for your comments.
	British Association of Dermatologists	The AA severity definitions used in the BAD's AA living guideline (2024) 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. 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.	Thank you for your comments. The population of interest in this appraisal is severe alopecia areata No change to scope required.
	Alopecia UK	Please consider the subgroups as mentioned – higher incidence in young adults, and link to social deprivation. You do not mention the possible higher incidence in some ethnic groups	Thank you for your comments. The technology will be appraised within its marketing authorisation.

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			We have updated the scope to reflect that the prevalence in some ethnic minority and socioeconomic groups may be underestimated.
Comparators	Sun Pharma	Yes, ritlecitinib is the appropriate comparator for a cost-comparison appraisal.	Thank you for your comment.
	British Association of Dermatologists	Currently accepted UK treatment for AA is very variable and is clinician-dependant. In specialist centres, contact immunotherapy may be considered a helpful comparator but this is only available in a limited number of dermatology centres and increasingly, the raw ingredient for this has been difficult to source which has led to several services no longer offering this treatment. Various treatments have been used over the years, but their efficacy has been variable. See the expert consensus paper published recently that summarises the main options (Meah *et al.* https://pubmed.ncbi.nlm.nih.gov/32165196/). This paper is useful as the current quality of evidence for most AA therapies is poor. The only available licensed and NICE-approved systemic therapy for severe AA in the NHS is ritlecitinib (JAK 3/TEC inhibitor). Deuruxolitinib (JAK1/JAK2 inhibitor) has a different mode of action to ritlecitinib. Around 40% of patients respond to ritlecitinib so there is a large group of people who will not respond. Therefore, a different targeted therapy such as deuruxolitinib (JAK1/JAK2 inhibitor) will give patients more options and with two dosing regimens available, the dose can be titrated accordingly. It should also be noted that	Thank you for your comments. The scope defines the comparator as established clinical management without deuruxolitinib, which may include ritlecitinib. No change to scope required.

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		ritlecitinib can take a longer timeframe to achieve regrowth, in certain cases up to 9-12 months and even beyond 12 months. Deuruxolitinib trial data suggests patients demonstrated faster hair regrowth. With ritlecitinib, 23% of patients achieved 80% regrowth by week 24, versus 41.9% of patients on a higher dose of deuruxolitinib.	
	Alopecia UK	Clinical management of alopecia areata is poor. We hope that deuroxolitinib is compared to ritlecitinib for effectiveness and cost effectiveness.	Thank you for your comment.
Outcomes	Sun Pharma	All key outcomes are listed.	Thank you for your comment.
	British Association of Dermatologists	AA hair-loss assessment is generally done by the % extent of hair loss – usually using the Severity of Alopecia Tool (SALT) score. SALT outcomes can be expressed in different ways including absolute SALT score or % reduction in surface area affected. Certain hair loss sites may have a disproportionate impact on an individual (e.g. beard or eyebrow loss), or more limited patches may be in an area more difficult to camouflage (e.g. frontal hairline). The main hair loss sites to consider are scalp, eyebrows, and eyelashes. However, beard hair loss should also be considered specifically as this can have religious implications, e.g. in the Sikh and Jewish faiths. For clinical trial purposes, severe AA has been defined based on scalp hair loss of ≥50% and this has been measured using the SALT score. However, we know from treating these patients; that loss of facial hair and psychological morbidity can have a tremendous impact which would upscale someone with scalp loss of 21-49% to severe when these additional factors are found. An example of a scale utilised to demonstrate this is Alopecia Areata Symptom Impact Scale (AASIS) [N.B. For disease severity, SALT would only be applicable for scalp AA.]	Thank you for your comments. Percentage of area affected by hair loss and severity of alopecia areata are included as broad outcomes. No change to scope required.

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	Alopecia UK	Please consider an appropriate health related quality of life measure which is appropriate to the psychosocial challenges experienced by people with alopecia areata. Hair regrowth is what is most valued by patients so that they no longer suffer from a visible difference	Thank you for your comments. The scope includes quality of life as an outcome, but specific measures are not included. No change to scope required.
Equality	Sun Pharma	Please refer to the equality issues raised in the ritlecitinib appraisal [TA958], which are also applicable to this appraisal considering the same context.	Thank you for your comment. Potential equalities issues will be noted on the equalities impact assessment and considered by the committee as part of the evaluation.
	British Association of Dermatologists	Epidemiological data has shown that AA is more common in those of Asian background and those of lower socioeconomic status and urban location, but referral to secondary care is lower in these lower socioeconomic groups (Harries et al. https://onlinelibrary.wiley.com/doi/10.1111/bjd.20628). Inclusion of individuals with these characteristics is important in the clinical and cost-effectiveness data and in the patient representation in the consultation process. Beard hair loss can have some religious implications, e.g. some from the Sikh and Jewish faiths. Here, many standard treatments are more challenging for beard hair loss, where systemic medication is often required at an earlier stage.	Thank you for your comments. Potential equalities issues will be noted on the equalities impact assessment and considered by the committee as part of the evaluation. We have updated the scope to reflect that the prevalence in some ethnic minority and

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		Some health-related quality of life measures may not adequately capture the impact of living with health conditions in older people (questions about work, studying, sport) or those who are not in a relationship (question about sexual activity); they may also not capture anxiety and depression across all groups – two parameters that are commonly and negatively influenced by AA. Additionally, they may discriminate against those who are non-native English speakers	socioeconomic groups may be underestimated.
	Alopecia UK	Please consider the subgroups of young adults and ethnic minority needs.	Thank you for your comment.
Questions for consultation	Sun Pharma	**Where do you consider deuruxolitinib will fit into the existing care pathway for alopecia areata?** Deuruxolitinib is expected to be at least as efficacious as ritlecitinib and become a treatment option for patients in the existing care pathway for severe alopecia, available alongside ritlecitinib. **Which types of alopecia areata would deuruxolitinib be considered for?** Deuruxolitinib would be considered as a treatment for all types of severe alopecia areata (including patchy, ophiasis, totalis, universalis) **Would deuruxolitinib be a candidate for managed access?** No. **Please select from the following, will deuruxolitinib be:** **A. Prescribed in secondary care with routine follow-up in secondary care**	Thank you for your comments.

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		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.** A. Deuruxolitinib is expected to be prescribed and followed up in secondary or tertiary care dermatology clinics. This is also the case for ritlecitinib. **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.** As deuruxolitinib can be assessed using a cost-comparison approach, a QALY calculation will not be necessary.	
	British Association of Dermatologists	**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?** Currently, ritlecitinib is the only licensed and NICE-approved treatment for AA. JAK inhibitors, in general, fit at the stage when (unlicensed) topical contact immunotherapy (if available) is considered, i.e. ≥50% hair loss that has not responded to topical +/- oral corticosteroids and intralesional corticosteroids (where appropriate). N.B. topical contact immunotherapy can only treat *scalp* hair loss. See also the expert consensus report (Meah *et al.* https://pubmed.ncbi.nlm.nih.gov/32165196/). Consensus was achieved for the following statement regarding preferred second-line agents for AA “If all	Thank you for your comments.

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		treatments were equally reimbursed, JAK inhibitors would be the ideal choice for systemic therapy in adults". **Would deuruxolitinib be a candidate for managed access?** Possibly, this would be useful to help shape and inform its long-term use as it is still unclear who will achieve complete remission, who may need just dose reduction for maintenance, etc. It would depend on what additional information is required before the treatment is approved. This approach may answer questions about demand and test eligibility criteria, but it is unlikely to answer longer term questions about efficacy, safety, patient stratification and treatment duration – this will be best answered by a national AA pharmacovigilance registry (N.B. A national UK registry for AA, funded by the British Skin Foundation, has been established with pilot sites soon to recruit patients). **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.** Deuruxolitinib would require similar screening/ monitoring blood tests and follow-up as other JAK inhibitors utilised in dermatology already, for atopic dermatitis/psoriasis and alopecia areata. Follow-up rates would be the same as for ritlecitinib patients. For deuruxolitinib, CYP2C9 genotype determination test is required, and it is already utilised in the NHS for multiple sclerosis patients. This test helps us determine how patients will metabolise the treatment, which provides further information on safety/efficacy. In dermatology, we are familiar with this type of	

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		practice as we routinely check G6PD prior to starting dapsone or TPMT for azathioprine. This is a move towards personalised medicine providing the right treatment to the right patient. **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?** JAK inhibitors are innovative in their use for AA and may make a significant impact on this patient group, as currently the treatment of severe AA is very difficult. There are no evidence-based treatments available on the NHS that have been evaluated successfully in high-quality clinical trials, except for topical corticosteroids, which are usually ineffective in severe disease, and NICE-approved ritlecitinib, which is still not available in *all* NHS trusts. Those with AA have a significant mental health burden associated with their disease and hopefully the availability of evidence-based treatments will improve the mental health burden. AA is also associated with time away from work, which will have a significant economic impact on the wider population. Current available therapies for AA are often ineffective. Regular clinic visits, blood monitoring and drug costs, along with wig prescription and wider societal issues (e.g. unemployment) all contribute the impact of AA on the individual, NHS and society more widely. Effective treatment options are needed urgently to prevent the longer-term sequelae of ongoing AA (e.g. mental health issues). **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** It is difficult to know the best way to capture disease impact in the AA population. Poor quality of life, anxiety and depression can be prominent in this group. There are a number of disease specific quality of life tools now	

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		available (e.g. AASIS – Winnette *et al.* https://pubmed.ncbi.nlm.nih.gov/35000236/). The disease burden of AA in relation to other conditions is explored in these publications (Karimkhani *et al.* https://onlinelibrary.wiley.com/doi/10.1111/bjd.13559 and Korta *et al.* https://pubmed.ncbi.nlm.nih.gov/29548423/). **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.** Epidemiological UK-based study has shown detailed information on age of onset, risk groups (e.g. more frequently in those of Asian background, and from socially deprived and urban areas), as well as referral rates. The increased prevalence in ethnic minority and deprived populations may be underestimated as these groups may be less likely to present to health services. Hair can have a strong cultural/religious association.	

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		It should also be noted that alexithymia, which is considered potentially a form of neurodiversity, has been reported in patients with severe alopecia areata. This has been demonstrated through several studies (10.1176/appi.psy.44.5.374; 10.4103/0019-5154.135525). Therefore, alopecia areata patients may not be able to communicate clearly the impact of their disease or needs. We have to support them with treatment options that are accessible, effective and convenient.	

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope:

Genetic Alliance