Single Technology Appraisal

Baricitinib for treating severe alopecia areata [ID3979]

Committee Papers

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SINGLE TECHNOLOGY APPRAISAL

Baricitinib for treating severe alopecia areata [ID3979]

Contents:

The following documents are made available to stakeholders:

Any information supplied to NICE which has been marked as confidential, has been redacted. All personal information has also been redacted.

Baricitinib for treating severe alopecia areata (ID3979)

Single Technology Appraisal

Response to consultee, commentator and public comments on the Draft Guidance Document (DGD)

Type of stakeholder:

Consultees – Organisations that accept an invitation to participate in the appraisal including the companies, national professional organisations, national patient organisations, the Department of Health and Social Care and the Welsh Government and relevant NHS organisations in England. Consultees can make a submission and participate in the consultation on the draft guidance document (DGD; if produced). All non-company consultees can nominate clinical experts and/or patient experts to verbally present their personal views to the Appraisal Committee. Company consultees can also nominate clinical experts. Representatives from NHS England and clinical commissioning groups invited to participate in the appraisal may also attend the Appraisal Committee as NHS commissioning experts. All consultees have the opportunity to consider an appeal against the final recommendations, or report any factual errors, within the final draft guidance (FDG).

Clinical and patient experts and NHS commissioning experts – The Chair of the Appraisal Committee and the NICE project team select clinical experts and patient experts from nominations by consultees and commentators. They attend the Appraisal Committee meeting as individuals to answer questions to help clarify issues about the submitted evidence and to provide their views and experiences of the technology and/or condition. Before they attend the meeting, all experts must either submit a written statement (using a template) or indicate they agree with the submission made by their nominating organisation..

Commentators – Commentators can participate in the consultation on the DGD (if produced), but NICE does not ask them to make any submission for the appraisal. Non-company commentator organisations can nominate clinical experts and patient experts to verbally present their personal views to the Appraisal Committee. Commentator organisations representing relevant comparator technology companies can also nominate clinical experts. These organisations receive the FDG and have opportunity to report any factual errors. These organisations include comparator technology companies, Healthcare Improvement Scotland any relevant National Collaborating Centre (a group commissioned by NICE to develop clinical guidelines), other related research groups where appropriate (for example, the Medical Research Council and National Cancer Research Institute); other groups such as the NHS Confederation, the NHS Commercial Medicines Unit, the Scottish Medicines Consortium, the Medicines and Healthcare Products Regulatory Agency, the Department of Health and Social Care, Social Services and Public Safety for Northern Ireland).

Public – Members of the public have the opportunity to comment on the DGD when it is posted on the Institute's web site 5 days after it is sent to consultees and commentators. These comments are usually presented to the appraisal committee in full, but NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

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 number	Type of stakeholder	Organisation name	Stakeholder comment Please insert each new comment in a new row	NICE Response Please respond to each comment
1	Company	Eli Lilly	**Executive Summary** Lilly is disappointed with the draft decision not to recommend baricitinib for the treatment of patients with severe alopecia areata (AA), especially considering that NICE has recognised that there is an unmet need for safe and effective treatments in this indication, and given that "*clinical experts considered baricitinib to be a step-change in managing severe alopecia areata for which there are limited licensed treatment options*" (Section 3.16). Lilly is particularly concerned that the committee conclusion on the choice of utility values implies that the committee does not believe that there is any meaningful value for the NHS in treating this disease. Nevertheless, Lilly is grateful for the opportunity to respond to the draft guidance document (DGD) with a focus on the key areas of uncertainty that were discussed in the appraisal committee meeting (ACM). These include: • The use of the Adelphi Disease-Specific Programme (DSP) study to inform the cost-effectiveness model (CEM) utilities • Source of data informing the composition of best supportive care (BSC) • Differential use of BSC following loss of response • The impact of the uncertainties in this indication on the willingness-to-pay (WTP) threshold The face validity of the Committee-preferred assumptions in the CEM	The committee acknowledged that baricitinib is innovative (see section 3.18 of the FDG), the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG) and the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG).
2	Company	Eli Lilly	**Use of the Adelphi DSP study to inform the CEM utilities:**	The committee acknowledged the

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			Summary points: • Severe AA has a significant impact on patient's health-related quality of life (HRQoL), especially those seeking treatment, but this was not adequately captured in the BRAVE-AA trials; utilities generated from these data therefore lack face validity and ultimately imply that treatment of severe AA is not of value to the healthcare service when used in the CEM • The Company consider that the preference for the use of the BRAVE-AA trial utilities in the CEM directly contradicts many of the earlier conclusions made by the Committee regarding the HRQoL impact of severe AA • The Company maintain their position that the Adelphi DSP is a more appropriate source of utilities for use in the CEM given that these data have greater face validity, and represent a robust, objective, and impartial source of evidence that is aligned with the NICE reference case[1] **Limitations of the BRAVE-AA trial utilities** The Company welcomes many of the key conclusions made by the Committee regarding the HRQoL impact of severe AA on patients. In Section 3.1, the Committee concludes that "*severe alopecia areata can have a profound psychosocial impact on a person's quality of life".* The Company considers that this closely aligns with the evidence presented throughout the duration of this appraisal, in which patients with severe AA consistently report an impairment in their HRQoL, and negative consequences on their daily activities, relationships and careers.[2-5] In Section 3.6, the Committee also acknowledge that this profound impact on quality of life is "*not shown in overall baseline EQ-5D scores for people taking part in the BRAVE trials*". Finally, the Committee acknowledge in Section 3.7 that "*hair regrowth can have a profound impact on improving a person's quality of life*", again aligning	psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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			closely with the evidence presented by the Company, whereby controls and patients with mild disease frequently report greater HRQoL relative to those with severe hair loss.[2-4, 6] Importantly, the Committee's conclusions above exemplify the lack of face validity of the EQ-5D data from the BRAVE-AA trials for the population of relevance for this appraisal – individuals with severe AA who would become eligible for treatment with baricitinib (in secondary care) if recommended by NICE: • Firstly, use of the BRAVE-AA trial EQ-5D trial data would imply that [redacted] of this population have perfect health ([redacted]). This, by definition, appears to contradict the fact that these patients are considered to have a **severe disease** and that **they are actively engaging with the healthcare system** as a result of their condition. The Company would like to emphasise that those patients (if any) who do not experience an impairment in their HRQoL would be unlikely to engage with the healthcare system, and therefore would not receive baricitinib in secondary care. • Use of these BRAVE-AA trial EQ-5D data would also suggest that [redacted] of these patients experience little to no anxiety and/or depression as a result of their disease (EQ-5D scores of 1 or 2 in the anxiety/depression domain). This is in contrast to clinical expert input received during the ACM, whereby it was noted that "***high levels*** *of anxiety and depression are common, occurring in about* ***1 in 3 people****"* (Section 3.6). • Finally, due to this ceiling effect, use of these data would suggest that significant hair regrowth does not result in any significant improvement in HRQoL. In fact, the Committee-preferred assumptions (including use of the trial utilities) suggest that additional hair regrowth (to Severity of Alopecia Tool [SALT]≤20)	

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			from the introduction of baricitinib would result in only [redacted] in full health per patient treated across their lifetime on average, relative to receiving 'no active treatment' (based on the [redacted] incremental quality-adjusted life years [QALYs] produced by the CEM when using the Committee-preferred assumptions). Considering this lack of face validity, the preference towards the BRAVE-AA trial utilities outlined in Section 3.14 directly contradicts the previous conclusions made by the Committee regarding the HRQoL impact of severe AA on patients. The Company would like to emphasise that preference towards the BRAVE-AA trial utilities implies that, contrary to the evidence presented throughout the ACM by the patient and clinical experts, severe AA does not have a significant impact on individuals, and hair regrowth would not result in any significant improvement in HRQoL among those responding to treatment (those achieving SALT≤20). As such, use of these trial data in the CEM ultimately implies that treatment of severe AA is not of value to the healthcare system. **Suitability of the independent Adelphi DSP real world evidence study utilities** Based on Section 3.12, it appears that the key driver behind the preference towards the trial utilities is the view that the BRAVE-AA trial data are "*more robust"* than the independent Adelphi DSP real world evidence (RWE) study. However, the Company consider that this conclusion ought to be heavily caveated by the lack of face validity associated with the trial utility data. While the independent Adelphi DSP RWE study is not a randomised controlled trial (RCT) and provides only one data point from each patient, these factors are greatly outweighed by the fact that the independent Adelphi DSP RWE study data more realistically reflect the evidence presented by the patient and clinical experts and the previous conclusions made by the Committee	

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			regarding the HRQoL impact of severe AA on patients. The Company would also like to clarify that contrary to Section 3.12, which suggests the sample size of the BRAVE-AA trials is "*more than 4 times that of the Adelphi study*", the independent Adelphi DSP RWE study included [redacted] patients in the mild group (used as a proxy for the HRQoL change from baseline) which is [redacted] of the population achieving SALT≤20 in the BRAVE-AA trials ([redacted]) – the population that would inform utility change from baseline in the CEM. It should also be noted that the collection and analysis of the Adelphi DSP RWE study data was conducted independently, with data collected only on the endpoints specified in the RWE study protocol. Furthermore, while Lilly contributed (by purchasing access) to the funding of the independent Adelphi DSP RWE study and collaborated on the data of relevance to be collected, the raw data do not belong to Lilly and can be, and have been, purchased and published by others. Moreover, the Company would like to emphasise that the independent Adelphi DSP RWE study for AA should be considered as suitable for decision-making as the BRAVE-AA trials, given that it represents a highly robust, objective, and impartial data source that aligns with the NICE reference case.[1, 7, 8] While not discussed during the ACM, Adelphi DSP RWE studies are an established method for investigating current treatment practices, and are designed to capture a cross-section of robust real-world data. They are conducted using specific procedures to reduce bias, which, "*in the context of observational research and real-world data collection, are considered at least as robust as those used in RCTs*".[8] As such, they have been conducted in over 30 different disease areas, and the results from many of these studies have been published at international meetings and in peer-reviewed journals, highlighting the robustness and validity of their findings.[7, 8] It should also be noted that Adelphi DSPs or similar evidence types (chart	

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			reviews/market research/treatment pattern studies) have been accepted in previous technology appraisals. As highlighted by the Medicines and Healthcare products Regulatory Agency (MHRA), "*evidence derived from real-world data may also be more representative of the true effects of a treatment in the community and more generalisable than data from the standardised setting of a traditional clinical trial*".[9] Moreover, the independent Adelphi DSP RWE study provides a real-world reflection of clinical practice in the **relevant presenting population**, i.e. patients in secondary care.[8] The Company therefore consider that the independent Adelphi DSP RWE study for AA is likely to provide a more accurate picture of the HRQoL impact of severe AA (and the subsequent utility gain associated with treatment response) due to the following reasons: • Contrary to the arguments presented by the EAG during Technical Engagement (TE), the independent Adelphi DSP RWE study is more representative of the population of patients who would receive baricitinib if it was licensed, given that the independent Adelphi DSP RWE study in AA was conducted among patients seeking treatment from their dermatologist in secondary care (i.e. those that would become eligible for treatment with baricitinib if recommended by NICE). • BRAVE-AA participants were recruited based on their willingness to participate in an experimental medication trial and may therefore not representative of all patients with severe AA in clinical practice.[8] • As noted by the patient expert in Section 3.6, people who were more psychologically impacted by their condition may not have been eligible to take part in the trials due to the exclusion of patients with severe neuropsychiatric disorder, and therefore not put forward for screening for trial entry, leading to overestimates	

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of the baseline utility of patients with severe AA.

- As noted by the patient expert in Section 3.6, "*people who were enrolled into the BRAVE-AA trials may have had lower rates of anxiety than would be expected in the NHS, because people in trials have hope of being treated".*
- During TE, the EAG highlight that the ALLEGRO-LT trial also demonstrated [redacted].[10] The EAG suggests this supports the accuracy of the BRAVE-AA trial utilities whereas the Company consider that this is in fact a reflection of the challenges and complexities associated with capturing HRQoL in this disease area within a clinical trial setting using generic instruments such as EQ-5D.

Overall, the Company maintain that the Adelphi DSP represents a better source of evidence for the utilities used in the CEM, as these data are likely to be more representative of patients in real-world clinical practice (in a disease area where this may be particularly valuable), were collected using robust methodology and have greater face validity when considering the evidence presented throughout the ACM. The utilities from the BRAVE-AA studies and the Adelphi DSP are presented in **Error! Reference source not found.** and **Error! Reference source not found.**, respectively, for reference.

Table 1. Utility values from the BRAVE-AA trials informing CEM

Baseline utility	CfB among responders at Week 36
[redacted]	[redacted]

Table 2. Utility values from the independent Adelphi DSP RWE study informing CEM

Severe/very severe group – proxy for baseline utility	Mild group – proxy for CfB among responders at Week 36

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			[redacted]	
3	Company	Eli Lilly	**<u>Source of data informing the composition of BSC</u>** **Summary points** • The arguments put forward by the EAG are of limited relevance to the current appraisal, since they focus on a situation in which "*all treatment options have been exhausted"* rather than considering the wider population of patients with severe AA who receive 'no active treatment' • Based on robust evidence of treatment patterns for severe AA in the population of relevance for this appraisal from the independent Adelphi DSP RWE study, the company maintain that these data should inform the composition of the BSC basket in the CEM **Critique of the EAG's arguments** In Section 3.10, it is noted that most people in the independent Adelphi DSP RWE study were treatment-experienced, having already tried many previous treatments. The EAG suggest that this is likely to mean that people would be less willing to try further pharmacological treatments that have limited effectiveness "*after all other options had been exhausted*" and subsequently argue that BSC should therefore only include wigs and orthotics. In response to this argument, the Company would like to emphasise that the relevant comparator for this appraisal (as accepted by the Committee in Section 3.14) is 'no active treatment'. Accordingly, in the CEM, patients receive 'no active treatment' (or baricitinib) for 36 weeks, at which point they may transition to BSC if they fail to respond (SALT≤20). This comparator reflects the fact that patients often initially receive no active treatment for their disease in the hope that their AA will spontaneously regrow, as well as the extended wait times for secondary care.[11]	The committee acknowledged the uncertainty surrounding the composition of best supportive care (see section 3.11 of the FDG).

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			In this context, the Company consider that the arguments put forward by the EAG to be of limited relevance to the economic analysis underpinning this appraisal, since they focus on a situation in which "*all other treatment options had been exhausted"* rather than a situation in which more people are "*likely to be treatment-naïve"* (Section 3.10), having been referred to secondary care following receipt of 'no active treatment'. Indeed, the Company acknowledge that there is likely to be a proportion of prevalent patients who *are* highly treatment-experienced, but who would likely receive baricitinib if it is licensed. However, it would be expected that over time the proportion of prevalent patients receiving baricitinib would gradually decrease, as baricitinib would become the first-line option for people with severe AA. **Composition and time horizon of BSC use** Focussing on the population of relevance for this appraisal, the Company would like to re-iterate the robustness and relevance of the independent Adelphi DSP RWE study, given that it was conducted amongst patients under the care of a dermatologist in secondary care. It should therefore be considered that these data, in which [redacted] were on BSC treatments (in a population were most patients were treatment experienced), provide robust and accurate data informing the composition of BSC in the model. Furthermore, as mentioned previously, independent Adelphi DSP RWE studies are an established method for investigating treatment patterns in real-world clinical practice, and this type of evidence (sometimes referred to as chart reviews/market research/treatment pattern studies) has also been accepted in previous technology appraisals for informing treatment patterns. As such, the Company consider that the use of only wigs and orthotics in the Committee-preferred base case following non-response in unrealistic and unreflective of current treatment practices within secondary care within the	

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			population of relevance for this appraisal. While the Company maintain that the independent Adelphi DSP RWE study should inform the composition of the BSC basket, Lilly acknowledges that it is unlikely that [redacted] of patients would on average remain on BSC drug treatments (and therefore incur BSC treatment costs) over the full lifetime time horizon of the model. Lilly have therefore provided an updated CEM alongside these responses, in which they have explored the effect of limiting the application of BSC drug costs only to a 10-year time horizon within the model, rather than over the full lifetime time horizon of the model, as presented in **Error! Reference source not found.**. This BSC drug cost time horizon was considered the most realistic time horizon over which to apply BSC treatment costs for the following reasons: • In the Adelphi DSP, [redacted] of patients were on current treatment, despite [redacted] being pre-treated. Moreover, of all the participants in the Adelphi DSP, [redacted] had previously received 1 line of therapy, [redacted] had received 2 lines of therapy, [redacted] received 3 lines of therapy and [redacted] had received 4 lines of therapy. These data demonstrate that patients with severe AA frequently cycle through multiple treatments, likely over an extended period. In addition, as patients in the model are assumed to start treatment at 37.5 years (aligned with the baseline characteristics in the BRAVE-AA trials), the Company consider that it is likely that patients would continue to seek treatment for their severe AA until at least the age of 47.5 years, as during this time the potential impact of age-related hair loss is less pronounced and the incidence of comorbidities that would contraindicate some of the BSC drugs likely remains low.	
4	Company	Eli Lilly	**<u>Differential use of BSC following loss of response</u>** **Summary points** • The Company maintain that it is likely that patients who have lost	The committee acknowledged the uncertainty surrounding the use of best supportive care after non-response (see section 3.12 of the

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			response after treatment with the only treatment licensed for severe AA, baricitinib, would be less likely to engage with BSC treatments compared with those receiving 'no active treatment', and would emphasise that clinical and patient expert opinion may particularly help to resolve this issue in the second ACM • The Company have proposed a revised base case and two scenarios each based on a reduction in BSC use following baricitinib as well as incorporating the limitation of BSC drug costs to a 10-year time horizon, as discussed above. **Extent of BSC use following non-response to baricitinib versus no active treatment** In the scenarios presented in **Error! Reference source not found.**, the Company has also further explored the impact of reducing the extent of BSC use within the baricitinib arm versus the 'no active treatment arm' following non-response. This is because the Company maintain that, compared to someone who had received baricitinib – a licensed treatment with proven efficacy and a tolerable safety profile – a patient who had received 'no active treatment' would be more willing to experiment with off-label treatments after failing to respond. This is because these patients would likely still feel hopeful that an off-label, low efficacy treatment could work if all they had received up to that point was a similar or poorer alternative ('no active treatment' and maybe other off-label treatments prior to this). Therefore, these patients would be more likely to engage with off-label treatments that have painful and/or uncomfortable side effects as there would be some justification for doing so (i.e. the hope of response). Using the same rationale, patients who had received baricitinib would likely feel less hopeful for subsequent treatment success with BSC, given the most effective and tolerable option had already failed. Prescribing dermatologists	FDG).

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			would similarly become less willing and/or confident in prescribing these poorly tolerated and low efficacy treatments if the best available option (baricitinib) had already failed. Within the economic analysis, this concept is captured by assuming that the introduction of baricitinib would reduce BSC use compared to current treatment practices (as modelled in the comparator arm) if a patient were to fail to respond to baricitinib (Table 3). Due to the forward-looking nature of this issue, the Company would like to note that it is not feasible to gather any supporting quantitative data for the qualitative arguments made above. Clinical and patient expert opinion on this topic may therefore be particularly valuable during the second ACM, especially given that discussion of this issue was limited in the public portion of the first ACM and that this issue is a key driver of the cost-effectiveness analysis for baricitinib in this indication. **Revised base case** For the reasons above, Lilly has proposed a revised base case, and two additional scenarios for the Committee to consider, highlighted in Table 3 below. In the first scenario, the Company have assumed that [redacted] of patients in the model receive BSC treatments (using evidence on the proportion of patients receiving BSC treatments in the independent Adelphi DSP RWE study) following non-response to 'no active treatment'. Consistent with the Company base case post-TE, this scenario includes a [redacted] reduction in BSC use after baricitinib, relative to BSC use after 'no active treatment'. However, this scenario now includes a **10-year time horizon** for BSC drug costs, resulting in a more conservative ICER than the Company base case post-TE. The second analysis in Table 3 presents the revised Company base case	

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<tr><td></td><td></td><td></td><td>post-DGD, in which [redacted] of patients in the model receive BSC treatments over a 10-year period (using evidence on the proportion of patients receiving BSC treatments in the independent Adelphi DSP RWE study) following non-response to ‘no active treatment’. The Company’s revised base case then assumes that there would only be a [redacted] relative reduction in BSC use following the introduction of baricitinib versus current treatment practices, which is a significantly more conservative assumption than proposed post-TE, and also represents only a small reduction when considering the anticipated step change that baricitinib will offer in the treatment of severe AA.

The final scenario presented retains the committee-preferred assumption of no BSC use following baricitinib discontinuation, but rejects this assumption following ‘no active treatment’ and instead applies an assumed 30% BSC drug cost for such patients over a 10-year period. This scenario represents an even more conservative option when considering the RWE presented, but may help to reduce the decision uncertainty as to whether baricitinib should be considered a cost-effective use of NHS resources.

It should be noted that in all cases the analyses below incorporate the 10-year time horizon on BSC drug costs only, as discussed above, while continuing to model a lifetime time horizon in all other respects.

Table 3. Revised base case and additional scenarios applying a 10-year time horizon for BSC drug costs within the overall model lifetime time horizon
<table>
<tr><th>Utilities</th><th>Extent of BSC use after failure on baricitinib</th><th>Extent of BSC use after failure on ‘no active treatment’</th><th>ICER</th></tr>
<tr><td>Adelphi DSP</td><td>[redacted]%*</td><td>[redacted]%†</td><td>Dominant</td></tr>
<tr><td>Adelphi DSP</td><td>[redacted]%*</td><td>[redacted]%†</td><td>£12,403 ‡</td></tr>
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			<table><tr><td>Adelphi DSP</td><td>0%</td><td>30%</td><td>£20,088</td></tr></table> **Footnotes:** * Represents 50% reduction and 25% reduction in BSC use following the introduction of baricitinib for treatment of severe AA, respectively; † Based on the proportion of patients in the Adelphi DSP study currently on treatment; ‡ This result reflects the company's preferred base case following Draft Guidance Consultation The Company would request that the Committee explicitly consider the feasibility of the assumptions within this revised base case, and particularly whether the use of baricitinib would reduce engagement with BSC after treatment failure compared to current treatment practices, given that a small difference in this regard is potentially a major driver of the decision as to whether baricitinib is a cost-effective use of NHS resource.	
5	Company	Eli Lilly	**<u>The impact of the uncertainties in this indication on the WTP threshold</u>** **Summary points** • The Company note that several of the uncertainties listed by the Committee in Section 3.13 are actually in favour of accepting an incremental cost-effectiveness ratio (ICER) on the upper end of the range considered a cost-effective use of NHS resources, rather than on the lower end and request that this distinction be recognised • The lack of a standardised treatment pathway for severe AA in the NHS at the present time should not hinder access to baricitinib given that the introduction of baricitinib would resolve this uncertainty • Underestimation of the effectiveness and quality-adjusted life year (QALY) gains associated with baricitinib treatment in the BRAVE-AA trials produces a conservative ICER that should favour the use of a higher WTP threshold, not a lower one	The ICERs using the committee's preferred assumptions were higher than the range of £20,000 to £30,000 per QALY gained normally considered to be a cost-effective use of NHS resources (see section 3.15 of the FDG).

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			In Section 3.13, the acceptable ICER for this appraisal is discussed, and it is noted that due to the uncertainty around various aspects of this appraisal "*an acceptable ICER would be towards the lower end of the range normally considered a cost-effective use of NHS resources*". As part of this discussion, a list of uncertainties is provided. However, the Company would like to note that, contrary to the way it is framed, several of the uncertainties listed would indicate that, if anything, the higher end of the WTP threshold range would be more suitable for baricitinib: **"*no clear consensus on standard of care*"** Although the Company agree that there is no standardised treatment pathway in this indication, the Company strongly disagree that this uncertainty should contribute towards a lower WTP threshold. This is because, if granted marketing authorisation in this indication, baricitinib could become the standard of care for patients with severe AA, and would therefore ultimately resolve this uncertainty in the current treatment pathway. Baricitinib may also resolve the 'postcode lottery' currently associated with treatment of AA in the NHS, since baricitinib would become widely available across all secondary care settings. The Company therefore consider that this uncertainty should not hinder access to baricitinib, particularly given that the lack of clear consensus on the standard of care has thus far, contributed to the significant burden associated with the disease (Section 3.1). **"*the evidence of baricitinib's effectiveness in the treatment-naive population is uncertain but likely to be underestimated based on BRAVE outcomes*"** The Company would like to emphasise that an underestimation of the effectiveness of baricitinib in clinical practice within the CEM will lead to a conservative ICER, and subsequently should contribute to a higher WTP	

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			threshold, not a lower one. ***"the QALY gains with treatment may be underestimated in the BRAVE trials"*** Similarly to the underestimation of the effectiveness of baricitinib that is discussed above, the Company consider than this uncertainty should contribute toward a higher WTP threshold, rather than one closer to £20,000 per QALY gained. While this would in part be resolved by acceptance of the Adelphi DSP utilities (see above), it is likely that even the DSP data still represent a conservative estimate of the utility gain associated with response to baricitinib treatment, given the challenges of accurately capturing the impact of AA on HRQoL using EQ-5D as an instrument. The uncertainty that the "long term safety of baricitinib is unknown" is discussed below.	
6	Company	Eli Lilly	**<u>The long-term safety of baricitinib</u>** • Baricitinib has been authorised since February 2017 and it is estimated that approximately [redacted] patients (representing [redacted] patient-years of exposure) have received baricitinib worldwide post-approval within rheumatoid arthritis (RA), atopic dermatitis (AD), and alopecia areata (AA) indications • Based on post-approval reports, suspected adverse drug reactions remain low and are consistent with either the known safety profile of baricitinib • The long-term safety profile of baricitinib should not be considered a key area of concern or uncertainty, and should therefore not contribute to a lower WTP threshold. Within Section 3.8, the long-term safety of baricitinib was suggested to be an uncertainty. However, the Company would like to point out that this issue is	The committee acknowledged the long-term safety of baricitinib in other conditions (see section 3.9 of the FDG).

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			not discussed within the DGD, and was also not highlighted as a concern during the public portion of the first ACM. The Company would note that baricitinib has been authorised (in other indications) since February 2017, with marketing authorisations in 76 countries for RA, 64 countries for AD and 31 countries for AA. In a clinical trial setting, [redacted] patients have received baricitinib for the treatment of RA, AD, and AA. Moreover, as of 31st July 2022, cumulatively, it is estimated that approximately [redacted] patients (representing [redacted] patient-years of exposure) have received baricitinib worldwide in post-approval (non-clinical trial) settings for the treatment of RA, AD and AA. Importantly, based on post-approval reports, suspected adverse drug reactions remain low and are consistent with either the known safety profile of baricitinib or are non-specific symptoms that can occur due to multiple causes.[12] The Company would also like to highlight the existence of several published long-term safety datasets following treatment with baricitinib in AA, RA and AD: • In the RA dataset, the mean age of patients at baseline was 53 years and exposure lasted up to 9.3 years, with a median exposure of 4.6 years, for a total of 14,744 person-years of exposure (PYE).[13] • The AD dataset includes exposure up to 3.9 years with a median exposure of 1.6 years, for a total of 4,628 PYE with a mean age of patients at baseline of 37 years.[14] • As the most recently-approved indication for baricitinib, published data from the AA dataset includes a median follow-up period of 1.5 years (maximum 3.1 years), for a total of 1,868 PYE with mean age of patients at baseline of 38 years.[15] However, the updated dataset for this population, with exposure up to 3.6 years	

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			(2,217.9 PYE), will be disclosed at the March 2023 American Academy of Dermatology Association Annual meeting. This updated safety analysis in patients with severe AA enrolled in the BRAVE-AA trials is consistent with previous observations. Given these data, the Company would like to highlight that the long-term safety profile of baricitinib should not be considered a key area of concern or uncertainty, and should therefore not contribute to a lower WTP threshold.	
7	Company	Eli Lilly	**Validity of the Committee-preferred assumptions in the CEM** In conclusion, Lilly is disappointed with the Committee-preferred assumptions for the source of utilities and the composition and extent of BSC use following non-response. The implications of these assumptions are that treatment of severe AA is not of value to the healthcare service, and that these patients should continue to endure their disease and limited treatment options simply because of the nature of the condition and a methodological preference for utility values that lack face validity and directly contradict the Committee's prior conclusions on HRQoL in severe AA. Lilly also considers that lowering the acceptable ICER threshold in this appraisal does not reflect the considerable unmet need in this indication and the step-change that baricitinib could offer as a novel and innovative treatment. The above points are exemplified by the fact that when the Committee-preferred assumptions are employed in the CEM, baricitinib would still not be considered cost-effective at the Committee-preferred WTP threshold (~£20,000 per QALY gained) if it were made available at no cost. While this is not an unknown scenario in appraisals for treatments that extend life (where the extra life incurs significant ongoing costs), this is not the case with baricitinib. In this case, the Committee have explicitly recognised that baricitinib "*is clinically effective"* in allowing hair regrowth; such hair regrowth does not incur any additional costs for the NHS, instead the benefits of hair regrowth have simply been considered (through the choice of utility inputs which lack face validity) to be of almost no value to the NHS. The Company therefore considers that these results point to the inadequacy of the modelling	The have committee reconsidered its preferred assumptions after the second committee meeting (see section 3.14 of the FDG).

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			assumptions preferred by the Committee in terms of valuing the treatment of severe AA within the NHS. As such, the Company urges the Committee to consider the wider implications and meaning of their conclusions for any effective therapy, and would invite the Committee to reconsider their assumptions in the context of the responses presented above. **References** the manual. January 2022. Available at: https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741. Last accessed: April 2022. 2. Abedini R, Hallaji Z, Lajevardi V, et al. Quality of life in mild and severe alopecia areata patients. Int J Womens Dermatol 2018;4:91-94. 3. Liu LY, King BA, Craiglow BG. Health-related quality of life (HRQoL) among patients with alopecia areata (AA): A systematic review. J Am Acad Dermatol 2016;75:806-812.e3. 4. Rencz F, Gulácsi L, Péntek M, et al. Alopecia areata and health-related quality of life: a systematic review and meta-analysis. Br J Dermatol 2016;175:561-71. 5. Shi Q, Duvic M, Osei JS, et al. Health-Related Quality of Life (HRQoL) in alopecia areata patients-a secondary analysis of the National Alopecia Areata Registry Data. J Investig Dermatol Symp Proc 2013;16:S49-50. 6. Dalgard FJ, Bewley A, Evers AW, et al. Stigmatisation and body image impairment in dermatological patients: protocol for an observational multicentre study in 16 European countries. BMJ Open 2018;8:e024877. 7. Adelphi Real World. Disease Specific Programmes™. Available at: https://adelphirealworld.com/our-approaches/disease-specific-programmes/. Last accessed: March 2023. 8. Anderson P, Benford M, Harris N, et al. Real-world physician and patient behaviour across countries: Disease-Specific Programmes - a means to understand. Curr Med Res Opin 2008;24:3063-72. 9. Medicines Healthcare Regulatory Agency (MHRA). MHRA guidance on the use of real-world data in clinical studies to support regulatory	

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			decisions. 2021. Available at: https://www.gov.uk/government/publications/mhra-guidance-on-the-use-of-real-world-data-in-clinical-studies-to-support-regulatory-decisions/mhra-guidance-on-the-use-of-real-world-data-in-clinical-studies-to-support-regulatory-decisions. Last accessed: March 2023. 10. Pfizer. B7981015 Clinical Study Report Synosis: Public Disclosure Synopsis, 2022. Available at : https://www.pfizer.com/node/554011. Last accessed: March 2023. 11. Messenger A, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. British journal of dermatology 2012;166:916-926. 12. Eli Lilly. Periodic safety update report (PSUR) in the Format of ICH E2C (R2). October 2022. 13. Taylor PC, Takeuchi T, Burmester GR, et al. Safety of baricitinib for the treatment of rheumatoid arthritis over a median of 4.6 and up to 9.3 years of treatment: final results from long-term extension study and integrated database. Annals of the Rheumatic Diseases 2022;81:335-343. 14. Bieber T, Katoh N, Simpson EL, et al. Safety of baricitinib for the treatment of atopic dermatitis over a median of 1.6 years and up to 3.9 years of treatment: an updated integrated analysis of eight clinical trials. J Dermatolog Treat 2023;34:2161812. 15. King B, Mostaghimi A, Shimomura Y, et al. Integrated safety analysis of baricitinib in adults with severe alopecia areata from two randomized clinical trials. British Journal of Dermatology 2022;188:218-227.	
8	Patient group	Alopecia UK	**1.Alopecia UK – Summary:** We are disappointed to see that The National Institute for Health and Care Excellence (NICE) could not recommend baricitinib for routine commissioning in the NHS for treating severe alopecia areata in adults. The NICE committee noted the lack of licenced, effective treatments for severe alopecia areata and hence the unmet medical need for an effective and safe treatment such as baricitinib. The committee discussed the lack of	The committee acknowledged the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged the psychosocial impact of severe alopecia areata on a person's

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			clarity of a 'best standard of care' and acknowledged the regional differences in treatment of patients with severe alopecia areata. Despite this, the committee could not recommend baricitinib for routine commissioning in the NHS. The fact that the committee discuss 'no active treatment' as a 'comparator' just shows that there are currently no real effective treatments available for people with severe alopecia areata. We are disappointed and concerned by the numerous people we hear from suffering from this lifelong, incurable, auto-immune condition (many of whom have other concurrent auto-immune conditions). We believe people with severe alopecia areata deserve the opportunity to have a treatment that can enable hair regrowth. With no licensed and very few effective treatments for alopecia areata, long waiting lists for dermatology appointments and a post code lottery for access to treatments, baricitinib offers real hope as an effective treatment to enable hair regrowth and not having to endure a lifelong condition of a visible difference, and the very real struggles that come along with that. While NICE have reviewed the direct cost-effectiveness of baricitinib in the treatment of severe alopecia areata, they have failed to account for the direct NHS costs involved in treating conditions secondary to alopecia including depression, anxiety, substance abuse/addiction and the increased prevalence of dementia (which is theorised to result from the social isolation that is frequent among those suffering alopecia). At Alopecia UK, we also see the cost to individuals, and wider society, of absenteeism from education, work, and the reduction in social activities. In addition, there is also the financial burden to individuals and their families of the costs of wigs, eyebrow microblading, camouflage clothing and private counselling. You really cannot imagine the psychosocial impact of having severe alopecia areata and the weight that every social interaction carries, hence why anxiety, depression and agoraphobia are so common, which result in absenteeism from work, education, and social interactions. Even during this first committee process we heard from two mothers with young adult sons who were unable to continue their studies, were suffering severe anxiety and depression, and had both contemplated suicide. We hear of the suicides due to people with severe alopecia areata unable to cope with the condition and the associated	quality of life (see section 3.1 of the FDG).

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			stigma. How do you think those mothers and young adults feel seeing that baricitinib has not been recommended for commissioning in the NHS, and part of the reason seems to be that hair regrowth does not seem to improve a persons quality of life enough? It appears that the trials and data Eli Lilly presented to NICE did not show enough improvement in quality of life (QoL) for it to be assessed as cost-effective for the NHS. We certainly hear the absolute opposite from the alopecia community and those that have been fortunate enough to access JAK inhibitor treatment privately frequently claim that they have 'gotten their life back' because of the regrowth of hair. We ask that the NICE committee look at further 'real life' data around the positive changes in QoL from hair regrowth. We really hope that Eli Lilly can submit some further data to demonstrate that baricitinib is 'cost-effective' for NICE parameters, and that, along with comments from Alopecia UK, clinical and patient experts, we can persuade NICE to approve Baricitinib for use in the NHS.	
9	Patient group	Alopecia UK	**2.Has all of the relevant evidence been taken into account** **We ask the committee to consider a wider evidence pool to substantiate the negative quality of life impact of severe alopecia areata; as through our patient research, social media groups and support calls, we hear and we understand the true impact of alopecia areata. Additionally, we believe there are several peer-reviewed publications in reputable journals that report a higher prevalence of depression, anxiety and suicidal ideation and suicides within this community. While anecdotal, we also see and hear how hair re-growth resulting from privately accessed baricitinib treatment has substantially improved peoples' QoL.** o A meta-analysis conducted by Okhovat et al. (2019) of 6,010 patients found that AA patients are at greater risk of both anxiety and depression. o One study in the review by Okhovat et al. (2019) assessed suicidality in patients with alopecia areata and demonstrated that patients with AA were at higher risk of suicide and self-harm (Singam et al., 2018) o One study has reported rates of mental health challenges as high as 47.5% in people with alopecia, 35.5% anxiety and 29% depression. The study was predominantly AA (82.6%) (Montgomery et al., 2017) o For newly diagnosed patients with AA studies suggest that people are	The committee recognised that severe alopecia areata can have a profound impact on quality of life (see section 3.6 of the FDG).

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			more likely to develop depression and anxiety disorders (Macbeth et al., 2022)  • Section 3.1: The comments made by Alopecia UK and the patient experts on the psychosocial impacts and negative effects on quality of life were noted. 'The committee concluded that severe alopecia areata can have profound psychosocial impact on a person's quality of life and that people with the condition would welcome new effective treatment options' • Section 3.7: We at Alopecia UK are disappointed to see comments from the committee as 'but based on the data from the BRAVE trials, the extent of this improvement on quality of life is uncertain' yet just in the paragraph earlier the comment was ' The EAG acknowledged that there is likely to be a group of people for whom severe alopecia areata can have a large negative impact on QOL and for whom treatment with baricitinib may results in large improvements in quality of life' References ○ Okhovat JP, Marks DH, Manatis-Lornell A, Hagigeorges D, Locascio JJ, Senna MM. Association between alopecia areata, anxiety, and depression: a systematic review and meta-analysis. Journal of the American Academy of Dermatology. 2019 Jun 1. ○ Singam V, Patel KR, Lee HH, Rastogi S, Silverberg JI. Association of alopecia areata with 57 hospitalization for mental health disorders in US adults. J Am Acad Dermatol. 2018 Aug. ○ Montgomery K, White C, Thompson A. A mixed methods survey of	

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			social anxiety, anxiety, depression and wig use in alopecia. BMJ open. 2017 Apr 1;7(4):e015468. ○ Macbeth AE, Holmes S, Harries M, Chiu WS, Tziotzios C, de Lusignan S, Messenger AG, Thompson AR. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. British Journal of Dermatology. 2022 Jul 1;187(1):73-81.	
10	Patient group	Alopecia UK	**3. Are the summaries of clinical and cost-effectiveness reasonable interpretations of the evidence** **Overall, we feel that the summaries of clinical and cost-effectiveness demonstrate how the severe alopecia areata population are currently totally neglected by the NHS. We ask the committee to reconsider the following key points, which are substantiated below:** ○ **The use of more true-to-life QoL scores, using a QoL tool other than EQ5D that is more appropriate for measuring the effects of AA, particularly its psychosocial impacts on QoL. In addition, a more equitable way of measuring change in QoL from baricitinib treatment and its resultant hair regrowth should be considered.** ○ **We believe the 'no active treatment' comparator used to be a poor and in-equitable comparator for cost effective assessment.** ○ **What is the ideal Best Supportive Care (BSC) for people with severe AA? The scenario used for BSC overlooks key aspects of the true real-world situation for people with severe AA. Why should people with severe AA be denied what is really the 'first' effective treatment for this population?** ○ Section 3.2: 'The committee agreed that there is wide variation in practice in treating severe alopecia areata'; therefore, the committee have acknowledged that people suffering severe alopecia areata are frequently 'abandoned' by the NHS. Therefore, 'no active treatment' as a comparator is actively perpetuating the lack of treatment and lack of attention that patients are given. The NICE review for baricitinib in the treatment of severe eczema serves as an example of how alopecia is overlooked compared to other (non-life threatening) conditions. In this previous review two comparators were deemed appropriate: ○ An active comparator of dupilumab (in which the inequity compared to the	The committee acknowledged that there are various, mostly off-label treatment options available on the NHS for severe alopecia areata and considered that it would have liked to have seen analyses that included comparisons with treatments used in the NHS such as immunosuppressants. But it, agreed that there is wide variation in practice both in terms of pharmacological options and wig provision and therefore concluded that the company's and EAG's comparisons with no active treatment in their base cases is an acceptable comparator for decision making (see section 3.2 of the FDG). The committee acknowledged the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG), the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG) and the uncaptured benefits (see section 3.18 of the FDG).

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			alopecia review is evident) ○ Best supportive care (BSC) which included (but was not limited to) education, psychological support, topical corticosteroids and hospitalisation. All these aspects of BSC are also true for alopecia, so why are they being overlooked? In our experience, multiple members of the alopecia community access NHS mental health services and many individuals will access these services several times in their lifetime, so why are these not included in the active comparator? Additionally, hospitalisation due to suicide attempts should not be overlooked, and although no studies have been conducted to quantify this, suicide attempts and death by suicide, is something we are sadly aware of within the community. ○ Section 3.2: The committee concluded that 'there is an unmet need for safe and effective treatments for severe alopecia areata' yet do not recommend baricitinib, which has proven via the BRAVE trials to be effective and safe for the treatment of severe AA. ○ Section 3.3: We agree that use of SALT 20 or less for treatment response is appropriate. When considering head hair. But SALT does not consider eyebrow and eyelash regrowth - which also has massive impact on QoL. I.e. even if SALT<20 not achieved, eyebrow+eyelash + partial scalp regrowth may still be meaningful <u>We have considerable concerns about the reliance of the EQ-5D tool in the assessment of cost effectiveness:</u> • Section 3.6: We at Alopecia UK are concerned about the emphasis and reliance on EQ-5D from the BRAVE trials and do not think EQ-5D shows the true impact of the affect of alopecia areata on QoL and hence question how this measure can be what is being used for the cost-effectiveness measure. 'The clinical experts noted that high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia areata. And even the committee comments: 'it considered whether EQ-5D may not be picking up important aspects of the condition or because the people in the trials are not representative of those with severe alopecia in terms of anxiety and depression'. We ask	

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			that you look beyond the BRAVE EQ-5D data and even beyond the Adelphi data, although that seems to show a more accurate reflection of reality. We have detailed below some additional comments about why the EQ-5D is an inappropriate measure: o Anxiety and depression are uniformly recognised by the committee, clinical experts and patient experts as the main secondary conditions of concern. However, the EQ-5D only has one of five domains that is specific to anxiety/depression (with the remaining four domains addressing mobility, self-care, usual activities and pain/discomfort). o 80% of the EQ-5D questionnaire is not relevant to the clinical presentation of alopecia. Therefore, inclusion of irrelevant domains very likely dilute the true negative mental health impacts of alopecia (and the associated mental health improvements with baricitinib-induced hair regrowth) More specific questionnaires that have mental health as their predominant focus would be more appropriate e.g. Skindex-16 Alopecia Areata, phq-9 and GAD-7. o Additionally, we ask NICE to consider the most appropriate tool to measure the effect of severe alopecia areata on mental health, considering that some reviews suggest it should be used in conjunction with condition specific measures (Brazier, 2010; Payakachat et al., 2015). o Section 3.6: as noted by us, the patient experts, the baseline QOL scores in BRAVE are not generalisable. This is due to the hope that participation in a clinical trial provides. There are frequent complaints within the alopecia community of loss of hope and concern that they will 'look like this forever'; therefore, a patient population that is somewhat alleviated of these concerns through clinical trial participation is not reflective of reality. There is also likely to be some form of initial elation within clinical trial participants who have likely spent 6 months to many years feeling they have been offered little to no helpful advice or treatment for a condition that is so often overlooked by the medical community. NICE should not underestimate the positive mental impact that is associated with engagement from medical professionals and validation that alopecia is a condition worthy of treatment (and not simply cosmetic). o The EQ5D is an effective measure but only where it has demonstrated	

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			effectiveness of responsiveness and to our knowledge this is not the case in AA. Where this is no evidence or mixed evidence of responsiveness researchers should consider using the EQ5D with other specific measures. This was not the case in this trial? In a systematic review of the EQ5D and its ability to detect meaningful change, there was mixed evidence of responsiveness across 48% of the conditions included and 7% of the conditions the EQ5D was not responsive. Interestingly the EQ5D was not found to be responsive to health status change after limb reconstruction. The EQ5D did also not detect changes after different hearing interventions (Payakachat et al., 2015). ○ A further study examined if the patient experience is adequately captured by the EQ5D. Findings suggested that the EQ5D showed poor-moderate responsiveness to clinical change that did not adequately reflect the views of the patients (Tordrup et al., 2014). ○ Section 3.10: Discussion of Best Supportive Care – We are really disappointed by the comments around 'Best Supportive Care' and that the only consideration of this seems to be to test the health economic model. We are concerned that this could negatively affect the cost-effectiveness of baricitinib. ○ As the draft guidance comments 'best supportive care is uncertain' – can the committee not see that this reflects that patients with severe alopecia areata are currently neglected by the NHS – there is no cure, there are no licenced treatments readily available and yet a first licenced treatment in a new category of drugs, baricitinib has so far been rejected by NICE for availability on the NHS. We hear and see individual patients' stories to the full impact on QOL and the positive difference that baricitinib and hair regrowth can have on a patient with this auto-immune condition (And as per our comments to 3.2). ○ Section 3.12: While we as expert patients and the patient organisation stakeholder are lay people and do not fully understand the health economic modelling, we do understand how alopecia areata affects QoL. We do not feel that the BRAVE EQ-5D data is a true representation of the QoL effects on people with alopecia areata and therefore encourage NICE to pay attention to Eli Lilly, clinical experts and patient experts to consider the EQ-5D from its Adelphi study (as per our comments of section 3.6 above).	

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			Areas where cost evidence is lacking altogether: ○ Direct NHS costs that have not been considered: these include the treatment of conditions that are secondary to the development of alopecia such as depression, anxiety, substance abuse/addiction and the increased prevalence of dementia that has been published in a peer-reviewed journal (which is theorised to result from the social isolation that is frequent among those suffering alopecia). Additionally, people with alopecia frequently discuss withdrawing from exercise-based activities where, due to increased heat and sweating, it is difficult to wear the wigs or hats they rely on ○ Indirect costs to the NHS: although NICE do not often model the loss of GDP associated with a disease, we view this as a mistake. According to a study published in the British Journal of Dermatology, people with alopecia are significantly more likely to be issued with time off work certificates and to be recorded as unemployed (Macbeth, et al. 2022). We also have collected anecdotal evidence of people disengaging from work responsibilities due to the associated shame of turning up to work and being visibly different to co-workers. The median average UK salary in 2022 was £32,300 which equates to £6,917 tax and national insurance. If you were to assume that the average UK citizen were afflicted with alopecia and were too depressed to work, there would be an annual loss of £6,917 plus the addition of any costs associated with Universal Credit claims. **<u>References</u>** ○ Brazier, J. (2010). Is the EQ–5D fit for purpose in mental health? *The British Journal of Psychiatry, 197*(5), 348-349. doi:10.1192/bjp.bp.110.082453 ○ Payakachat N, Ali MM, Tilford JM. Can The EQ-5D Detect Meaningful Change? A Systematic Review. Pharmacoeconomics. 2015 Nov;33(11):1137-54. doi: 10.1007/s40273-015-0295-6. PMID: 26040242; PMCID: PMC4609224. ○ Tordrup D, Mossman J, Kanavos P. Responsiveness of the EQ-5D to clinical change: is the patient experience adequately represented?. International journal of technology assessment in health care. 2014	

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			Jan;30(1):10-9. ○ Macbeth AE, Holmes S, Harries M, Chiu WS, Tziotzios C, de Lusignan S, Messenger AG, Thompson AR. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. British Journal of Dermatology. 2022 Jul 1;187(1):73-81.	
11	Patient Group	Alopecia UK	**4. <u>Are the recommendations sound and a suitable basis for guidance to the NHS</u>** **We do not consider the recommendations 'sound' and 'suitable' for guidance to the NHS** • **People with severe AA are currently neglected and abandoned by the NHS, as there is no cure and no effective long-term and longstanding (can be taken beyond 6months) treatment.** • **While there is really no 'Best Supportive Care', we do not consider 'no active treatment' as a fair comparator. Please consider what should be 'Best Supportive Care', and a fair 'active comparator when assessing cost effectiveness of baricitinib.** • **The clinical experts raised the % people suffering from anxiety, depression, negative psychosocial impact and suicidal ideation – hence people with severe AA do have a much lower QoL, and while anecdotal, we hear the difference that privately-accessed baricitinib treatment and the resulting hair regrowth makes. Please be open to appropriate QoL measures.** • **We believe that other non-life threatening dermatological conditions e.g. severe eczema, have several treatment options approved on the NHS. If baricitinib is 'cost effective' for eczema, then why is it not cost effective for severe alopecia areata?** • Section 3.13 – We do not agree with the conclusions that NICE make in this section stating: 'the committee will be more cautious about recommending a technology if it is less certain about the ICERs presented'. The issues where the committee noted 'high levels of uncertainty' surely demonstrate that patients with severe alopecia areata are currently being let down by the NHS including: ○ We hope that Lilly can provide the data that NICE seemingly requires in	The committee recognised the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG).

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			order to demonstrate that baricitinib is cost-effective in line with NICE parameters. o We also hope that NICE can look beyond the uncertainties which Alopecia UK feel are down to the lack of effective standard of care at baseline. Additionally, we implore NICE to really listen to the positive impacts on QoL of privately-accessed baricitinib treatment that Alopecia UK have observed in the real world.	
12	Patient group	Alopecia UK	**5. <u>Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination</u>** • Section 3.15 states that alopecia areata may be more common in those with lower socioeconomic status. Access to baricitinib in the UK is therefore only manageable for those who can afford prescription prices and private medical healthcare. Additionally, as stated previously, there are inconsistent wig provisions across the UK and patients frequently have to pay out of pocket for something that is often deemed as an absolute necessity to feel comfortable leaving the house. Therefore, there is a massive equity concern with alopecia areata and those with a lower socioeconomic status will be hit the hardest. To not actively treat alopecia is to discriminate against those who cannot afford the most basic of necessities that many with the condition rely on. • Those of Asian ethnicity, we believe, are three times more likely to experience AA (Harries et al) and [redacted] Not prescribing would therefore potentially put them at a disadvantage • Severe alopecia areata is associated with 'severe physical disfigurement' which is classed as a disability by the UK Disability and the Equality Act 2010; therefore we view it as a form of discrimination to individuals with alopecia to be denied an effective	The committee considered equality issues in section 3.17 of the FDG.

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			treatment that is available. ○ Additionally, baricitinib is available on the NHS to individuals with severe eczema and rheumatoid arthritis (both of which had active comparators in their NICE review and both of which have several other approved treatment options). To deny the same treatment to people suffering with severe alopecia areata is to overlook and de-prioritise the distress of their condition and therefore give higher priority to conditions that already have treatment options. References ○ Harries M, Macbeth AE, Holmes S, Chiu WS, Gallardo WR, Nijher M, de Lusignan S, Tziotzios C, Messenger AG. The epidemiology of alopecia areata: a population-based cohort study in UK primary care. British journal of dermatology. 2022 Feb 1;186(2):257-65.	
13	Professional group	British Association of Dermatologists (BAD)	We are concerned that NICE TA committee A has failed to act fairly in making its decision not to recommend baricitinib for the treatment of severe alopecia areata. The preferred assumptions made by the committee in evaluating the cost effectiveness of the intervention are inconsistent with the recommendations made by clinical experts and patient representatives. Therefore, the economic modelling on which the decision is based is unsound and does not represent clinical practice in the NHS.	The have committee reconsidered its preferred assumptions after the second committee meeting (see section 3.14 of the FDG).
14	Professional group	British Association of Dermatologists (BAD)	The NICE TA committee's preferences in considering only the cost of NHS wigs and orthotics as representative of best supportive care (BSC) is not consistent with the recommendations made by clinical experts, patient experts or the evidence presented by the company (Adelphi study). The EAG base case is an *exceptionally* conservative assumption and not supported by any underlying evidence (that BSC *only* includes costs of wigs and orthotics), and we are concerned that this scenario has been chosen as the preference by the NICE TA committee. The ACD/draft guidance states that this is an area of high uncertainty, and we agree – however, it seems perverse in a situation of high uncertainty to select a scenario with no evidential support over those with evidence.	The committee acknowledged the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG).

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			From the draft guidance, *"Treatments available on the NHS for severe alopecia areata include **topical corticosteroids, which are usually prescribed in primary care**. If they do not work, people may be referred to a dermatologist and offered a range of medicines many of which are not licensed for this condition, or a wig."* (p3), and *"The clinical experts explained that they would **use baricitinib** at the same position as contact immunotherapy and immunosuppressants, in a **secondary care** setting rather than tertiary care."* (p.7) Therefore, the likelihood of patients being treatment-naïve in real-world practice is highly unlikely. We present below evidence from a survey collected independently of this appraisal (collection period ended prior to ACM1, data released during consultation period) which supports the company base case data from the Adelphi study but was generated independently of the company and with no input from them. **These data have not been published yet and remain confidential.** On costs of wigs and hair pieces on NHS prescriptions – patients are entitled to one real hair item per year or two non-real-hair items per year. Many NHS Trusts require that prescriptions be renewed annually, and this can only be achieved in secondary care, and not primary care with its associated costs. https://www.nhs.uk/nhs-services/help-with-health-costs/wigs-and-fabric-supports-on-the-nhs/ Patients still require secondary care appointments for ongoing wig prescriptions and the frequency of this depends on each Trust. There is a huge discrepancy on accessibility of wig prescriptions and type of wigs for patients, and there is variability in how these are funded in different regions. Some Trusts incur the cost, others are funded by CCGs. Therefore, patients and clinicians are facing several barriers in obtaining wigs. There is also issues around appropriate wigs for different types of hair based on ethnicity. Our Afro-textured hair patients and Asian patients can sometimes struggle to find appropriate wigs. Epidemiological studies have shown that alopecia areata can be more prevalent in Asian and African patients (Harries *et al.*,	

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			BJD 2022, 10.1111/bjd.20628; Feaster *et al.*, JAAD 2022, 10.1016/j.jaad.2022.01.033). This adds to the anxiety and mental health burden seen in these patients. Additionally, wigs will not be addressing eyebrow and eyelash loss which can have functional consequences such as eye irritation, etc. Nail disease can also be very symptomatic with brittle nails causing pain and impacting on patients' activities. Clinicians have limited treatment options, with the main treatments used being systemic agents.	
15	Professional group	British Association of Dermatologists (BAD)	Survey results with figures A. [redacted] response rate. B. Lines of treatments: • First line: ○ [redacted] oral CS ○ [redacted] TCS ○ [redacted] intralesional CS • Second line: ○ [redacted] MTX ○ [redacted] oral CS ○ [redacted] DPCP • Third line: ○ [redacted] CiA ○ [redacted] DPCP C. Best treatment (ranking): 	The committee acknowledged the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG).

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			[redacted] D. Frequency of systemics use: **Figure removed** E. Frequency of localised scalp treatments use: **Figure removed** F. Frequency of prosthetic prescription/recommendation: **Figure removed**	
16	Professional group	British Association of Dermatologists (BAD)	We are concerned that the impact of AA on HRQoL has been significantly underestimated in the economic models, and that the committee's choice of BRAVE HRQoL data is a potentially unfair one. As acknowledged by the committee in the ACD, EQ5D results from BRAVE may lack face validity as model inputs (section 3.6). We would like to direct the NICE TA committee's attention to independent analysis of HRQoL in skin diseases for European patients, including those with AA, which showed a 10-point decrement in HRQoL due to AA compared with healthy controls. Although use of direct trial data is preferred in the methods manual, there is flexibility to use independent data sources where the data from the trial fails to match the clinical experience of experts, and therefore is potentially misleading. We would encourage the NICE TA committee to consider the wider body of evidence in this regard and recommend that scenario analysis with HRQoL inputs from independent RWE be conducted. We are concerned that the NICE TA committee's decision to choose the BRAVE EQ5D data over other sources which match clinical experience more closely (as expressed by the clinical experts, accepted by the committee in part 1, and confirmed by independently published data) primarily due to its convenience in populating an economic model is not a fair one.	The committee acknowledged the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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			Balieva, F., Kupfer, J., Lien, L., Gieler, U., Finlay, A.Y., Tomás-Aragonés, L., Poot, F., Misery, L., Sampogna, F., van Middendorp, H., Halvorsen, J.A., Szepietowski, J.C., Lvov, A., Marrón, S.E., Salek, M.S. and Dalgard, F.J. (2017), The burden of common skin diseases assessed with the EQ5D™: a European multicentre study in 13 countries. *Br J Dermatol*, 176: 1170-1178. https://doi.org/10.1111/bjd.15280	
17	Professional group	British Association of Dermatologists (BAD)	We are concerned that there are NHS-related costs that have not been included in the company or EAG base cases, and which will influence the total costs of both BSC and baricitinib treatment. Significant numbers of patients with AA require referral for psychological support, the cost for which did not appear to be included in the total cost of disease. A population-based study carried out in the UK has demonstrated that depression and anxiety were more prevalent in people diagnosed with AA than in controls (P < 0·001). People with AA were also more likely to subsequently develop new-onset depression and anxiety: adjusted hazard ratio (aHR) for recurrent depressive disorder 1·38 [95% confidence interval (CI) 1·13-1·69], depressive episodes aHR 1·30 (95% CI 1·04-1·62) and anxiety disorder aHR 1·33 (95% CI 1·09-1·63); to be issued time off work certificates (aHR 1·56, 95% CI 1·43-1·71); and to be recorded as unemployed (aHR 1·82, 95% CI 1·33-2·49). Higher rates of antidepressant prescribing were also seen in people with AA (Macbeth *et al.*, BJD 2022, https://doi.org/10.1111/bjd.21055) A UK-based study performed by Alopecia UK reviewed the impact of wig use on social anxiety, anxiety and depression. There were 313 participants commenting on the impact wigs has on their confidence with only 26% stating it would have a positive impact. However 43% of participants stated the wig would have a negative impact due to their concern about other people knowing they are wearing a wig or due to the discomfort caused by the wig or the wig not fitting and falling off. There were 33% of participants who felt the wig restricted their activities. (Montgomery *et al.*, BMJ Open 2017 http://dx.doi.org/10.1136/bmjopen-2016-015468). Patients have to resort to using wigs as a coping strategy. However, the wigs do not help alleviate the anxiety these patients experience from their	Within best supportive care, pharmacological psychological treatments are included in the company's and EAG's base case. In the company's original base case before technical engagement, it also included non-pharmacological psychological treatments. The committee noted feedback from stakeholders in response to the draft guidance document suggesting variation in access to mental health services and the limited evidence informing best supportive care composition (see section 3.11 of the FDG).

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			condition. In certain cases, they have had extremely negative and traumatising experiences such as young patients who have had their wigs pulled off their heads on a night out or in a social setting.	
18	Professional group	British Association of Dermatologists (BAD)	We believe this treatment to be innovative, with significant uncaptured benefits which have not been included in the economic modelling of this appraisal. We recognise that NICE methods include NHS costs but not patient-borne ones, however, the NICE TA committee should be aware that wig and orthotic provision in the NHS result in lifetime costs >£10,000 per patient to each patient with the condition. Furthermore, the system impact of patients who are treated with broad immunosuppressive medication has not been fully considered (particularly, in view of the apparent preference to ignore pharmacological therapy for AA as detailed above). These medications require both costly (included in company base case) and burdensome monitoring with significant morbidity long-term from their use. Costs associated with adverse effects due to ciclosporin, methotrexate, etc. (including increased rates of cancers, renal and liver failure, and secondary infections) appear to have not been included, and the benefit of avoiding those remain uncaptured.	The committee acknowledged that baricitinib is innovative and there may be uncaptured benefits not included in the modelling (see section 3.18 of the FDG).
19	Professional group	Royal College of Physicians	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Association of Dermatologists (BAD).	Comments noted.
20	Clinical expert	Abby Macbeth	**I am concerned that the use of wigs/orthotics as standard care does not represent the usual care provided by UK dermatologists.** Following my attendance at the committee meeting as an independent expert, I have reflected on the discussions of the day around the definition of standard care/ best supportive care. In my practice, for patients with severe or very severe alopecia areata (AA) of at least 6 months duration, I would offer methotrexate. My regimen for commencing methotrexate includes a 6-week tapered course of prednisolone (starting at 40mg) as per the trial protocol of Professor P Joly (Clinical trials Reg: NCT02037191- The Efficiency of The Methotrexate At Patients Affected By Grave Pelade.) The weekly dose of methotrexate required is often 20-25mg. Treatment would continue for 12-18 months before deciding that there is no treatment effect. The resultant trial, I believe, has not yet been published but preliminary data suggested approximately 1/3 of participants showed	The committee acknowledged that there are various, mostly off-label treatment options available on the NHS for severe alopecia areata but that there is wide variation in practice both in terms of pharmacological options and wig provision (see section 3.2 of the FDG). It acknowledged the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG).

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			significant improvement. Whilst I understand that this may not be the practice of all dermatologists and represents my personal position, I have spoken to many tertiary specialists and many colleagues in secondary care over my years in practice, who will either use a systemic immunosuppressant themselves, or refer to me for consideration of a systemic immunosuppressant (usually Methotrexate), or for contact immunotherapy with DPCP. The use of wigs alone, or discharge back to primary care, tends to be a “last resort” as expressed by my patients who are most frequently seeking active treatment. Wigs are also used in addition to immunosuppressant therapies and DPCP, whilst the treatment begins to work, and so the two pathways are not mutually exclusive and costs of wigs for at least 6 months should also be included in any cost comparison of immunosuppression or DPCP. Concealing the scalp from daylight, with the use of a wig liner and wig, can enhance the efficacy of DPCP contact immunotherapy. With the use of immunosuppression, patients will often also continue on potent or very potent topical steroids in addition. With the use of DPCP contact immunotherapy, Fexofenadine will frequently be co-prescribed as a daily dose to improve local adverse effects and improve concordance. These additions must also be considered within cost-efficacy comparisons, if the selection of best supportive care is substituted.	
21	Clinical expert	Abby Macbeth	**I have concerns that the use of the EQ5D alone for alopecia areata will lead to significant uncaptured benefit during committee discussions.** I appeal to the committee to consider benefits not represented within the EQ5D, including the impact of improvement in visible difference with treatment on employment, relationships, and other social interactions. The mechanical impacts of alopecia including impaired temperature regulation and mechanical eye injury from grit/dirt in the eyes (from loss of eyebrows/eyelashes) are also not represented within this health utility assessment. In addition, for cost considerations, published epidemiological data demonstrated that those with alopecia areata consulted in Primary care at a greater rate than controls (4·32 (4·27–4·38) visits per year compared with 2·58 (2·56–2·60) in matched controls.)(*Harries et al. The epidemiology of alopecia areata: a population-based cohort study in UK primary care. Br J*	The committee acknowledged the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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			Dermatol 2022; ***186:*** *257- 65.)* Wider cost implications for the NHS could include reduction in the cost of primary care consultations. Whilst I appreciate that population level employment data does not ordinarily guide the committee, there is also a population level impact of the potential for those with alopecia areata to return to work. Employment is significantly impacted by alopecia areata with those with AA being more likely to be issued time off work certificates (aHR 1·56, 95% CI 1·43–1·71); and to be recorded as unemployed (aHR 1·82, 95% CI 1·33–2·49).*(Macbeth et al. The associated burden of mental health conditions in alopecia areata: a population-based study in primary care. Br J Dermatol 2022;* ***187****: 73– 81.)* To reiterate the comments of the committee, it is a significant concern that participants are reporting perfect health as measured by the EQ5D in the BRAVE trial, when we know that people with AA are more likely to have depression and anxiety: adjusted hazard ratio (aHR) for recurrent depressive disorder 1·38 [95% confidence interval (CI) 1·13–1·69], depressive episodes aHR 1·30 (95% CI 1·04–1·62) and anxiety disorder aHR 1·33 (95% CI 1·09–1·63) *(Macbeth et al. The associated burden of mental health conditions in alopecia areata: a population-based study in primary care. Br J Dermatol 2022; 187: 73– 81.)* As briefly discussed, this likely represents selection bias in the trial population, but could also evidence the inability of the EQ5D to capture the impact of significant visible difference and hair loss, likely underestimating the impact and improvement after treatment with Baricitinib.	
22	Clinical expert	Abby Macbeth	**I have concerns that the impact of financial costs for the patient of alopecia areata are underrepresented in the draft guidance and do not factor in cost-utility data.** Patient costs and out of pocket expenses are also difficult to quantify, and whilst I do recognise that these costs did factor in discussions, I worry that these may have been underrepresented. Costs include own wig costs, wig maintenance costs, scalp applications, supplements, over the counter treatments (e.g. Minoxidil), private trichology consultations, eyebrow/ eyeline/ scalp tattooing, eyelash prostheses, make-up for cosmetic camouflage, colour matched sprays, and also loss of earnings from social withdrawal and resultant depression and anxiety.	In accordance with the NICE health technology evaluations manual 2022, costs should relate to NHS and PSS in the reference case.
23	Clinical expert	Matthew Harries	I am concerned about the very conservative assumptions made in this appraisal regarding “best supportive care”. These assumptions are not consistent with my experience of current clinical practice. Although I did	The committee have reconsidered its preferred assumptions after the second committee meeting (see

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			caveat in the discussion of treatment options for AA in the original meeting that my experience is from a tertiary care viewpoint, I am concerned that my comments were misinterpreted. I still work in a large department alongside non-hair specialist dermatology colleagues and receive referrals from across the region. From these interactions there are clearly several treatments currently pursued, with variable success, for treating this condition outside specialist hair loss clinics. As outlined previously, we and other centres across the UK use topical immunotherapy for extensive AA in both adults and children. This position is supported by our evidence-based national AA treatment guidelines from the British Association of Dermatologists (BAD) that recommends topical immunotherapy for extensive AA [Messenger, A.G., et al., *British Association of Dermatologists' guidelines for the management of alopecia areata 2012.* Br J Dermatol, 2012. **166**(5): p. 916-26]. A significant proportion of referrals into my clinic is to access this topical immunotherapy option. Further, many general dermatologists who do not have access to topical immunotherapy will use a range of other options including topical and oral corticosteroids, and various immunosuppressant medications. It is not uncommon for patients to try multiple therapies over time. For example, we have previously looked at the records of 50 consecutive patients with *alopecia totalis* / *alopecia universalis* (i.e. SALT = 100) attending Salford Royal Hospital Hair Clinic; multiple treatments were usual in this population, with >50% receiving three or more secondary care therapies for their AA (MH unpublished data). These treatments may include courses of oral steroids, ciclosporin, mycophenolate and methotrexate, as well as topical immunotherapy. The cumulative costs of these frequently unsuccessful therapies, on top of the personal impact to the patient, are significant to the NHS. Drug monitoring is intensive for most standard immunosuppressants (i.e. baseline screening, weekly bloods initially and regular clinic appointments), and must always be initiated in secondary care, irrespective as to whether there is ultimately shared care monitoring options available once stabilised. Further, virtually all patients will require wig provision in addition and throughout the time of their hair loss, which may be lifelong for some.	section 3.14 of the FDG).

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			Unfortunately, those AA patients who do not receive appropriate advice or options to pursue available treatments highlights a significant health inequality but should not distract from what is being provided currently by many dermatologists across the UK and so it feels unfair not to take these used treatments into account for the economic model.	
24	Clinical expert	Matthew Harries	I appreciate that the two phase 3 studies did not demonstrate a significant improvement in EQ5D, and the potential reasons for this are discussed in the appraisal document. Importantly, these scores do not reflect my experience of the impact of extensive AA on my patients and using these data alone fails to capture the impact of the disease, and hence the potential benefits of baricitinib. Unfortunately, I am unaware of anyone routinely collecting EQ5D data in their UK clinical practice to inform this discussion [NB. EQ5D will be a measure collected as part of a prospective AA disease register currently being built (due to start summer 2023) that is supported by the British Association of Dermatologists and funded by the British Skin Foundation so these data will be available moving forward]. The Adelphi data, despite its shortcomings, resonate better with my experiences and those shared by the patient representatives in the first meeting. When one looks at the wider literature there are several studies that support the marked emotional impact experienced by people with AA. A recent study suggests a bi-directional association between severe depression and AA, indicating that both conditions are independent risk factors for development of the other [Vallerand, I.A., et al., *Assessment of a Bidirectional Association Between Major Depressive Disorder and Alopecia Areata.* JAMA Dermatol, 2019. **155**(4): p. 475-479]. Biologically, systemic inflammation may contribute, with serum IL-22 and IL-17E levels correlating with depression symptoms [Bain, K.A., et al., *Alopecia areata is characterized by dysregulation in systemic type 17 and type 2 cytokines, which may contribute to disease-associated psychological morbidity.* Br J Dermatol, 2020. **182**(1): p. 130-137] These impacts are highlighted in a UK large primary care database study [Macbeth AE et al. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. Br J Dermatol. 2022; 187: 73-81]. Here, 5,435 people with newly diagnosed AA in UK	The committee acknowledged the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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			primary care were identified from the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network database and matched to 21,740 controls. The results were as follows: "Depression and anxiety were more prevalent in people diagnosed with AA compared to controls (p<0.001). People with AA were also more likely to subsequently develop new onset depression and anxiety (adjusted hazard ratio [aHR] DE 1.38 [95%CI 1.13-1.69], RDD aHR 1.30 [95%CI 1.04-1.62], AD aHR 1.33 [95%CI 1.09-1.63]), be issued time-off work certificates (aHR 1.56, 95%CI 1.43-1.71), and be recorded as unemployed (aHR 1.82, 95%CI 1.33-2.49). Higher rates of antidepressant prescribing were also seen in people with AA." The impact of AA is further highlighted in the Global Burden of Disease 2010 estimates of years lost to disability, with mean age-adjusted Disability-Adjusted Life Years (DALYs) attributed to AA being 19.4 globally, where one DALY is equivalent to 1 year of healthy life lost. Alopecia areata was ranking 137th out of 176 diseases in terms of disability burden; ranking higher than psoriasis (144th) and melanoma (138th) [Hay, R.J., et al., *The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions.* J Invest Dermatol, 2014. **134**(6): p. 1527-1534. Karimkhani, C., et al., *The global burden of disease associated with alopecia areata.* Br J Dermatol, 2015. **172**(5): p. 1424-6. Korta, D.Z., et al., *Alopecia areata is a medical disease.* J Am Acad Dermatol, 2018. **78**(4): p. 832-834.] My direct experience comes from running the hair loss service at Salford Royal Hospital for over 10 years. Here we see the significant psychological impact every week in clinic, and these are routinely captured using other validated measures (DLQI / PHQ9 / GAD7). Data collected sequentially from all new AA patients (2017 -2019) into our clinic revealed the following results: Mean DLQI 8.62 with 64/168 (38%) DLQI >10 Mean PHQ9 6.81 with 46/168 (27%) PHQ9 >10 Mean GAD7 5.81 with 41/168 (24%) GAD7>10 Unfortunately, our analysis has not stratified these results by disease severity, so may further underestimate the impact of more severe disease. Strikingly, 10% expressed suicidal ideation because of their hair loss on the PHQ9 questionnaire [Asfour et al. The role of psychological interventions in	

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			hair loss patients. British Association of Dermatologist Annual meeting 2021 – abstract]. Finally, AA is one of the commonest reasons for clinical psychology referral from dermatology in our Trust (Psychology services, Salford Royal Hospital – unpublished data), and many more seeking advice outside the trust through their GP or local psychology services. Together, these data show significant emotional and functional impacts of AA that are not captured in the clinical trial EQ5D data.	
25	Web comment	Person with alopecia areata	I've suffered from alopecia for 2 years since I was 14, it started off as small bald patches. I felt disheartened initially, i had suicidal thoughts at 14 because of this disease and the isolation from covid was killing me. When school started back up again I was able to cover my patches for about a year and a half because I grew my hair out to cover the patches. Then came about the steriod injections which completely cured my alopecia by july 2022. Then, by october it started again... 1 patch grew into 2 and 2 to 3 and so on. Every small task i would do I would see hair everywhere, on my laptop, desk, textbook, when i ran my fingers through my hair bundles of hair would fall. By January I had lost all hair, scalp, eyebrows, eyelashes, pubic. I had lost all hope and was at an all time low with my head flooding with depression and suicidal thoughts everyday. But then i heard about a new drug called olumiant "could this possibly help me when I reach 18" i thought, I was given hope and the past 2 months i was actually feeling happy. I regularly check this website to see i anything had changed and when i found out olumiant was not reccommened by NICE i was shattered and the thoughts came back (although they really never left). reading an article from alopecia UK they stated that the commitee found that "hair regrowth can have a profound impact on improving a person's quality of life, but based on the data from the clinical trials, the extent of this improvement in quality of life is uncertain" and that the commitee uses a "cost-effectiveness" system. your probably wondering what my story has to do with me commenting. Well... I'm here to say [text removed], YOU PEOPLE DONT THINK WE'RE WORTH THE MONEY, "improvement in quality of life is uncertain" OF COURSE MY QUALITIY OF LIFE WOULD INCREASE, I WOULDN'T TO HAVE TO WEAR A HAT ALL THE TIME, I WOULDNT HAVE TO MAKE UP STUPID EXCUSES OF MY MY NAILS ARE SO [text removed], I WOULDN'T HAVE TO LOOK AT MYSELF AND WONDER WHY I'M SO [text removed] UGLY	The committee recognised the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).

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			SO [text removed]	
26	Web comment	Person with alopecia areata	I am a patient at York hospital who has been suffering from severe alopecia areata for around the last 6-7 years. I previously lost c.50% of the hair on my head in around 2009 as well and was treated then using diphencyprone (DPC) at a London hospital, where I lived at the time. This seemed to be successful and my hair regrew until it fell out again in around 2016. I had previously received oral steroids and steroid injections, which appeared to have no impact on my condition. My recent hair loss has been more extensive and over the past 6-7 years I have lost all the hair on my head, my eyebrows and some patches of hair elsewhere on my body. Currently I have zero hair on my head and patchy eyebrows, but my eyelashes and body hair are unaffected. I recently stopped the DPC treatment I had been receiving at York for around 5 years on and off, as whilst it had contributed to extensive regrowth, this ultimately always fell out again, causing a significant amount of distress and a belief that the treatment was a waste of time for everyone involved. I had been attending a weekly clinic and had also experienced severe discomfort on occasion, for example when the DPC accidentally got onto my eyelids, causing blistering. Following a recent consultation with the Dermatology consultants, I understood I had their support for treatment using baricitinib once it had been approved for use by NICE, and that it was considered a safe and effective treatment that was already in use for patients with severe eczema. Subject to being mindful of potential side effects, this made me feel positive for the future, having lived with this condition for such a long time. Now I am concerned that this door will be closed to me, which makes me feel rather hopeless. **Effects on quality of life** Having severe alopecia areata affects my daily activities and mental health. I am unable to leave the house (or even answer the door) without a wig or head covering. Swimming used to be something I enjoyed, but now I avoid it, as I do not feel comfortable wearing a swimming cap, and a fabric head scarf makes my head very cold. People sometimes approach me and ask me if I have cancer, and while I know they mean well, this makes me feel uncomfortable and disheartened. Wearing a wig can be itchy, hot and uncomfortable, but wearing a head scarf can lead to questions or comments - for example, I feel I have to wear a wig to work to avoid causing colleagues	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). Within best supportive care, pharmacological psychological treatments are included in the company's and EAG's base case. In the company's original base case before technical engagement, it also included non-pharmacological psychological treatments. The committee noted feedback from stakeholders in response to the draft guidance document suggesting variation in access to mental health services and the limited evidence informing best supportive care composition (see section 3.11 of the FDG).

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			and clients to become confused or uncomfortable. My kids "use up" their birthday wishes, wishing for my hair to grow back. I am only grateful that I have a loving husband and family as I think if I had experienced hair loss as a young person that would have been very difficult for me indeed. **Treatment options** As noted in my general comments, I feel fortunate to have been able to access DPC treatment in both London and York. This has worked for me in the past, but unfortunately in recent years the hair has always started falling out again - even whilst the treatment is ongoing. Having previously tried oral steroids and injected steroids, as well as minoxidil, I believe I have exhausted existing treatment options. At my last appointment light therapy was mentioned, but it was felt this would be unlikely to work even as well as the DPC. I have never had a wig on prescription as my understanding was that only limited choices would be available to me. However, I do not see a wig as a 'treatment' as such anyway. **Positioning of baricitinib** I would be grateful for the opportunity to try baricitinib, as my clinicians are supportive of this in my circumstances. As noted above, apart from trying light therapy, I understand I have exhausted existing options. Light therapy would mean a return to weekly clinic visits with little confidence of success. **Conclusion** I understand that the NHS has finite resources but I want to conclude my comments by stressing that severe alopecia areata is a condition which I think is deserving of greater treatment options. I have seen what is available and it is limited. DPC was unlicensed and carried no guarantee of success. It worked for me to begin with but despite persevering with it, my later experience was a cycle of regrowth and further hair loss. This has had a significant impact on me and has caused me further stress and potentially exacerbated other stress-related conditions that I have. I don't think I should have to look forward to a future in which I am bald for the rest of my life and just have to cover my head with a wig or a head scarf. Thank you for reading and considering my input.	
27	Web	Person with	**Has all of the relevant evidence been taken into account?**	The committee acknowledged the

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	comment	alopecia areata	Recent research published in Acta Derm Venereol 2023 Jan 25;103:adv00855. doi: 10.2340/actadv.v103.4536. Comparative Efficacy and Safety of Janus Kinase Inhibitors Used in Alopecia Areata: A Systematic Review and Meta-analysis by Farnam Barati Sedeh et al Link available at 10.2340/actadv.v103.4536 clearly states that Alopecia Areata sufferers have a 66-74% lifetime prevalence of psychiatric disorders with a 38-39% lifetime prevalence of depression and a 39-62% prevalence of generalized anxiety disorder. The NHS are currently spending significant amounts on counselling, hospitalisation for mental health and medication for people with AA. Money would be better spent on effective medication such as Baricitinib that could help patients manage the condition. Many UK citizens, including myself, are having great success with Baricitinib that we buy from abroad under the supervision of private dermatalogists. In addition, these dermatalogists are predominantly working in the NHS and are frustrated by the lack of support for this medication. I believe AA is largely a hidden disease, I have not been to an NHS dermatologist for 20 years (I have Alopecia Universalis) as there was nothing further they could offer me. Therefore I am not in any of your statistics about the prevalence of Alopecia in this country. The studies highlighted were flawed in their assessment of mental health improvements, as noted by the dermatalogists who took part in the meeting. Hope that your hair will grow at the beginning of a trial obviously improves mental wellbeing. There was no evidence provided to the current cost of mental health services for Alopecia sufferers. Most sufferers require psychological and mental health support form the NHS. The fact that the USA have granted approval for Baricitinib and experts such as Dr King et al from the USA are reporting significant hair growth for alopecia sufferers was not mentioned. Also I do not believe that Alopecia UK should have been the only patient representatives, with two members present. This organisation does not represent all UK sufferers and the failure to have other patient voices was unfair. The two members spoke well but their case lacked any real data that may have swayed the commitees decision. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** The cost effectiveness does not account for mental health treatments that are	issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). Within best supportive care, pharmacological psychological treatments are included in the company's and EAG's base case. In the company's original base case before technical engagement, it also included non-pharmacological psychological treatments. The committee noted feedback from stakeholders in response to the draft guidance document suggesting variation in access to mental health services and the limited evidence informing best supportive care composition (see section 3.11 of the FDG). The committee considered equality issues in section 3.17 of the FDG.

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			currently provided by the NHS. The poor use of wig prescibing is currently a farce. I have had one prescription in 20 years despite being Alpocia Universalis. The cost to the NHS to process requests is costly in itself and not fit for purpose. I spend at least £800 a year on a real hair wig as lots of alopecia sufferers also have eczema and nylon wigs are impossible to wear without causing a skin reaction. You have not calculated loss of earnings and therefore tax revenue for this country. Due to the effect on sufferers mental health most people have a significant period of time where they are not in the workforce and contributing to society. I count myself in this group. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No. Evidence from the alopecia community was severely lacking. No statistical evidence was provided regarding the costs of mental health services and the effectiveness of those of us using Baricitinib (which there are many). I have substantial regrowth after 4 months on Baricitinib after 20 years Alopecia Universalis. I now have eyelashes and eyebrows too. I have to pay a private dermatologist at significant expense. The recommendations don't take into account monies that are currently spent on treating Alopecia patients other associated autoimmune and mental health ailments. This money could be saved by the use of Baricitinib. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Yes. There has been discrimination in a number of areas. The implication that it is not as bad for men was ill-informed and discriminatory. Losing your head and facial hair completely strips you of your identity to the point where people no longer recognise you. There was no patient viewpoint from men or young people who have a massively different perspective from the middle aged women from Alopecia UK. The assumption that wigs would be a solution for a young male is ridiculous. Wearing a wig as an adult woman is humiliating enough. I think there is also discrimination on older age groups with more research	

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			linking autoimmune disease with dementia surely the NHS has a duty of care to help us all have a better old age and live a full life. I see the NHS has funded an anti-obesity drug this week. I am not overweight, I've always lived a healthy lifestyle and through no fault of my own I have Alopecia Universalis. Is it not discriminatory to help one group of patients and not another? And finally please try and empathise - put yourself in our shoes for a day and imagine the mental toll of having no hair. You never get used to it and a wig certainly does not compensate. Baricitinib is helping me in all areas of my health and with your support long may this continue. Thank you	
28	Web comment	-	**Has all of the relevant evidence been taken into account?** Yes, I have read all of the evidence. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No, the summaries are not appropriate and reasonable interpretations of the evidence; they seem patriarchal and condescending to sufferers of alopecia. The cost of treatment as a sole determiner of whether or not a patient should receive the drug to remedy the problem is short sited. There are many hidden costs that occur with a person having alopecia that have not been included in the outcome. Providing money for a wig is not a solution to the problem. Also. the disease can also mean loss of eyebrows, eyelashes, etc. Physical appearance equates with mental well being. Having to operate in life, school, work, etc. can be excrutiatingor even unbearable for some with alopecia. Taking away the opportunity to rectify this issue can only hamper efforts for these people to live fully functioning lives and contribute completely to society. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No, the recommendations are not sound. A superficial idea of the costs involved for patients dealing with Alopecia is what is considered. Also, because women are effected by the side effects of alopecia more than men because of societal norms, the decision is a patriarchal and condescending one that doesn't fully consider the role of women in society and how important it is to look and feel one's best in order to contribute.	The committee considered equality issues in section 3.17 of the FDG. In accordance with the NICE health technology evaluations manual 2022, costs should relate to NHS and PSS in the reference case.

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			A generic form of the drug could be substituted for Eli Lilly's version, saving the NHS money. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** This initial decision is discriminatory towards women, claiming that protocols in use now are cheaper and satisfactory for patients, most of whom are women. This is not the case and could result in costing the NHS more in the long run as women patients have to deal with loss of work, depression, anxiety, etc. so much more than men who encounter a different standard for looks in our society.	
29	Web comment	Parent of person with alopecia areata	My 21 year old son has alopecia universalis and has suffered for over two years. His GP didn't offer any type of treatment at all including any counselling, which we paid for privately in the end. My son is studying drama at Falmouth University and I can't emphasise enough the impact this disease has had on his life and mental health. It has been severely stressful for him and for my mental health too as obviously I worry about him. About 18 months ago, he was having suicidal thoughts - thankfully his is coping better now. The prospect of a treatment being available - i.e. the JAK inhibitors - that are readily available for other auto immune conditions has given us some hope. So to hear that NICE has not approved it in this first round is profoundly upsetting to say the least. Please can we implore you to approve this treatment for Alopecia suffers so at least it might work for some of them and give them back some semblance of a normal life. GP and treatment support needs to be radically improved. Many thanks [redacted]	The committee recognise the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).
30	Web comment	Parent of person with	The document talks about the psychological impacts of alopecia areata and that these are not improved with the use of Baricitinib. I am very surprised by	The committee recognise the profound psychosocial impact of

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		alopecia areata	this response. As a parent to a 15 year old boy who started with AA at 3 years of age and has had extensive >70% hair loss issues over the last 12 months I would be interested to see the research that shows that hair regrowth caused by this medication does not significantly improve mental health. My 15 year old wanted to take his own life due to his AA and we found little help from the NHS and were only offered topical treatments of which evidence shows has little effect with over 50% hair loss. He felt there was no hope wearing a wig at 15 years old offers no comfort at all. We have been forced to access private health care at huge financial cost and have been using Baricitinib for 4 months with significant hair growth. The change in my sons mental health is huge he is attending school which for a lot of young people with this disease becomes not an option . I would urge NICE to look at figures on the percentage of young people with alopecia that are home schooled. These drugs are used for rheumatoid arthritis and it seems that if you are in physical pain then NICE can justify the costs of Jak inhibitors as a treatment. But as alopecia is continually referred to as cosmetic the same courtesy is not applied. As a parent who has lived with a child suffering with this disease I can clearly state this I s not cosmetic and I would hope NiCE have worked closely with alopecia uk to look into the many factors of alopecia and its long term devastating effects. As a health care professional it saddens me to see that this group of patients and their suffering is not validated by NICE. This drug makes hair grow back and the impact of this on individuals is life changing. I hope the many views of alopecia sufferers are considered by NICE for these recommendations. Also looking at how these drugs have been recommended for AA treatment in both Europe and the USA. I hope the UK follow suit. **Has all of the relevant evidence been taken into account?** No I do not think so. When talking about alopecia suffers who have been questioned as no one in the alopecia community I am part of have answered any questionnaires. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No. As have the costs to mental healths services and private counsellors	severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).

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			been factored in as many people have to access this due to the psychological impact of AA. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No as currently there are no options to AA sufferers for a treatment that can work potentially long term. There is clear evidence this is a treatment that has clear clinical benefits for the first time in AA.	
31	Web comment		**Has all of the relevant evidence been taken into account?** I don't think enough has been said about the true cost of severe alopecia areata. Those who as a result of their severe alopecia areata are not participating fully in society. Lost work days - how can you quantify that? It's hard but it is happening. The cost of those with alopecia areata accessing mental health services, antidepressants, wigs, various other treatments, dermatology appointments. I think the 'no active treatment' comparator is not relevant in itself. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** I am gravely concerned that 'no active treatment' was used as the comparator for cost-effectiveness! This is wholly unreasonable. Many people with severe alopecia areata are not on an active treatment because there aren't any other licensed treatments available. We don't have drug options! We are often dismissed without any treatment offered to us. Many people with severe alopecia areata are not choosing to be on no active treatment! It's not a fair comparator. Baricitinib offers true hope to patients with severe alopecia areata. **Are the recommendations sound and a suitable basis for guidance to the NHS?** I do not believe the recommendations to be sound. I have big concerns about the quality of life assessment tool that has been used. I do not believe that EQ5D measures the psychological impact of living with a visible difference. I know that people feel they are 'getting their lives back' when their hair comes back when taking this drug privately (at huge cost, or huge risk if purchasing from online overseas pharmacies and not getting appropriate supervision), so	In accordance with the NICE health technology evaluations manual 2022, costs should relate to NHS and PSS in the reference case. The committee acknowledged that there are various, mostly off-label treatment options available on the NHS for severe alopecia areata and considered that it would have liked to have seen analyses that included comparisons with treatments used in the NHS such as immunosuppressants. But it, agreed that there is wide variation in practice both in terms of pharmacological options and wig provision and therefore concluded that the company's and EAG's comparisons with no active treatment in their base cases is an acceptable comparator for decision making (see section 3.2 of the FDG). It acknowledged the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG) and

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			I do not understand how a conclusion has been reached that a significant improvement in QoL is not evident. More needs to be done on this. This drug needs to be available via the NHS because too many people are taking this privately, with different attitudes to health risk and financial risk. Some are purchasing the drug and not putting in place adequate health-monitoring. Others are opting for private treatment as they are so desperate to get their life back that i've heard of people wracking up thousands of pounds of credit card debt, or even remortgaging their home! If this very same drug can be approved for the treatment of atopic dermatitis and rheumatoid arthritis, I do not understand why NICE is not recommended for alopecia areata. I really hope there is not any 'it's just hair' bias creeping in to anyone's decision making. Alopecia areata is an autoimmune disease. It is something that causes huge amounts of emotional distress and leads to mental health impacts for so many of us with this condition. We really deserve to be able to have the option of a treatment. I write this as a patient with severe alopecia areata. One who, herself, does not wish to take baricitinib. I have concerns about the lack of long-term safety data, and I have reached a place of acceptance with my hair loss. Not everyone with severe alopecia areata will wish to take this drug. But it absolutely should be made an option for those who struggle EVERY SINGLE DAY to live rather than simply exist. That's what alopecia areata does for some people. It takes them from someone living life, participating in society, to someone who merely exists, perhaps not even going to work, education or having any form of social life. If baricitinib can give some people their hair back, as the clinical trial data clearly shows it does, it should be recommended as a treatment option for those with severe alopecia areata to allow those who suddenly develop this autoimmune disease, often very quickly without warning, to have a chance of a normal life. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** People with severe alopecia areata would fall under the 'disability' group on	considered equality issues in section 3.17 of the FDG.

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			the basis of 'severe disfugurement'. This is supported by many other visible difference groups and charities. I feel by not recommending this drug, this group of patients is once again being overlooked and dismissed. Whilst this might not be unlawful discrimination (I'm not a lawyer so unclear on what constitutes discrimination), I would be very interested to understand why this drug can be recommended for the treatment of two other medical conditions and not for severe alopecia areata. As i've alluded to earlier, I really hope there is no 'it's just hair' bias creeping in to any decision making as this would be hugely unfair and not recognise or understand the mental anguish that alopecia areata can cause.	
32	Web comment		**Has all of the relevant evidence been taken into account?** Don't feel that evidence from America studies by Brett king have been fully taken into account as these have good hair regrowth and much better efficacy than other treatments - these are first new treatments in over 15 years. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** This treatment would have a huge psychological and social effect on people with alopecia universalis. This hasn't been fully taken into account. AU can be life limiting and have mental health concerns attached. **Are the recommendations sound and a suitable basis for guidance to the NHS?** I don't believe they are.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).
33	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** The committee have heard evidence from the patient representatives and clinical experts of trauma, anxiety, depression, isolation and disrupted identity due to alopecia areata, with a major impact on a sufferer's ability to work, socialise and have intimate relationships. This is very much in line with my own experience as a person suffering from severe alopecia areata. Severe alopecia areata has had a life changing effect on me. I have total hair loss that has led to significant ongoing issues of anxiety and depression, for which I receive anti-depressant treatment on the NHS. I am also paying for private counselling because of difficulties accessing NHS mental health treatment. The mental health impact of my hair loss has been a very significant factor in me requiring 3 months sick leave from work and ultimately has led to the	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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			breakdown of my marriage. The patient representatives' and clinical experts' evidence, as well as my own experiences of severe alopecia areata, is significantly at odds with the BRAVE health-related quality of life measures. This study has a baseline where almost half of people are classed as at full health. While the committee acknowledges that the health-related quality of life measures in the BRAVE study is likely to underestimate the impact of severe alopecia areata, I do not believe the committee have given sufficient weight to the evidence presented by the patient representatives and clinical experts. The evidence of the patient representatives and clinical experts is qualitative in nature, based on their life or clinical experience, rather than the quantitative nature of that provided by the BRAVE trials. The more intangible nature of qualitative data makes it more challenging to use as a definitive numerical basis for cost-effectiveness. This results in a situation where it is acknowledged that the BRAVE study's health-related quality of life measures are flawed and not truly representative, but are still used as the basis of the assessment as there is no quantitative evidence available on the true impact of severe alopecia areata. The high baseline in the BRAVE study also means that there is difficulty in proving a statistically significant or clinically meaningful treatment response on mental health, further skewing the assessment of the cost effectiveness of the treatment. These issues are acknowledged by the committee and an attempt made to correct for this. However, for a truly effective appraisal of baricitinib for treatment of severe alopecia areata, in the absence of reliable quantitative data, greater weight must be given to the qualitative evidence of the patient representatives and clinical experts. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** The committee have concluded that baricitinib is clinically effective at improving hair regrowth, as demonstrated by the BRAVE study. The cost effectiveness of this treatment has been derived from health-related quality of life measures based on qualitative data from a large clinical trial (BRAVE). At face value, the source of the data for the health-related quality of life	

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			measures appears more reliable than other possible data sources, but when the committee itself acknowledges that it underrepresents the impact of severe alopecia areata, it is still a flawed and a misrepresentative measure to use as the basis for cost effectiveness. The summary of the cost effectiveness cannot be a reasonable interpretation of the evidence. **Are the recommendations sound and a suitable basis for guidance to the NHS?** The contents of the draft guidance clearly highlights the disparate nature of treatment of alopecia areata on the NHS. The report concludes that there is little consistency on the current approach to treatments, with geographical limitation on access to these treatments. This is typified by the assumed best supportive care approach in the report being limited to wigs and orthotics at best. The people who are impacted by the current arrangement are the sufferers of severe alopecia areata. It is a condition that has a life changing affect on a person's wellbeing but is met with little to no support and treatment provided on the NHS. For a condition that itself is isolating for sufferers, this effect is further enhanced by the antipathy shown by the NHS. Clinical experts have described baricitinib as a step-change in managing severe alopecia areata. The committee itself concludes that baricitinib is innovative and clinically effective at improving hair regrowth. This treatment could, for the first time, provide for those who wish to follow this path, the basis for a clear, consistent and effective treatment pathway for people who have suffered the most severe detrimental trauma/impact to their quality of life, through the psychosocial impact of hair loss. The basis of the recommendations in the report are based on the cost effectiveness of the treatment being assessed using data that is acknowledged to underrepresent the true impact of severe alopecia areata. The recommendation cannot therefore be judged as sound and suitable.	
34	Web comment	Person with alopecia areata	Hi Just wanted to share my experiences with Alopecia Universalis . I waited months for an appointment with an NHS dermatologist who have provided no help at all.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).s

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			I was told I was a poor prognosis and that nothing could be done to help me and that I'd have to "live with it". I first noticed a coin sized patch in my beard in 2019. I am a Cognitive Behaviour Therapist and work for the NHS. At the time I was under a lot of stress and pressure at work which I thought may have contributed towards the hair loss. The patch slowly started to get larger and in 2020 I noticed I was also getting patches in my hair. In 2021, over the course of around a month, I lost all the hair on my head, including eyelashes and eyebrows. The following month I lost all the hair on my body. Adapting to such a dramatic change in appearance was not easy and is still tough. As a father of three young children, I have to try and deal with the impact such a dramatic change in my appearance has had. Unless you have suffered with this condition you will never know the extent of the impact it has on you. I don't recognise myself anymore and I have to battle everyday with the sense of anxiety it evokes in me. Losing all the hair on your face, head and body has a dramatic impact on your mental health and I think it's disgusting that we are so far behind the USA in addressing this life changing condition.	
35	Web comment	Health care professional	As a GP I have seen several patients with alopecia and the devastating effects it has on their mental health. Alopecia is not a cosmetic condition! This condition should be treated as seriously as rheumatoid arthritis for which this drug is licensed. The cost to the health care system and the economy to treat mental health issues suffered by people with Alopecia is great and to deny sufferers this drug is unfair (given this is the only drug for which we have evidence of effectiveness).	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).
36	Web comment	Person with alopecia areata	Dear Sir\Madam In November 2022 my entire life was turned upside down when my first bald patch appeared (roughly 5% hair loss) on my scalp. I telephoned for a GP appointment which wasn't given but instead a telephone call who sent me to a nurse for blood test (2 week wait for blood test). These tests showed inflammation in the body and I required further tests that needed to be taken	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).

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			3 weeks apart. 3 weeks later the test came back all normal. I telephoned for another GP appointment due to even more loss (20% hair loss), again refused an appointment but a telephone call that basically said a large majority of people suffer hair loss and that mine was just severe and the NHS doesn't really treat it. I pushed and pushed to be referred to a dermatologist. 5th January 2023 received a letter from Aneurin Bevan University Health Board that stated that the Welsh Government had set targets of 36 weeks wait but they were nowhere near this target. When I phoned for more clarity, they said it could be up to 2 years! 16th January - I attended a private dermatologist and was diagnosed with Alopecia Areata and it's most probably one of the worst cases she seen since it only started in November, 50% hair loss at this point. They recommended Steroid Injections to the scalp but because of the severity it may require oral steroid on top. They administered the steroid injections and I was to return in 4 weeks for another set of Injection and a prescription for oral steroid. 15th February – Appointment with the private dermatologist who gave a second set of steroid injections and also prescribed oral steroids. My hair is now at 80% loss and they've told me that this will be my last set of treatment as they feel it's just prolonging the hair loss and I should prepare for total loss. They were quite surprised I still had eyebrows and eyelashes. 22nd February – I was declined the 2 free wigs on the NHS due to being diagnosed privately as only an NHS dermatologist can prescribe the wigs. I've now had to purchased one privately. The last 3 months have been an absolute rollercoaster that has not only taken its toll mentally on myself but also my son and husband. The first 2 months my son would get up early in the morning to help conceal my bald patches with spray to give me the confidence to go to work. I would go to bed around 9pm each night but would lie awake for hours worrying how much hair was going to be on the pillow the next morning. You try and relax by having a nice hot bath but there's nothing relaxing about having hundreds of strands of hair just floating around in the water. You switch to a shower to try and get	

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			away from the anxiety of the bath but then the shower tray overflows because the hair has blocked the plug hole. Socially I have withdrawn from everything, we didn't celebrate my birthday because I didn't want to be the freak sat in a restaurant with a hat on. My son plays for a rugby team and whilst I support him every match because it's winter, I can stand in the cold with a hat on but we don't go back to the club house anymore for food and celebrations afterwards. The only reason I drag myself out of bed each morning is because I need the wage to pay privately to treat my alopecia. With regards to the decision to not approve Baricitinib for use on the NHS I find this decision absolutely appalling, especially as the treatment is given for other conditions. Whilst I agree that arthritis patients do suffer physical pain the mental impact for hair loss patients can out way any physical pain. For the trial to show that the drug was 50% effective for treating severe alopecia areata, that's 50% of people whose mental health has improved massively. In reality, hair loss patients are being forced to pay into an NHS which provides inadequate services and also inadequate medication. This drug needs to be approved for use in the NHS. The NHS is FAILING people with hair loss!	
37	Web comment	Parent of person with alopecia areata	It is utterly heartbreaking to see that the use of Baricitinib has been rejected in the UK for apparently just being too expensive. Can a cost be put on mental health? Children have literally killed themselves due to the effects of Alopecia and the impact it has on their life. It's not enough to say that counselling is available. It's not good enough. The board who have rejected this need to seek out more first hand experience of the utter devastation that Alopecia can cause on individuals and their families. As the parent of a 12 year old who has suffered from alopecia for 18 months in a constant cycle of loss, regrowth, loss, regrowth, loss I have seen first hand the physical and mental impacts it can have - not just on my child but also on the parents. Even our own dermatologist recognises that JAK inhibitors are the best option, and were we living in a host of other countries we would be able to	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).

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			access JAKs. I wonder whether the same outcome would have been reached if any of the board suffered from Alopecia? Baricitinib, and JAKs in general, are proven to work. They need to be approved. **Has all of the relevant evidence been taken into account?** No. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No.	
38	Web comment	Health care professional /Parent of person with alopecia areata	**Has all of the relevant evidence been taken into account?** There is no appropriate evidence on the Impact on Quality of life. It is ludicrous and simplistic to use the quality-of-life assessment tool for alopecia as it only focuses on the physical aspect of illnesses. There are physical ramifications from having alopecia and these include difficulties with wearing wigs, and eye/nasal problems due to lack of protection from hair. Sports participation in and out of doors is very challenging and requires sheer determination. However, the tool does not acknowledge the devastating psychological effects. Alopecia affects patients every moment of every single day as it is impossible to forget about it. This is comparable to other illnesses, it is just more difficult to measure. However, literature is full of evidence on this: https://pubmed.ncbi.nlm.nih.gov/23700152/ “We found a high prevalence of comorbid conditions among individuals with AA presenting to academic medical centers in Boston.” https://www.sciencedirect.com/science/article/abs/pii/S0190962219308904	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person’s quality of life (see section 3.1 of the FDG), the wide variation in practice both in terms of pharmacological options and wig provision in the NHS, the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). The committee considered equality issues in section 3.17 of the FDG.

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			"This study suggests that patients with AA are at higher risk of both anxiety and depression". https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8260215/ "AA has substantial psychosocial impact on patients and results in reduced health-related quality of life. Addressing this should be an active part of treatment". https://medicaljournalssweden.se/actadv/article/view/1622/3038 The results indicate that patients with alopecia areata had greater odds of subsequent depression within 2 years from alopecia areata diagnosis, and showed a steeper increase in cumulative probability of depression as time progressed (log-rank =336.38, $p < 0.001$), compared with the opposite trajectory. All patients with alopecia areata had comorbid depression within 10 years of alopecia areata, compared with 70% of depression patients receiving diagnoses of comorbid alopecia areata within the same time-frame. https://dermnetnz.org/topics/psychological-effects-of-hair-loss "These symptoms can have a severe impact on an individual's mental health, ability to work or study, and well-being". I truly hope that NICE read every single patient experience report and take on board the massive impact this has on alopecia sufferers. Some alopecia sufferers may feel the psychological burden is too great to bear. To deny a trial of an effective treatment for alopecia is scientifically wrong and morally reprehensible. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** Baricitinib has been shown to work for many patients, with hair growth in around 50% of people with severe alopecia. It is a licenced treatment and NICE have made the decision not to approve this in the NHS due to cost	

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			effectiveness. As a doctor myself, I would like to argue this: • This is an autoimmune disease which is hugely under resourced and underfunded, with support being a lottery in different regions. The current upfront current cost to the NHS is minimal due to the lack of licenced medications. There are however unseen costs which include time off work (my daughter works in the NHS), and counselling/CBT costs. • NICE acknowledge that there is an unmet need for alopecia. It is therefore very unjust to look at the increased costs of prescribing Baricitinib when it is acknowledged that there has been no effective treatment to date! This is surely how medical treatments progress. More and more treatments become available following research for many different illnesses, particularly in oncology. • NICE have approved more expensive treatments with far less than a 50% chance of success in the past. • NICE acknowledge that Baricitinib is an “innovative treatment”. The cost of private prescribing and monitoring is prohibitive to the vast majority of patients. This is likely to place further psychological and financial burden on alopecia sufferers. **Are the recommendations sound and a suitable basis for guidance to the NHS?** The NHS is a wonderful organisation albeit with limitations. Ultimately it is here to provide the best possible treatment possible for patients. My beautiful 30-year-old daughter has been struggling with alopecia for more than 10 years, and with alopecia totalis for 3 years. It has been a heart-breaking journey for her and for all the people who love her. She is an active, outgoing, and sociable young woman and alopecia has hugely affected her everyday life and impacted on her confidence and mental health. She works as a nurse in intensive care and regularly receives wonderful feedback, which is not surprising as she is a hugely caring and empathetic person in and out of work. She slogged through the pandemic whilst coping with isolation and the devastating impact of her progressive alopecia. She has been incredibly proactive in learning about alopecia, joining alopecia UK and attending local meetings. She is lucky to have a very understanding and empathetic dermatologist locally who has given her scalp steroid injections.	

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			Unfortunately, this may have caused her to rupture her Achilles tendon and injections were stopped. She has been attending weekly sessions for phototherapy for more than six months, being determined to do all that she can to reverse her alopecia. Sadly, there has been no sustained response to this therapy. I cannot begin to describe how difficult it is to watch my daughter going through this. She is very well informed about treatment options and is very realistic about these. To deny her and others the opportunity to try new innovative treatments goes against the whole ethos of the NHS. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** I believe that the disability provision of the equality act applies to severe alopecia. This is of course ultimately a legal decision. To argue this is not the case will leave NICE open to legal challenges. As per the definition of the disability provision of the Equality Act: "'substantial' is more than minor or trivial, eg it takes much longer than it usually would to complete a daily task like getting dressed". It is clear that this applies to many daily tasks of daily living across the spectrum of normal life. • Getting ready to go out/go to work is a daily battle. Alopecia totalis sufferers have no eyelashes or eyebrows in addition to managing the challenges of wearing a wig. Options are to go out with no eyelashes/eyebrows or spend a significant length of time applying false brows/lashes. Many people would struggle in a public facing role for these reasons. It is therefore possible that they limit work choices because of this. What adjustments would be possible in these types of roles to make the workplace a level playing field as per the Act? • Social occasions are also challenging, and many sufferers becomes very anxious, leading to social isolation. • Participation in sports is difficult. Having no nasal hair or eye lashes removes the natural defence which hair provides for filtering debris entering	

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			the nose and eyes in addition to secretions flowing rather than being slowed down by nasal hair. Sweat irritates the eyes due to removal of the barrier provided by hair. "'long-term' means 12 months or more, eg a breathing condition that develops as a result of a lung infection". The majority of alopecia sufferers have difficulties ongoing for more than 12 months.	
39	Web comment	Person with alopecia areata	**Effects on quality of life** My anxiety levels are 'through the roof' as I see no future ahead for me. I have anxiety and panic attacks when leaving the house and interacting with other people. I recently had an opticians appointment where I complained about a pricking sensation in my eyes and the clinician commented on the amount of debris that had accumulated underneath the skin of my eyelids which was causing the discomfort was caused by my lack of eyelashes so this is also another symptom of the condition which the optician could do nothing about. I used to be a confident female but that has all changed as this has all gone now. I cannot lead a normal life and this is not helped by repeated hospital appointments where no help can be offered. I find it very unfair that this treatment is now offered in the EU with Germany seeming to be leading the way. Also available in the US. This treatment has been approved for use so why is it not available? I wear a wig which is easily identified as one which makes me very anxious also extremely uncomfortable and hot and causes me constant headaches. I would urge a different decision at your next meeting as you have no idea how distressing this condition is. It has impacted my family immensely also. **Has all of the relevant evidence been taken into account?** As far as I can tell **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** What is the cost versus a persons life? **Are the recommendations sound and a suitable basis for guidance to the NHS?** I my opinion yes	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).

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40	Web comment	Person with alopecia areata	I have lived with alopecia in various forms for 20 years and I have never been able to come to terms with this condition. We get very little sympathy as it's not life threatening as far as medical terms go but I can tell you it most certainly is life threatening. I have considered suicide several times because of how it has made me feel about myself I've seen at least 9 dermatologists and non of them have been helpful or sympathetic towards me. They just hand you a prescription for a wig and tell you to be on your way. I am on anti depression tablets and on a waiting list to see a psychologist for help but how much is that all costing the NHS?? when there seems to be a obvious cure out there why not let people like me try it? I hope that who ever reads this sees how easy it would be to make so many lives worth living. Thank you	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).
41	Web comment		Alopecia itself may not currently cost the NHS much in terms of funding, there is currently no treatment for Alopecia, so any form of treatment will be more costly. The implications of Alopecia, however, are most certainly costly to the NHS, in the form of antidepressants being prescribed for the depression it causes, self harm, counselling the is prescribed for those suffering from a lose of self identity. Treatment for self medication and binge eating disorders it triggers and the repercussions of those - for instance obesity, type 2 diabetes, liver disease. The psychological impact of severe Alopecia has been completely disregarded and most certainly hugely under estimated in this recommendation. Severe Alopecia impacts every aspect of life, from your job - reluctance of going for interviews or promotions as you look different and perspective employers and colleagues may judge you negatively. Exercise / not being able to confidently undertake healthy pastimes such a swimming for fear of ridicule in a public setting. Romantic relationships suffer due to fear of rejection and intimacy inevitably suffers. These are just a few aspects of life that are affected and collectively these all have a huge impact on the mental and emotional health of those with severe Alopecia. **Has all of the relevant evidence been taken into account?** The psychological implications of severe Alopecia have been dramatically down played if not completely ignored. Severe Alopecia impacts every aspect of a persons life.	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). The committee acknowledged that there are various, mostly off-label treatment options available on the NHS for severe alopecia areata and considered that it would have liked to have seen analyses that included comparisons with treatments used in the NHS such as immunosuppressants. But it, agreed that there is wide variation in practice both in terms of pharmacological options and wig provision and therefore concluded that the company's and EAG's comparisons with no active treatment in their base cases is an acceptable comparator for decision making (see section 3.2 of the FDG). The committee considered equality issues in

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			Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? There is currently no treatment for Alopecia, so of course it is not costly to the NHS, so any form of treatment will cost the NHS more than is currently does. Although Alopecia directly does not cost the NHS, the implications of certainly do. Antidepressants, counselling, treatment for self harm caused the by the depression it triggers. Treatment for self medication and eating disorders (leading to obesity or anorexia) that are triggered by the complete loss of identity and control. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No the recommendation is not sound or suitable, severe Alopecia is a life changing condition which huge mental health implications and also physical implications that have been completely disregarded in the recommendation. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Alopecia affects both men and women, however it is more socially accepted that men suffer with hair loss, female hair loss is a taboo subject the women feel they are forced to hide. A man with hair loss walking down the street would not receive any like the number of looks, or negative comments that a female with hair loss would.	section 3.17 of the FDG.
42	Web comment	Daughter of person with alopecia areata	Baricitinib not being approved by NICE for use on the NHS for the treatment of Alopecia is extremely devastating to me and my family. My mum has suffered with Alopecia on and off for many years and the impact it has had on me, her daughter is huge but nothing compared to the impact it has had on my poor mum. She is the strongest and bravest person I know and she fights with her mental health as a result of her Alopecia everyday. She remains a pillar of strength for our family and always puts everyone else first. She isn't the person she should be and is capable of being due to the stress and worry of having Alopecia. As a woman, hair is a huge part of feeling feminine and beautiful. To me & my	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the uncaptured benefits (see section 3.18 of the FDG).

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			family she is still the most beautiful person in the world but in hurts us so much that she can't see it due to her Alopecia. We love her so much and want nothing more than for her to be able to be happy. She's 70 next year and has worked so hard for her whole life! I want her to be able to enjoy her retirement like she deserves and be able to travel and socialise without the constant worry. She is also in constant discomfort, anyone who hasn't worn a hair piece day in day out has no idea how uncomfortable it is and how much it brings her down. The medication has been approved on the NHS for treatment of other autoimmune diseases and so this makes no sense to me. It has also been proven to be successful in the treatment of Alopecia privately and in other countries so this seems hugely unfair. The fact that Alopecia isn't taken seriously as a condition that needs this medication is an insult. Especially in this day and age when so much emphasis is being put on the importance of mental health. Please help my lovely mum! She is one of the most important people in the world to me & I want nothing more than for her to be happy.	
43	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** The Quality of Life Assessment tool EQ-5D is not a suitable tool for using against this condition. A separate assessment tool should be used. This tool is not a true reflection of an assessment of our quality of life and how it impacts us. The tool is totally inappropriate for measuring our daily life. I may not have a physical pain but it's an emotional pain. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** Alopecia universalis has been part of my life for 13 years. The trauma of losing my hair has been immeasurable. It causes me psychological pain with high levels of anxiety, depression and embarrassment. It's very damaging and causes emotional turmoil and suffering which has led to personal marital problems with intimacy, social phobia with paranoia that everyone is looking at me. I have lost my identity with feeling feminine, attractive and I feel ugly in my appearance. It has led to a total change in my personality to being withdrawn and a lack of self esteem. Panic attacks happen sometimes as it all becomes too much.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG), the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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			Many times I have suicidal thoughts as there is no cure or treatment that lasts longer than 6 months. This disease I feel has robbed me of 13 years of my life. It has a considerable impact on my quality of life with this burden constantly with me on a daily basis. Dealing with windy days or considering leisure activities stops me because of the consequences just in case my wig comes off. I live in anticipation of the thought of this successful treatment on the horizon that can change everything for me and my life. I am not having any treatment and do not use prescriptions for wigs as I pay for them myself. This is not costing the NHS anything. I feel that this is about what it will cost and not about supporting my care as a human being and having a duty of care. I hope NICE will approve this drug and not continually not recommend other drugs as we are an easy option to save money. **Are the recommendations sound and a suitable basis for guidance to the NHS?** Many patients including myself with severe alopecia will want the opportunity to try Baricitinib. I recognise that not everyone will be willing or able to take the drug. All patients must be given the opportunity to be given this drug through the excellent care of the NHS and not privately. Why can't patients take Baricitinib on a 36 week basis to see if there is any growth and if tolerated? I have waited for years patiently and with eagerness and hope for the development of Baricitinib to be given the chance this year to possibly change my life. The drug has been approved in USA, Europe and MHRA. To not have it as a recommended treatment in Uk, when there is not anything else is soul destroying for those suffering. Baricitinib will give me the chance of getting back to a proper decent life with confidence and self esteem. You need to have compassion and give us hope.	
44	Web comment	Person with alopecia areata	I unfortunately suffer with severe alopecia areata and so far failed to respond to treatment available in my area . Alopecia areata has affected my life so much physically, mentally and emotionally. There is no standard of care which there should be and to be told by nhs gps its only hair is beyond a joke . We all deserve the right to fair treatment medically. The nhs provides wig prescriptions in my area but only to the value of just £112 each wig and only 2	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It recognised the wide variation in practice both in terms

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			wigs per year In my area which don't last with every day wear . Please feel free to check good quality wig prices and you will see just how little the NHS actually help us people with alopecia. I'm just lucky I have a large caring family to help me financially buy nice wigs but I shouldn't have to buy wigs just to feel & look like a normal female. I should be given the chance to decide and have decisions about treatments with the specialists that know & understand this horrible condition . I personally think the specialists should decide what treatments are appropriate for each individual.	of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).
45	Web comment	Person with alopecia areata	It is extremely disappointing that Baricitinib has not been recommended by NICE to treat the most severe forms of alopecia, considering it is approved for Rheumatoid arthritis and eczema sufferers. Since the age of twelve, I have had alopecia and I have tried the approved ways of treating it including, steroid injections in my scalp (which was a very painful experience) and oral steroids, these options had a short-term positive outcomes but then they did not work. I now suffer from alopecia universalis and this significantly impacts my day-to-day life. The synthetic wigs provided by the NHS cause daily pain and lead to my head becoming infected on a regular basis. I have open lesions on my scalp which are painful and I have to apply a steroid cream to treat the infections, this is an ongoing vicious circle. Due to my current situation I have had to leave my profession, as a secondary History teacher, this was due to the regular comments made by the students about my alopecia, calling me the bald teacher etc. Alopecia prevented me from taking part in sporting events and attending school trips. Standing outside the school on duty on a windy day would increase my anxiety because I was always worried the wig would blow off. The loss of my eyelashes has resulted in regular eye infections and sore eyes. When I exercise at home (I cannot exercise at the gym in a synthetic wig) I will obviously perspire, this goes straight into my eyes and stings because I no longer have eyebrows. Alopecia has affected my physical, and mental health, my profession and, social interactions. I find it hard to believe that 'baricitinib did not show a meaningful improvement in many of the health-related quality of life assessments'. For me, this drug offered hope and would be life-changing. I implore you to review and reconsider your recommendations. The synthetic wigs that are offered by the NHS are extremely uncomfortable to wear. For example, I find they significantly rub on my head and dig in to my	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person’s quality of life (see section 3.1 of the FDG) and the uncaptured benefits (see section 3.18 of the FDG).

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			scalp causing lesions, which then lead to infections. My head weeps and this causes pain. The repetition of wearing the wig on a daily basis means that my scalp is never able to heal and I am in constant pain, and this impacts on my physical and mental wellbeing. I am a secondary teacher and it is very obvious to the students I am wearing a wig. This has led to the children commenting on the fact I am bald. It has destroyed my confidence and has led my to leave the profession which I am devastated about. **Hair loss can cause severe psychological distress, but baricitinib did not show a meaningful improvement in many of the health-related quality of life assessments undertaken in the trials compared with placebo.** Although I have not been a part of the clinical trial, as someone who suffers from alopecia universalis, I find it very difficult to believe that this medication and its positive outcomes of regrowth of hair, including eyelashes and eyebrows would not have a 'meaningful improvement' on peoples' lives. Wearing a wig on a daily basis causes my scalp to be irritated to the point where I have lesions on my head and these get infected. Having no eyelashes and eyebrows results in frequent eye infections and sore eyes. Having alopecia restricts the activities I can do, e.g. because the synthetic wig is not secured properly I cannot do certain activities which people living without alopecia would take for granted i.e. walking outside on a windy day because the wig could blow off. Having alopecia has even impacted me professionally. The constant pain and worry has significantly affected my confidence and mental well-being.	
46	Web comment	Person with alopecia areata	I feel that this document demonstrates how far resources for Alopecia has come on I have suffered from alopecia from age 11 on and off from loosing all my hair to patches and even part on one side. I feel this is positive I have now gotten to the point where I don't really go out unless it is absolutely necessary for me to do so I have blood work done and nothing. However you provide millions every year for a methadone programme which patients constantly relapse which costs millions every year where as a simple tablet for alopecia is going to provide a life time of hope and even a cure and may have a chance of relapse. This is coming from a NHS worker also. Just feel we need a bit of support from this and proof is	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).

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			there that it is working! Please think of the positive effects this is going to have on one persons life maybe even millions. You do it for drug users so why not us.	
47	Web comment		**Has all of the relevant evidence been taken into account?** I think there should be a greater emphasis to look at the impact that alopecia has on self esteem, anxiety, depression, relationships and work attendance rather than focus on the more physical limitations scored by EQ 5. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** There are many patients who are not receiving active treatment due to low chance of success or potential toxicity and because we knew a better treatment may be available. The cost comparison for patients with severe disease should be against those on systemic immunosuppression - eg Combination of Prednisolone/Azathioprine or Ciclosporin. This needs to take into account 4 hospital visits and blood monitoring + wigs per year. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No. We have the first properly studied and effective treatment for Alopecia which is being potentially turned down because of cost effectiveness. The use of EQ5 is not helpful in appreciating the impact of this disease. Every committee member should consider themself as a patient, waking up one morning with 50% of their hair missing, no eyelashes, having to explain this to every person they meet, the impact it would have on their self esteem, identity etc **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** No **Hair loss can cause severe psychological distress, but baricitinib did**	The committee recognised the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG), the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). The committee have reconsidered its preferred assumptions after the second committee meeting (see section 3.14 of the FDG).

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			not show a meaningful improvement in many of the health-related quality of life assessments undertaken in the trials compared with placebo. Most quality of life scores underscore the psychological impact and QoL impact of this disease. There are no physical disabilities, messy treatments, symptoms etc however the impact on self identity, self esteem and knock on effect on anxiety and depression is really profound. **It concluded that the company's and EAG's comparison with no active treatment in their base cases is an acceptable comparator for decision making.** Whilst there is wide variation in the UK for treatment of severe AA, when considering alternatives if JAK inhibitors are not funded, one needs to compare to continuous use of systemic immunosuppression. Many patients are not on active treatment as we were all hopeful a better and safer treatment was on the horizon and what we have at present is unreliable and often toxic. However, if there is no funding for JAK inhibitors patients will be offered an alternative in my tertiary care clinic. This may include oral prednisolone, systemic azathioprine or methotrexate as a steroid sparing drug or cyclosporin as mono therapy. Patients will require a minimum of 4 hospital visits (4 x £150) per year and 4 x full blood counts, liver function tests, U&Es in additional to baseline testing (TPMT, Procollagen, HIV, Hep B, C, T spot etc). All of this has cost attached to it. Baricitinib cost per patient should therefore be compared to that and not to no treatment (= no cost). Patients will also have 3 x acrylic wigs and we subsidise this by £150 per wig so £450 per annum. **For example, some people may prefer to have a local treatment such as contact immunotherapy rather than a systemic medicine like baricitinib.** In my experience, contact immunotherapy works best for people with patchy disease < 50%. Immunotherapy should be more widely available in the UK and used for patients with less severe disease. JAK inhibitors should be used for more severe disease unresponsive to first line therapy eg topical or intralesional steroids. Once you have more than 30% hair loss it is very hard to disguise the loss. Patchy disease is often cosmetically more disfiguring that total loss. The only reason for setting the threshold for treatment at 50% is a	

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			financial one. I have had patients with 30-50% who respond at much higher rates that SALT 100 and achieve total regrowth and huge improvement in quality of life. **At baseline, almost half the people with severe or very severe alopecia areata in the trials had EQ-5D scores of full health** These general scoring tools are too blunt to detect the impact of alopecia areata. Alopecia does not impact mobility, self care, does not cause pain and most people can do their usual activities. The only domain it will score for is anxiety and depression and this can be variable.	
48	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** I do not feel that the mental impact of hair loss has been fully taken in to account. It is not a life threatening condition as such but can make you feel like ending your life and is certainly life changing. It impacts on everything that you do, it destroys relationships, causes stress, anxiety and depression. And places restrictions on everyday life e.g I regularly attended exercise classes previously but no longer do so for fear of wig falling off or embarrassment of wearing a head covering. I am grateful that my local authority offers support with synthetic wigs on prescription as lack of funds would cause an additional stress. I have put on weight due comfort eating. The lack of exercise, poor diet and low mood as a result of the alopecia has a detrimental effect to my health, potentially causing more cost to the nhs. I have seen some fantastic results from people purchasing these drugs from abroad but I am fearful at trying this method as I am concerned they may have not been properly regulated and would be unsure what I was purchasing.	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG).
49	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** From the perspective of a young woman who suffered severe alopecia areata (AA) and who has since (privately) received effective treatment with baricitinib (achieving a Severity of Alopecia Tool [SALT] score of zero), I have outlined below the areas where evidence is lacking. 1. Sections 3.7 and 3.9: The measure of quality of life (QoL) should have contained a subgroup analysis that specifically compared treatment responders (SALT score ≤20) to placebo	The committee recognised the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). Within best supportive care, pharmacological psychological treatments are included in the

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			• As noted in the draft guidance "only about 1 in 3 people having baricitinib had a treatment response". Any improvements in QoL scores are likely largely associated with hair regrowth. Therefore, the inclusion of 66% of patients that did not respond likely diluted the true positive QoL impact that hair regrowth causes. • As a personal example, I was attending cognitive behavioural therapy (CBT) due to the psychological distress of hair loss, and noted a linear decrease in my PHQ-7 and GAD-7 scores as baricitinib-induced hair regrowth occurred over time. My PHQ-9 score decreased from 17 (moderately severe depression) to 2 (within the healthy range), and my GAD-7 score decreased from 21 (severe anxiety) to 6 (mild anxiety) with full hair regrowth. • As noted in section 3.9, the economic model assumed that "no one can move from having a treatment non-response to a treatment response after the end of the 36 week induction period". Therefore, treatment non-responders are likely to discontinue treatment at the 36-week mark, reducing any further cost to the NHS. As such, more focus should be placed on the cost-effectiveness of baricitinib in the patient cohort that will receive long-term treatment. The QoL scores from this cohort may show a resultant reduction of cost per quality adjusted life year (QALY) and would be a more appropriate model input of utility to base NICE recommendations on. • In conclusion, the psychological symptoms associated with severe AA are only likely to improve in treatment responders. A subgroup analysis should therefore be conducted using the QoL scores from responders versus placebo. This subgroup analysis should be applied to the economic model to gauge the real cost per QALY of long-term treatment with baricitinib. 2. Section 3.9: The economic model failed to account for additional direct and indirect costs that are associated with not effectively treating severe alopecia areata (AA) • As stated in section 3.9, the economic model "assessed the cost-effectiveness of baricitinib 4 mg compared with no active treatment". No active treatment assumes a cost of zero with no other associated costs. I have outlined in question 2 ('Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?') why this is an incorrect assumption for several reasons. In addition, there are some direct and indirect costs that did not get mentioned in the draft guidance.	company's and EAG's base case. In the company's original base case before technical engagement, it also included non-pharmacological psychological treatments. The committee noted feedback from stakeholders in response to the draft guidance document suggesting variation in access to mental health services and the limited evidence informing best supportive care composition (see section 3.11 of the FDG). The committee acknowledged that there are various, mostly off-label treatment options available on the NHS for severe alopecia areata and considered that it would have liked to have seen analyses that included comparisons with treatments used in the NHS such as immunosuppressants. But it, agreed that there is wide variation in practice both in terms of pharmacological options and wig provision and therefore concluded that the company's and EAG's comparisons with no active treatment in their base cases is an acceptable comparator for decision making (see section 3.2 of the FDG). The committee recognised the limited evidence informing best

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			• Direct NHS costs that have not been considered: these include the treatment of conditions that are secondary to the development of alopecia such as depression, anxiety, substance abuse/addiction,(1-8) and the increased prevalence of dementia that has been published in a peer-reviewed journal (which is theorised to result from the social isolation that is frequent among those suffering alopecia).(9) With the World Health Organisation (WHO) quoting depression as the leading cause of disability worldwide,(10) it is associated with a massive economic burden.(11, 12) Depression was reported to as the largest contributor to disability in the UK at 22.8% of the total burden with an estimated cost of £105.2 billion in England each year in 2011 (which is likely currently higher due to 12 years of inflation since the study was conducted).(12) The clinical experts noted in the draft guidance that "high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia"; thus NHS treatment of depression secondary to severe AA is likely associated with a high cost. Additionally, people with AA frequently discuss withdrawing from exercise-based activities where, due to increased heat and sweating, it is difficult to wear the wigs or hats they rely on; therefore, although not presently quantified in a peer-reviewed study, individuals are more likely to gain weight which can be associated with obesity, type 2 diabetes and cardiovascular issues, to name a few. All these secondary conditions are expensive for the NHS to treat; therefore, treating the hair loss associated with these conditions should be viewed as a preventative measure. • Indirect costs to the NHS: people with alopecia are significantly more likely to be issued with time off work certificates and to be recorded as unemployed.(13-15) As a personal example, I quit my job 2 months after the onset of my AA as I could not cope with the distress of having a severe visible difference in the workplace. In that job role, I paid more in monthly income tax and national insurance than the listed monthly cost of baricitinib of "£805.56" in section 2.3. After a month out of work, I subsequently found a job that allowed me to work permanently from home without the need to switch my camera on during remote meetings. However, had I not found that job I would likely be claiming Universal Credit. Therefore, without effective treatment, there was a very real possibility of me going from a being financial asset to the UK economy to someone who depletes government resources. • In conclusion, the costs of treating conditions secondary to the onset	supportive care composition and use (see sections 3.11 and 3.12 of the FDG), that baricitinib is innovative and the uncaptured benefits (see section 3.18 of the FDG). The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). The committee considered equality issues in section 3.17 of the FDG.

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			of severe AA combined with the indirect governmental costs associated (including time off work, unemployment and Universal Credit claims) are likely extensive. These costs should be considered in the economic model to give an all-inclusive interpretation of the true financial cost of untreated severe AA. This will likely result in a reduction in the cost per QALY. Overall conclusion: The QoL input to the cost-effectiveness analysis should apply data specifically from baricitinib responders versus placebo; as responders are the patients who will likely continue long-term treatment as opposed to non-responders who will not. There are also multiple costs that should be factored into the cost-effectiveness model as a non-treatment comparator. These include the direct NHS cost of treating conditions secondary to AA onset such as depression, anxiety, substance abuse/addiction, dementia and weight gain (and all associated conditions). Additionally, indirect NHS costs associated with AA onset including time off work, unemployment and Universal Credit claims should be factored into the cost-effectiveness model. The combined (probable) increase in QoL from baricitinib responders offset by the true costs associated with non-AA treatment will likely result in a substantial reduction of cost per QALY gained. References: 1. Toussi A, Barton VR, Le ST, Agbai ON, Kiuru M. Psychosocial and psychiatric comorbidities and health-related quality of life in alopecia areata: A systematic review. J Am Acad Dermatol. 2021;85(1):162-75. 2. Vélez-Muñiz RDC, Peralta-Pedrero ML, Jurado-Santa Cruz F, Morales-Sánchez MA. Psychological Profile and Quality of Life of Patients with Alopecia Areata. Skin Appendage Disord. 2019;5(5):293-8. 3. Lauron S, Plasse C, Vaysset M, Pereira B, D'Incan M, Rondepierre F, et al. Prevalence and Odds of Depressive and Anxiety Disorders and Symptoms in Children and Adults With Alopecia Areata: A Systematic Review and Meta-analysis. JAMA Dermatol. 2023. 4. Mostaghimi A, Napatalung L, Sikirica V, Winnette R, Xenakis J, Zwillich SH, et al. Patient Perspectives of the Social, Emotional and Functional Impact of Alopecia Areata: A Systematic Literature Review. Dermatol Ther (Heidelb). 2021;11(3):867-83. 5. Okhovat JP, Marks DH, Manatis-Lornell A, Hagigeorges D, Locascio	

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			Venereol. 2023. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** From the perspective of a young woman who suffered severe AA and who has since (privately) received effective treatment with baricitinib (achieving a SALT score of zero), I have outlined below the areas where NICE interpretations of clinical and cost-effectiveness evidence are lacking. 1. Section 3.7: The baseline QoL scores from patients in the BRAVE trial are not generalisable to those with AA that are likely to be treated with baricitinib • As noted by the patient experts in section 3.6 “people who enrol into a trial may have lower rates of anxiety than would be expected in the NHS, because people in trials have hope of being treated”. Therefore, patients with AA who enter a clinical trial are likely to have higher baseline QoL scores due to the hope that is gained from clinical trial participation. This is because the treatment pathway for severe AA is so poor with no effective treatment options provided. As a young woman who has suffered with severe AA, and who has sought baricitinib treatment privately, I can attest that my hope and happiness surged when I found a dermatologist who was willing to explore this treatment option with me. Baricitinib, as a treatment option, allowed me to envision a future where I wouldn’t have to live the rest of my life with the associated shame of such a stark visible difference to other people. • As I have only had AA for one year, this surge in hope is likely amplified for those with longer-standing AA who have endured extensive periods without effective treatment options. Indeed, the mean baseline duration of the current episode of AA in BRAVE-AA1 and BRAVE-AA2 cohorts ranged from 3.5 to 4.7 years. • Engagement of physicians and the associated validation that AA is a disease worth treating can have a profound positive mental health impact on patients. In my experience, my first visit to an NHS dermatologist made me feel more depressed and isolated when anti-depressants were the only treatment option offered for my severe AA. In contrast, my subsequent visit to a private dermatologist gave me life-changing hope with the discussion of several treatment options (including baricitinib). This hope was likely amplified	

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			due to how let down I had felt after my initial NHS appointment. • Beyond personal anecdotal evidence, there have been several peer reviewed publications that report a higher prevalence of depression, anxiety and suicide ideation within those suffering AA.(1-7) The committee also acknowledged in section 3.1 and section 3.7 that “severe alopecia areata can have a profound psychosocial impact on a person’s quality of life and that people with the condition would welcome new effective treatment options” and that “hair regrowth can have a profound impact on improving a person’s quality of life”. • In conclusion, the QoL scores in the BRAVE-AA trials are unlikely to be reflective of the real world and thus assumptions made based on these scores should be treated with caution and skepticism. 2. Section 3.9: No active treatment is a poor and inequitable comparator for cost-effectiveness modelling • In section 3.9, the economic model “assessed the cost-effectiveness of baricitinib 4 mg compared with no active treatment”. As severe AA has historically had no effective treatment options, this is an exceedingly unfair comparator. • No active treatment comparator will drastically skew the cost-effectiveness of baricitinib with the obvious conclusion that £0 is substantially less expensive than any active comparator. This will render even the cheapest of medical technology unlikely to meet NICE’s cost-effectiveness threshold when applied to the economic model. • In other conditions, the NICE review comparator applied to the economic model is usually an active treatment that provides, at minimal, some form of symptom alleviation from the disease in question. Therefore, this comparator is akin to actively stating that people suffering severe psychological distress, as well as pain and intense pruritis (which is often associated with AA and something I have had the misfortune of experiencing) do not need or deserve effective treatment. • As a comparison, baricitinib is available on the NHS to individuals with severe eczema and rheumatoid arthritis. In both of these NICE reviews, there were active comparators in their cost-effectiveness models. Additionally, both conditions already have several other approved treatment options and therefore patients are not simply left to suffer.	

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			• "No active treatment" as a comparator also discounts the multiple other (in my experience) sub-par treatment options that (often desperate) individuals with severe AA will likely try at least once if they are made available to them. Indeed, clinical experts state in the draft guidance that treatment options include "oral or locally injected corticosteroids, dithranol, contact immunotherapy, minoxidil and immunosuppressive medicines such as oral azathioprine, ciclosporin, methotrexate and sulfasalazine". I have personally paid out-of-pocket for treatments including oral prednisolone, topical and oral minoxidil and plasma rich protein (PRP) injections before finally receiving effective (and privately sourced) treatment with baricitinib. • In conclusion, no active comparator substantially skews the cost-effectiveness results. It is an unfair assumption that no disease or symptom alleviation is a sufficient comparator when most other diseases assessed in a NICE HTA reviews have an active comparator to the health technology in question. Additionally, where treatment options are actually provided for severe AA, patients will often try multiple treatment options as they tend to be desperate to escape the psychological distress associated with severe AA. 3. Sections 3.9–3.11: The best supportive care (BSC) applied to the economic model does not contain enough elements that correspond to BSC applied in the real world, and BSC should be a comparator rather than a health state in the economic model • BSC, in the real world, extends far beyond wigs and orthotics for individuals with severe AA. Even if a patient has exhausted all treatment options available (which is unlikely, as few people suffering severe AA gain access to treatment on the NHS), they will likely require psychological support. As outlined above, the psychological distress of having a severe visible difference can be all-encompassing. • As a comparison, the NICE review for baricitinib in the treatment of severe eczema (which gained approval) had BSC as one of its comparators. In the baricitinib/severe eczema review, BSC included (but was not limited to) education, psychological support, topical corticosteroids and hospitalisation. All these elements are also applicable to severe AA, and therefore should have been included in the draft guidance in addition to wigs and orthotics. • As a personal example, I have suffered severe AA for less than a year. During that timeframe, I accessed NHS mental health services twice	

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			(counselling with six treatment sessions, and CBT with 12 treatment sessions). The need for these mental health services were as a direct result of the psychological distress that that severe hair loss caused. I only no longer require psychological support due to the immense relief that (privately accessed) baricitinib-induced regrowth has caused. • The cost to the NHS of treating this psychological distress should not be ignored, particularly since NHS mental health services, such as counselling and CBT, are often accessible through self referral and (in my experience) there are no limits to the number of times a person can access each service. • Additionally, suicide ideation and risk of suicide is reported in 13% of those with AA (with the prevalence unknown, but likely higher, in those with severe AA).(2) In my own experience of the disease, when my SALT score surpassed around 50, I contemplated suicide every single day and began self harming. The only thing that prevented me from attempting suicide was the hope that I gained from online research of JAK inhibitors and the subsequent treatment with baricitinib. When suffering severe AA, I completely withdrew from all social activities and only left the house (in a hat) for necessities such as shopping and medical appointments. Social withdrawal as a result of AA has also been reported in peer-reviewed publications,(8, 9) with social isolation being a key risk factor for suicide.(10) As such, hospitalisation due to suicide attempts should be included as part of the BSC that is applied to the economic model. • As outlined above, BSC will likely be accessed by many patients until sufficient hair regrowth, and subsequent alleviation of psychological distress occurs. Therefore, BSC should be applied as comparator to economic model, not a health state. • In conclusion, real world BSC extends far beyond wigs and orthotics. Many of those suffering with severe AA experience intense psychological distress and will likely access mental health support through NHS services. As the QoL impact of severe AA is unlikely to disappear until significant hair regrowth occurs (SALT score of ≤20), BSC should be included as a comparator in the economic model, not a health state. 4. Sections 3.7 and 3.12: EQ-5D is a poorly chosen tool to measure QoL changes in patients with severe AA, as such the utility values applied to the	

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			economic model are inadequate • The clinical experts noted that “high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia areata” and the committee noted that “hair loss can cause severe psychological distress” and that “severe alopecia areata can have a profound psychosocial impact on a person’s quality of life”. Therefore, psychosocial impacts including anxiety and depression were recognised as the main secondary conditions of concern. • The EQ-5D only contains one of five domains that are specific to anxiety and depression (with the remaining four domains addressing mobility, self-care, usual activities and pain/discomfort). Inclusion of irrelevant domains likely dilute scores and therefore are unlikely to reflect the true baseline psychological distress that is felt. As such, any psychological improvement associated with baricitinib treatment and hair regrowth is likely to be overlooked. • More specific questionnaires that have mental health as their predominant focus would be appropriate e.g. Skindex-16 Alopecia Areata, PHQ-9 and GAD-7. Indeed, “statistically significant improvements in the emotions and functioning domains Skindex-16 Alopecia Areata scores” are noted in section 3.7 of the draft guidance. • As a comparison, the NICE review for baricitinib in the treatment of severe eczema used the dermatology life quality index (DLQI) tool to measure QoL. The DLQI tool is substantially more specific to aspects of severe eczema that impact QoL then the EQ-5D is to severe AA. • As a personal example, I was attending CBT (due to the psychological distress of hair loss) and noted a linear decrease in my PHQ-7 and GAD-7 scores as baricitinib-induced hair regrowth occurred over time. My PHQ-9 score decreased from 17 (moderately severe depression) to 2 (within the healthy range), and my GAD-7 score decreased from 21 (severe anxiety) to 6 (mild anxiety) with full hair regrowth. • In conclusion, the EQ-5D tool does not directly address the key secondary conditions of anxiety and depression that result from severe AA. Therefore, it is an inappropriate tool, and tools that more specifically address the psychological impact of severe AA would be more appropriate. QoL/utility conclusion: A combination of issues with QoL measures has	

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			resulted in a (likely) poor/false interpretation of the true QoL impact of baricitinib-induced hair regrowth. These include: (1) not accounting for the increase in baseline QoL scores upon clinical trial entrance (due to increased hope of participants); (2) using EQ-5D to measure QoL which is a non-specific tool that does not properly address the depression/anxiety that are key secondary conditions associated with AA onset; (3) measuring QoL improvement in the full baricitinib-receiving cohort as opposed to specifically measuring QoL impact in the 34% of baricitinib responders (as discussed in response to question 1). Therefore, a combination of unusually high baseline QoL scores, a non-specific QoL tool, and QoL impact being measured in both responders (34%) and non-responders (66%) combined (vs placebo) has likely amounted to QoL results that are substantially diminish the true positive impact of baricitinib-induced hair regrowth. QoL scores are diluted by background noise, including the 64% non-responders, as well as the 80% of EQ-5D domains that are not applicable to AA. Cost input conclusion: the cost inputs to the economic model were inequitable and fell short of the true costs of non-AA treatment. No active comparator equates to NICE/the NHS normalising and tolerating the severe psychological suffering that severe AA causes. I cannot fathom how a comparator that provides zero symptom alleviation and leaves patients depressed, anxious and suicidal is good practice. At the very least, BSC should be applied as a comparator which includes the cost of wigs/orthotics, mental health support (for anxiety and depression) and hospitalisation for suicide attempts. Active treatment options are also used within the NHS, but are unequally distributed. However, it is a failing of the NHS that these are not common practice and therefore should also be considered as a comparator. As a comparison, in the eczema/baricitinib review, both BSC and active treatment (dupilumab) were applied as comparators within the economic model; NICE should ensure that certain non-life threatening diseases are not treated more favourably than others. In this instance, it is evident that baricitinib treatment in severe eczema was tested with a substantially fairer economic model that was more reflective of the disease reality. Overall conclusion: an accumulation of poor QoL measures and associated utility inputs, as well as an inappropriate cost comparator likely skewed the	

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			economic model toward a high cost per QALY. Application of QoL measures that better reflect the real world, combined with a fairer and more accurate cost comparator will likely result in a substantial reduction in cost per QALY. References: 1. Toussi A, Barton VR, Le ST, Agbai ON, Kiuru M. Psychosocial and psychiatric comorbidities and health-related quality of life in alopecia areata: A systematic review. J Am Acad Dermatol. 2021;85(1):162-75. 2. Vélez-Muñiz RDC, Peralta-Pedrero ML, Jurado-Santa Cruz F, Morales-Sánchez MA. Psychological Profile and Quality of Life of Patients with Alopecia Areata. Skin Appendage Disord. 2019;5(5):293-8. 3. Lauron S, Plasse C, Vaysset M, Pereira B, D'Incan M, Rondepierre F, et al. Prevalence and Odds of Depressive and Anxiety Disorders and Symptoms in Children and Adults With Alopecia Areata: A Systematic Review and Meta-analysis. JAMA Dermatol. 2023. 4. Mostaghimi A, Napatalung L, Sikirica V, Winnette R, Xenakis J, Zwillich SH, et al. Patient Perspectives of the Social, Emotional and Functional Impact of Alopecia Areata: A Systematic Literature Review. Dermatol Ther (Heidelb). 2021;11(3):867-83. 5. Okhovat JP, Marks DH, Manatis-Lornell A, Hagigeorges D, Locascio JJ, Senna MM. Association Between Alopecia Areata, Anxiety, and Depression: A Systematic Review and Meta-analysis. J Am Acad Dermatol. 2019. 6. Rencz F, Gulácsi L, Péntek M, Wikonkál N, Baji P, Brodszky V. Alopecia areata and health-related quality of life: a systematic review and meta-analysis. Br J Dermatol. 2016;175(3):561-71. 7. Villasante Fricke AC, Miteva M. Epidemiology and burden of alopecia areata: a systematic review. Clin Cosmet Investig Dermatol. 2015;8:397-403. 8. Hunt N, McHale S. The psychological impact of alopecia. Bmj. 2005;331(7522):951-3. 9. Aldhouse NVJ, Kitchen H, Knight S, Macey J, Nunes FP, Dutronc Y, et al. "'You lose your hair, what's the big deal?' I was so embarrassed, I was so self-conscious, I was so depressed:" a qualitative interview study to understand the psychosocial burden of alopecia areata. J Patient Rep Outcomes. 2020;4(1):76. 10. Calati R, Ferrari C, Brittner M, Oasi O, Olié E, Carvalho AF, et al.	

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			Suicidal thoughts and behaviors and social isolation: A narrative review of the literature. J Affect Disord. 2019;245:653-67. **Are the recommendations sound and a suitable basis for guidance to the NHS?** From the perspective of a young woman who suffered severe AA and who has since (privately) received effective treatment with baricitinib (achieving a SALT score of zero), I have outlined below why I do not believe the recommendations to be "sound" or "suitable" for application to the NHS. 1. The recommendation contradicts the NHS value that "everyone counts" • The NHS has no effective long-term treatments for longstanding (lasting beyond 6 months) severe AA. Any treatments available are largely inaccessible to the majority of patients, as clinical experts noted that "there is no standard care for severe alopecia areata and treatment options vary widely depending on geographic location, healthcare setting, availability and the person's preference". As I stated previously, the only treatment option I was offered for 95% scalp hair loss was anti-depressants, with no wig provision provided (I had to spend £1,500 out-of-pocket on a wig for a sensitive scalp due to excessive scalp pruritus and pain associated with active AA — I still found the wig exacerbated the scalp symptoms, despite this expenditure). • The clinical experts also noted that "high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia areata". Additionally, there are several peer-reviewed publications that report a higher prevalence of depression, anxiety and suicide ideation within those suffering AA.(1-7) Therefore, there remains a large unmet need within this patient population and only those who are not financially constrained can access baricitinib treatment through expensive private consultation, private blood monitoring and pharmaceutical expenditure. One of the six NHS values is that "everyone counts". However, the outcome of the draft guidance translates to only those wealthy enough "count" when it comes to treating severe AA. • Additionally, other non-life threatening dermatological conditions have several treatment options. For example, severe eczema has baricitinib as a	

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			treatment option available on the NHS. Severe eczema and severe AA have many similarities in that they can result in intense pruritis, pain and psychological distress. Severe AA also causes severe physical disfigurement (which is classed as a disability by the UK Disability and the Equality Act 2010).(8) Therefore, this appears as preferential treatment of other conditions and directly contradicts the NHS value of “everyone counts”. Due to its cosmetic nature, this can be translated to “those whose psychological distress is largely caused by a visible difference (among other symptoms) do not count”. Overall conclusion: the 33.3% of people that suffer anxiety and depression as a result of severe AA are overlooked by this guidance and therefore it is not “sound” or suitable”. It directly contradicts the NHS value of “everyone counts”, with only those with the ‘right’ non-life threating condition, or with enough money being able to access baricitinib treatment. References: 1. Toussi A, Barton VR, Le ST, Agbai ON, Kiuru M. Psychosocial and psychiatric comorbidities and health-related quality of life in alopecia areata: A systematic review. J Am Acad Dermatol. 2021;85(1):162-75. 2. Vélez-Muñiz RDC, Peralta-Pedrero ML, Jurado-Santa Cruz F, Morales-Sánchez MA. Psychological Profile and Quality of Life of Patients with Alopecia Areata. Skin Appendage Disord. 2019;5(5):293-8. 3. Lauron S, Plasse C, Vaysset M, Pereira B, D'Incan M, Rondepierre F, et al. Prevalence and Odds of Depressive and Anxiety Disorders and Symptoms in Children and Adults With Alopecia Areata: A Systematic Review and Meta-analysis. JAMA Dermatol. 2023. 4. Mostaghimi A, Napatalung L, Sikirica V, Winnette R, Xenakis J, Zwillich SH, et al. Patient Perspectives of the Social, Emotional and Functional Impact of Alopecia Areata: A Systematic Literature Review. Dermatol Ther (Heidelb). 2021;11(3):867-83. 5. Okhovat JP, Marks DH, Manatis-Lornell A, Hagigeorges D, Locascio JJ, Senna MM. Association Between Alopecia Areata, Anxiety, and Depression: A Systematic Review and Meta-analysis. J Am Acad Dermatol. 2019. 6. Rencz F, Gulácsi L, Péntek M, Wikonkál N, Baji P, Brodszky V.	

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			Alopecia areata and health-related quality of life: a systematic review and meta-analysis. Br J Dermatol. 2016;175(3):561-71. 7. Villasante Fricke AC, Miteva M. Epidemiology and burden of alopecia areata: a systematic review. Clin Cosmet Investig Dermatol. 2015;8:397-403. 8. Advisory CaAS. What disability means by law 2023 [Available from: https://www.acas.org.uk/what-disability-means-by-law#:~:text=Severe%20disfigurement%20will%20usually%20be,considered%20to%20be%20a%20disability. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** From the perspective of a young woman who suffered severe alopecia areata (AA) and who has since (privately) received effective treatment with baricitinib (achieving a SALT score of zero), I have outlined below where I think recommendations verge into discriminatory territory. 1. Section 1.1: the fact that "baricitinib is not recommended" for treatment of severe AA shows that a condition that causes visible difference is of a lower priority than other non-life threatening conditions • Severe AA is associated with 'severe physical disfigurement' which is classed as a disability by the UK Disability and the Equality Act 2010.(1) However, myself and other people suffering AA often state that psychological impact of a visible difference is often overlooked or downplayed by both the medical community and general public; this further adds to the distress of the disease. • Baricitinib is available on the NHS to individuals with severe eczema (of which several other approved treatment options are also available). As outlined in my responses to question 2, the parameters applied to the economic model in the eczema/baricitinib NICE review were substantially more favourable and disease-specific, resulting in a much lower cost per QALY. In contrast, the parameters applied to the severe AA/baricitinib review were non-specific to the disease and failed to account for many of the additional NHS costs associated with not effectively treating patients (as	

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			outlined in my responses to question 2). • Parameters in the eczema/baricitinib review included the more specific DLQI QoL tool vs the non-specific EQ-5D tool applied to the AA/baricitinib review. Additionally, the treatment comparators in the eczema/baricitinib review included BSC and dupilumab whilst the AA/baricitinib review had no active comparator; this translates to severe eczema being viewed as deserving of symptom alleviation whilst severe AA is not. The BSC for severe eczema also included several elements that are applicable to AA that were not included for the BSC in the AA/baricitinib review (which was applied as a health state to the economic model). Namely, the BSC in the eczema model factored in mental health treatment which was not factored into the AA/baricitinib review. It is frequently acknowledged in the draft guidance that AA is associated with severe psychological suffering; therefore, lack of inclusion of mental health support in the BSC is perplexing and makes it appear as though the treatment of eczema is thought to be of higher importance than that severe AA. Overall, the eczema/baricitinib review was subject to a much fairer, more balanced cost-effectiveness analysis than that of the AA/baricitinib. A potential explanation for this ill-thought-out review is that people often fail to recognise the true detrimental QoL impact of a visible difference. As, myself and others suffering AA can attest, the psychological impact is frequently overlooked or downplayed by the medical community • In conclusion, to deny those suffering severe AA the only effective treatment option, is to overlook and de-prioritise the distress of their condition. In doing so, other non-life threatening conditions (that are not visible diseases) are given higher priority. This is particularly unfair when these diseases already have multiple treatment options available on the NHS. 2. Section 3.15: Those with lower socioeconomic status suffer disproportionately as a result of severe AA and the associated cost of treatment and/or tools for symptom management (wigs and orthotics) • Section 3.15 states that AA may be more common in those with “lower socioeconomic status”. Access to baricitinib in the UK is therefore only manageable for those who can afford the cost of prescription, private medical consultation and private blood monitoring. • Additionally, as stated in section 3.2, there are inconsistent wig provisions across the UK and patients frequently have to pay out-of-pocket.	

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			When I had not received baricitinib treatment, my wig was something that I deemed as an absolute necessity to feel comfortable when I (rarely) attended anything that involved socialising; as one patient expert noted (in section 3.2) “about 75% of people with severe alopecia areata wear a wig most of the time”. • As AA has such a poor and inconsistent treatment pathway within the UK, it often comes with a huge personal expense to those suffering. I have personally spent close to £10,000 in less than one year of suffering with AA (including a wig and various private treatments). • One study reported that patients with AA were “seriously (25.2%) or moderately (31.7%) affected by the financial burden”. Additionally, in a willingness-to-pay analysis of 40 adult patients (aged 18 and older), it was found that individuals were willing to pay 12%–20% of their monthly income for a permanent AA cure, with those experiencing severe disease willing to pay more. This emphasizes the desperation people feel when it comes to finding a treatment for AA.(2) • Therefore, there is a massive equity concern with AA and those with a lower socioeconomic status will be hit the hardest. To not recommend the only effective treatment option for severe AA is to discriminate against those who, not only cannot afford the treatment privately, but also cannot afford the most basic of necessities that many rely on to manage the psychological distress and ‘hide’ their visible difference. • In conclusion, the treatment of severe AA in the UK is poor and inconsistent and as such many people suffering bear a significant financial burden. Those with lower socioeconomic status are more likely to suffer AA and have greater difficulty funding treatment options for severe AA. The approval of baricitinib within the NHS would remove treatment access barriers and give those with a lower socioeconomic status a fairer chance at hair regrowth and improved QoL. 3. Certain religions prohibit hair cuts or the removal of facial hair, such as Orthodox Judaism, Rastafarianism, and Sikhism. This may result in people with AA being ostracised from their cultural community • Hair has a substantial social significance in most cultures and societies. In certain religions, hair is even viewed as sacred or a gift from God. As such, extensive hair loss can be particularly distressful for people	

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			within these communities and may lead to them being excluded or ostracized. • NICE have failed to account for the cultural and religious significance of hair in the draft guidance. As a viable treatment option is available that could alleviate this burden for members of certain religions, NICE have discriminated with their lack of recommendation. This may result in the continued persecution of those suffering severe AA within certain religions, which could have been avoided had these people gained access to the only known effective and approved (in certain countries) treatment for severe AA. Overall conclusion: the lack of recommendation is discriminatory in the sense that it favours a non-visible non-life threatening disease (severe eczema) over a visible one (severe AA). Baricitinib is approved for the treatment of severe eczema whose NICE review had more favourable, disease-specific inputs in the cost-effectiveness analysis than the inputs applied within the baricitinib/AA review. Additionally, those with lower socioeconomic status have a higher prevalence of AA. As the NHS provides few to no treatment options for severe AA (depending on your postcode), those with less money are left to pay for expensive wigs that are deemed as an absolute necessity for most (and barely address the root problem/unmet need). Effective treatment is therefore only accessible to those who can afford it. As such, those with a lower socioeconomic status suffer the double blow of increased AA prevalence coupled with the inability to afford treatment options that are not provided on the NHS. Furthermore, with baricitinib not currently recommended for the treatment of severe AA, NICE may be continuing to allow the ostracism of members of certain religious communities. This is because certain religions place great importance on hair and prohibit hair cuts or the removal of facial hair. Thus, involuntary severe hair loss may result in exclusion from a religious community, which otherwise may not occur if people with severe AA had access to baricitinib. References: 1. Advisory CaAS. What disability means by law 2023 [Available from: https://www.acas.org.uk/what-disability-means-by-law#:~:text=Severe%20disfigurement%20will%20usually%20be,considered%20to%20be%20a%20disability. 2. Muntyanu A, Gabrielli S, Donovan J, Gooderham M, Guenther L,	

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			Hanna S, et al. The burden of alopecia areata: A scoping review focusing on quality of life, mental health and work productivity. J Eur Acad Dermatol Venereol. 2023.	
50	Web comment	Health care professional /Person with alopecia areata	I was unhappy to hear that Baricitinib has not been improved in the first consultation period but I am hopeful that it will be in the future. I have Alopecia Universalis, my hair loss occurred over a 6month period whilst I was studying for my nursing degree. I have always made a conscious effort to not let my hair loss prevent me from doing the things I have wanted and have worked as a theatre nurse for 10years and have been able to travel the world. However, to do this comfortably and feeling secure, I have had to spend £1000's of my own money to buy wigs which look realistic, are comfortable and will not move on my head (or blow off in the wind). It is these wigs which have provided me this opportunity and this is not an option for many who do not have the opportunity to have realistic comfortable wigs provided by the NHS. I have never had a NHS wig as my area only allows synthetic wigs which don't suit my lifestyle or work (they get damaged easily under a theatre hat). If I had the opportunity to take this medication I would. I understand Alopecia at present doesn't cost the NHS much money (this is partly due to the appalling poor wig provisions offered) however cost of antidepressant medications and therapy's must also be taken into account aswell as increasing costs to the individuals.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).
51	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** I feel there are some questions regarding the way information has been collated for the impact on quality of life. In my experience, my quality of life was massively affected. This condition pushed me into disordered, dysmorphic, OCD type behaviour. A combination of the lack of medical support, lack of general understanding of the condition and lack of effective treatments means that i had to develop my own coping mechanisms. I changed my diet and developed strict rituals and routines to try and gain some control, the condition consumed me and eventually resulted in...basically a breakdown. I was unable to eat, sleep, look after my children,	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It recognised the unmet need for safe and effective

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			go to work etc. I eventually started taking sertraline, got a diagnosis of PTSD and started treatment for this. Im not sure the evidence you have access to really covers these nuances **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** Frustratingly i can see that this condition does not currently cost the NHS very much. However with regards the previous answer have the knock on conditions been taken into consideration. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** It is widely accepted that a person can straighten their teeth, have gender reassignment, access reconstructive procedures, receive fertility treatment etc on the NHS. I would like to see evidence that autoimmune hairloss has the same credence as some of these better supported differences. Severe alopecia is a disfigurement and in my opinion, when severe, the mental implications are in fact a hidden disability. Consideration of these points should be made	treatments for severe alopecia areata (see section 3.2 of the FDG). The committee recognised the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG). It considered equality issues in section 3.17 of the FDG and acknowledged the uncaptured benefits (see section 3.18 of the FDG).
52	Web comment		**Has all of the relevant evidence been taken into account?** Possibly **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** I do not believe so, the costs somewhat underestimate the true cost of treating alopecia, it is not simply the cost of a wig, it is the costs of numerous visits, numerous treatments and lost productivity across a wide range of people, mainly females. The stress levels and anxiety of many of these suffers has not been fully acknowledged. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No, this seems very biased against alopecia suffers and in no way is there a	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It recognised the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). In accordance with the NICE health technology

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			balance between alopecia suffers and those people with other diseases. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** In my humble opinion the recommendation is very much an anti female decision and discriminates against strongly against females. It in many ways underestimates the true impact of this disease and makes somewhat belittling statements about this disease as being trivial compared to other diseases. The mental health aspects of alopecia are not really addressed from a medical and general perspective and are clearly not factored into the appalling conclusion about making this treatment not available to sufferers. To not make this available to alopecia sufferers denies them hope that they may be cured, the NHS is supposed to look after sufferers and not to deny them at least a chance of being cured.	evaluations manual 2022, costs should relate to NHS and PSS in the reference case.
53	Web comment	Person with alopecia areata	I would like to express how disheartening it is to know how little alopecia is taken seriously. Your first point of the lack of people taking up treatment is down to the ridiculous waiting list for a referral (1-2 years) and by that time we are told there is nothing they can do once all the hair has fallen out. Secondly, your point about the quality of life shows how severely uneducated you are. Since being diagnosed with alopecia my quality of life has been significantly impacted. My mental health is rock bottom because it has been so distressing losing myself. Furthermore, there are physical impacts such as severely irritated scalp, painful eyes due to losing eyelashes and the list goes on. I have seen the incredible things Jak inhibiters have done for people, and the fact you're denying people the right to treatment at an affordable price is disgusting! I really hope you put yourself in our shoes and actually emphasise how desperate we are to get an affordable treatment to end our pain and suffering. Please listen to the people, we need our voices heard!	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It recognised the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).
54	Web comment		**Has all of the relevant evidence been taken into account?** Evidence relating to quality of life is poor. Markers used are not relevant to the harm caused by alopecia. For example it would be more useful to consider impact on self esteem than domains considered in EQ5D like	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of

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			mobility. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No they are not as the evidence to look at quality of life is insufficient. I have witnessed a friend of mine who has started this medication 6 weeks ago and had early signs of re growth. This has been very beneficial for her quality of life.	the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).
55	Web comment	Person with alopecia areata	Having read the document relating to the use of baricitinib to treat alopecia and NICE position on it's use within the NHS in England I felt compelled to contribute to the comments. I was diagnosed with alopecia in 2021, I now have complete hair loss across my entire body and the impact of this on my physical and mental health and the added pressure on my family cannot be over stated. I am not satisfied that the consultation fully considered the impact on quality of life or the associated cost of treating connected symptoms from this disease. Cost compared to current treatment - there are no suitable treatments available for alopecia at present and so patients with the condition are not currently a burden to the NHS due to the hair loss alone however, there are and will be costs associated with other symptoms especially around eye care, ear, nose and throat and mental health. Quality of life - comparisons are drawn with other physical conditions like arthritis, it is easier to assess improvements in such a condition as you can measure a reduction in physical pain and resulting increased movement etc. whereas not having hair is not considered to be physically painful or to limit movement. I have been wearing a wig for 18 months, I have no eyebrows, no eyelashes, no body hair at all and every single day is a miserable effort in everything that I do. I have pain in my eyes as I no longer have eyelashes to protect them, they are dry, itchy and red all of the time to the point that I find it challenging to do my job every day. I have issues with my sinuses and my nose bleeds daily, not having hair to act as a filter and protect me from allergens causes me no end of grief especially as I already suffer from eczema and asthma.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It recognised the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). The committee considered equality issues in section 3.17 of the FDG. It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			I have lost all confidence in myself, I struggle with work and all social situations, I think about my hair every minute of the day and I have nightmares about it. I am mentally exhausted and worry about my ability to continue for much longer. While I appreciate alopecia itself may not be considered a threat to life the impact it has on a person certainly does. In moments of clarity I can acknowledge that many other conditions would be worse to deal with but it is relative and as I write this with tears streaming from my eyes I think of the many people who suffer in silence, perhaps don't leave their house, no longer contributing to society, not supporting their families and friends because they can no longer function in the world and I ask that you please consider the seriousness of this condition before making your final decision. I would like to add that my condition was triggered by the administering of the Pfizer Covid Vaccine (which I have reported) I had two doses and a booster and the hair loss started and worsened after each dose. **Has all of the relevant evidence been taken into account?** **Have you fully considered costs resulting from associated symptoms?** **Have you fully considered the varied physical and mental challenges arising from the condition and the impact on quality of life not only of the patient but family, friends and impact in the workplace and society in general?** **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** To read that patients diagnosed with alopecia are not presently a financial burden to the NHS due to lack of available treatments is in itself depressing but not more that the thinking that providing hope in the form of a JAK inhibitor like baricitinib is not value for money. Measuring the value by cost alone is not sufficient. There are additional treatment costs connected to alopecia including other physical symptoms and of course associated mental health treatments. There is not enough data to properly consider the impact and wider costs that could be offset should an improved treatment option be available. **Are the recommendations sound and a suitable basis for guidance to**	

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			the NHS? I don't believe that there is enough evidence contained within the document to adequately make a recommendation. I would like to see more case studies, additional data from the USA and Europe and from trials. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Alopecia does not discriminate and neither should the NHS. Not recommending this treatment for use in the NHS could in itself be considered discriminatory, the suggestion that this is a cosmetic disease that isn't deserving of the same level of attention as arthritis or crohn's disease for example is prejudiced and unjustified. This consultation document does not go far enough to consider value for money in the context of improving quality of life across all characteristics or to understand how to proactively manage or deter against any future physical or mental health related issues.	
56	Web comment	Person with alopecia areata	**Recommendations** I believe that this drug is licensed all over the world and research is showing that it has positive effects and results with patients with AA If patients who are already on the drug are allowed to continue then surely this is showing positive results with the handful of people Others should have this chance to change their condition take control and have life changing results I understand that the cost would be large however so is the effect's physical and emotionally from AA. Let patients get their life back . I understand cost is high when purchased from companies that they gain financially. I know of many patients who have purchased from abroad for example Indian at a fraction of the price **Price** The cost is huge when purchased from profit making companies. Could the drug be outreached from drug companies abroad at a fraction of the price	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It recognised the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of

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			Effects on quality of life I totally agree with all this, the effects physically and psychologically are huge effecting all aspects of daily life. Personally it has effected myself in both even contemplating suicide . I have grown up watching my mother and how it effected me as a child growing up and now history is repeating itself with me with AU losing your hair has a huge impact on not just the individual but the whole family. I am second generation to have alopecia as a child the impact of having a parent was huge, limited activities, teasing and bullying which then had psychological impact on myself, then to become a sufferer history repeats itself. My life has been limited by alopecia areata. Do I need to be ruled by this all my life. This drug could change my life my families life. **Treatment options** Personally I have tried a few treatments, creams, injections etc Then sent away with a prescription for a wig..... a wig is not the answer its like putting a badly fitted bandage of a cut, a cut so deep it cant be covered. I have tried wigs, psychologically its not the answer for me, I know its a wig, stealing my identity!!! I want my own hair, to have my own lashes, eyebrows to regain my identity. Alopecia has stolen it, I want any chance to get it back! **Positioning of baricitinib** I understand that some treatments should be tried first, and also some patients may not want this treatment. But let patients choose. **Treatment response and health-related quality of life** if this treatment was widely available there would be better understanding of the benefits and the impact on quality of life **Adverse events** This maybe true but is this not the case of all drugs?	the FDG) and acknowledged the long-term safety of baricitinib in other conditions (see section 3.9 of the FDG). It noted the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG). The ICERs using the committee's preferred assumptions were higher than the range of £20,000 to £30,000 per QALY gained normally considered to be a cost-effective use of NHS resources (see section 3.15 of the FDG).

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			Composition of best supportive care I have tried some treatements. You state that patients may not be willing to try other treatments. I strongly disagree I would try anything and I am sure if you spoke to patients in the AA community they would agree with me **Best supportive care use after non-response** some patients may not respond to Baricitinib but why should wigs be the answer? Other Jak inhibitors have been proven to be effective. Patients should have the right to explore other drugs available **Acceptable ICER** why does have to cost this amount when drugs can be sourced out with the uk much cheaper **Has all of the relevant evidence been taken into account?** No I dont believe it has, the evidence on the psychological impact of AA on patients and the effects it has. Talk to the AA community we want a treatment that gives us hope **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** NO! source from abroad, much cheaper, could be monitored. Patients are ordering themselves some not being monitored. Surely having this drug more cheaply from abroad and being monitored by NHS doctors is a much better option	
57	Web comment		I believe this drug could be a complete life changing thing to not only an individual but to alopecia areata sufferers all over the uk. Compared to other traditional treatments ie wigs which I feel isn't getting to the root of the problem. I have know a close friend who has been on this drug and the change in health and mental health I have seen a incredible improvement. This person has been paying privately for a prescription of this drug and has already seen a good transformation. If you look at other treatments and drug costs for other conditions this needs to be approved and commissioned for treatment. Children and adults who have this condition will have a better quality of life are in need of this to happen.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).
58	Web		**Has all of the relevant evidence been taken into account?**	The ICERs using the committee's

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	comment		Yes **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** Yes **Are the recommendations sound and a suitable basis for guidance to the NHS?** I do not consider the recommendations to be fair for people who suffer from alopecia. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Not as far as I can see	preferred assumptions are higher than the range of £20,000 to £30,000 per QALY gained normally considered to be a cost-effective use of NHS resources (see section 3.15 of the FDG).
59	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** No. See below **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** There are two huge flaws in the cost effectiveness analyses that have been undertaken. The first relates to the evaluation of quality of life. To begin with, the EQ-5D, HADS and Short-Form 36 questionnaire are not appropriate tools for assessing quality of life in patients with alopecia areata. Alopecia areata does NOT cause ongoing physical pain or discomfort, affect mobility, impact self-care (e.g. washing/dressing), limit physical activities such as shopping/lifting/climbing stairs, directly affect energy levels, or impact "general health". These are therefore completely irrelevant assessments of quality of life and it is unsurprising that there were no improvements demonstrated within the trials. EQ-5D was not a primary end-point of the BRAVE trials. If it had been a primary end-point, there should have been a more representative distribution of baseline scores. Almost half of the patients with severe or very severe alopecia had EQ-5D scores of full health and were therefore unable to show	The committee acknowledged the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG), the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG), the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It also considered equality issues in section 3.17 of the FDG.

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			any improvement in their EQ-5D score, adding further evidence to the inappropriateness of this measure within the cost-effectiveness analysis. The Skindex-16 alopecia areata tool was primarily designed for the assessment of skin conditions not hair loss. A chronic autoimmune condition causing extensive hair loss is NOT comparable to a skin condition such as eczema. Hair loss does not cause persistent itching, burning, pain, or irritation making questions 1 to 4 irrelevant. Furthermore, patients with Alopecia Universalis, by definition, are at the maximum threshold of how bad their hair loss can get making questions about the “recurrence” and “worsening” of hair loss (questions 5 and 6) irrelevant as well. This means that 40% of this questionnaire is inappropriate. As a result, it is again not surprising that no significant improvements were demonstrated within the trials. In addition, many of these questionnaires ask about “today”, “the past week” or “the past 4 weeks”. Many people with alopecia areata, including myself, have been suffering with hair loss for several decades! We have been forced to adapt to our hair loss because there have been no treatments available. Our baseline quality of life assessments are likely very skewed and over-estimated as a result of these adaptive coping mechanisms. Asking about such short timeframes in the context of several decades of “severe psychological distress” cannot justifiably capture the long-term psychosocial impacts that this condition has had. It is notable that within the Skindex-16 assessments, there were statistically significant improvements in the emotional and functional domains. This covers areas such as feeling embarrassed, ashamed, and depressed about hair loss, as well as the impacts on interactions with other people and daily activities. These are the parts of this questionnaire which are relevant to patients with alopecia areata and the fact that this showed a significant difference are supportive of this. Anecdotally, if I completed the EQ5D (having looked at the questions) I would have full health at baseline. This does not reflect the impact that alopecia areata has had and will continue to have on my quality of life. I am 35 years old. Having lived with alopecia for 25 years, I can categorically tell you that taking medication that would make my hair grow back would improve my quality of life beyond comprehension. Living with this condition has significantly impacted my mental health, causing severe depression and anxiety, to the point where I have considered taking my own life on multiple	

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			occasions to end the mental pain. As clearly documented in the draft guidance, alopecia areata is inescapable and bleeds into every aspect of your life by eroding and destroying your self-worth and identity – things that cannot be measured and captured in such crude quality of life tools as those used within the trials and for the basis of this cost-effectiveness analysis. For prolonged periods I have been unable to look at myself in a mirror. I have struggled with exercise and physical activities, felt ashamed, embarrassed and self-conscious in social settings which has manifested in a severe social phobia, and have remained single (I am not married and have no children) for a prolonged period of time because of the difficulties it has created in forming intimate relationships and believing that someone could love me when I believe myself to be physically repulsive. In a world where social media and focus on external appearance is ever-increasing, I dread to think how young women will cope with hair loss having personally been subject to cruel comments and rejection whilst trying to navigate dating and romantic relationships with this condition. I also watched my sister who has alopecia areata get bullied relentlessly at school because of her hair loss. To conclude, alopecia areata, as clearly detailed within the draft guidance, causes “severe psychological distress” which is NOT being adequately captured within these quality of life assessments because they are not appropriately designed for hair loss. It is likely that the ICER is so high because the differences in measured quality of life in the trial are so small – this likely dominates the results of the ICER and means the ICER is flawed and inaccurate. The second flaw is the fact that there is no clear consensus on the standard of care or “best supportive care”. And yet, the reason for there being no consensus is because of the lack of evidence on cost effectiveness for this condition. This means that patients with alopecia are being penalised because there are no available treatments. As a result, a treatment with clear evidence of working is being withheld. It is incomprehensible that the basis of the ICER is that patients with alopecia are currently not costing the NHS money, when this is because there are no treatments available. This argument is entirely circular and ludicrous. We cannot directly cost the NHS money if there are no treatments available and this should not be allowed to be a reason to not provide us with a treatment that has finally been shown to work.	

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			People with alopecia are currently not “directly” costing the NHS money purely because there are no treatment options available. The bigger picture is that significant numbers of patients with alopecia are going to indirectly cost the NHS, and indeed the country, money through the proven high rates of depression (30% higher than average), anxiety (30% higher than average) and unemployment/sickness (80% higher than average). Anecdotally, I have been generally appalled at the care I’ve received over the past two decades. Not once has a medical professional ever offered me any sort of psychosocial support for my alopecia. I’ve been told continuously to essentially go away and get on with it because there is nothing that can be done. I have had countless dermatology appointments across four different NHS hospitals, wasting money on treatments that have no evidence base (dithranol, steroid creams, intravenous steroids, intralesional steroids, immunosuppressants). Surely this money is better spent on a treatment that has actual proven benefit? To withhold a treatment with clearly documented results after decades of such care is frustrating beyond comprehension. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No - as detailed above. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** There has been no differentiation of patient groups in the assessment of quality of life. For example, the impacts on quality of life are likely to differ according to age and gender. In addition, the “patient experts” are both of a similar demographic. There is no representation of males, younger patients, or ethnic minority groups. The impact of hair loss on males needs to be considered separately from females given the difficulties in trying to cover the loss of, for example, eyebrows and eyelashes, given that most males would likely not feel comfortable wearing, for example, false eyelashes. It is commonly accepted that patients from lower socioeconomic status and some ethnic minorities are much less likely to participate in clinical trials.	

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			Alopecia areata has been shown to disproportionately affect patients from a lower socioeconomic status and ethnic minority groups, as well as having a peak prevalence in the mid-twenties. It is therefore highly likely that the trial population is not truly representative of real-world practice, especially with regards to the quality of life assessments. The terminology of “best supportive care” is frankly offensive. This term is usually used to describe patients who are being managed in a palliative setting because they are dying. This terminology should not be used in relation to alopecia areata. In addition, patients from lower socioeconomic backgrounds are being discriminated against in the use of “best supportive care”. I have spent thousands of pounds on private therapy to try to deal with the mental issues my alopecia has caused. I have also spent thousands of pounds on wigs to try to replicate my own hair as much as possible. There is huge variation in who is eligible for support in buying wigs, and often the wigs offered on the NHS are synthetic rather than human hair. I have also now spent thousands of pounds to be seen by a private Dermatologist and to obtain this medicaiton privately. The personal financial implications of trying to manage this condition yourself need to be considered as this is extremely discrimantory to those of a lower socioeconomic standing. Finally, and most frustratingly, this medication is already available on the NHS, at the exact same price, for rheumatoid arthritis and eczema. This is because these conditions have had appropriate quality of life assessments undertaken, and there are comparable treatments. Patients with alopecia areata are being discriminated against for factors which are out of our control e.g., there are NO recognised treatments for comparison and an appropriate quality of life metric has not been validated and measured. Patients with alopecia areata are persistently discriminated against because this condition is often deemed to be “cosmetic” despite clearly being shown to be a chornic autoimmune condition with other associated diseases. This is yet another example of how chronically neglected proper care for this condition has been.	
60	Web comment	Person with alopecia areata	**Treatment response and health-related quality of life** There is a clear issue here when using this 'quality of life assessment tool'. The assessment is considering health related impacts as perhaps used when making decisions around the impact of a pain relief drug for example. Mental impact should be considered in the same way as physical impact, both can be debilitating and life limiting.	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person’s quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective

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			Please consider my lived experience, Having been on baricitinib 4mg for 8 months and having seen the full regrowth of my hair from SALT score of 99.9 to a SALT score of 0 please let me assure you all that the improvement to my quality of life has been significant. I lived with alopecia universalis for five years of my life. I lost my identlty and my confidence. I became isolated socially and suffered depression. Each day followed the same pattern; Getting up in the morning and avoiding looking in the mirror, then having to put on my 'disguise' of false hair, eyebrows and eyelashes to try to make myself look as normal as possible. Not wanting anyone to look at me when I was not in my 'disguise', including my family. Hiding away in my room and feeling ashamed of how I looked, which ruined my relationship with my partner and impacted my children's lives. Constantly self-conscious and afraid that someone was going to comment on my obviously fake features. Trying to avoid situations where people will scrutinise me. Worried that my wig, eyebrows or lashes would fall off or become smudged without me being aware. Avoiding doing activities that I would formerly of undertaken without issue - going to the gym, taking the children swimming, going to theme parks, going to dances or parties, going to music events. For fear of my wig falling off and issues around getting hot and wearing a full disguise that is itchy, hot and uncomfortable. Missing out on work opportunities due to my loss of confidence and shame of how I looked impacting on me going to interviews or doing work place presentations.	treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised the limited evidence informing best supportive care composition and use (see sections 3.11 and 3.12 of the FDG) and that there are uncaptured benefits (see section 3.18 of the FDG).

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			Not going out in the evening as by that point in the day I could not stand the discomfort of my wig and lashes and wearing glasses and needing to go home and get relief from them. During covid wearing a face mask on top of this was unbelievably difficult. Please consider this and try to imagine me as a 42 year old woman looking into the mirror and not recognising the face looking back. Hair is a massive part of our identity and the shame and helplessness I felt that I could not even have that most basic and universal feature pervaded every day, reminders of this fact were everywhere I looked - people with hair, adverts for hair and beauty products, people talking about going to the hairdressers. ect Please also consider the fact that my eyes were constantly sore and watery and gritty, eyelashes really are there for a reason. Without nostril hair my nose ran constantly as soon as the colder weather began and was always sore from having to use tissues all day every day. The difficulty of obtaining a wig on prescription and subsequently having to purchase them along with false lashes on a regular basis - wigs do not last like hair and once they have been washed a couple of times/ rub on clothes they start to look 'wiggy' making the wearer even more self-conscious. Many in society laugh at people wearing wigs, they have traditionally been a source of comedy, all of this is in the mind of those wearing them, the stigma is real. I could not even access counselling services due to the feelings outlined above, having someone I sit here now with a full head of dark and curly hair, eyebrows and eyelashes. My heart sings when I type that fact. I have been given the opportunity to live a normal life through this drug and I could never express in words what this difference has made to my life - it is not just hair. I am a sensible and professional woman, I work hard in social care and have built a good career in what I do, please understand I am not an emotional 'weak' person - every word that I have written is a true reflection on how living with no hair on any of my body made me feel every day.	

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			Baricitinib and the other JAKi's that are currently undergoing clinical evaluation will give those with currently no hope of successfully managing this disease hope that they may live normally again. Please consider this, I tried the handful of treatments currently available on the NHS to treat this and lets be honest, they are outdated and do not treat the systemic root of the condition in the same way that a JAKi can - we must embrace this in the same way that it has been used for those living with other debilitating conditions. Please follow the lead of the US and Europe and recommend Baricitinib as a treatment. In my opinion it is a glimmer of hope in a disease that has been up until now largely ignored and unsuccessfully treated, it would be cruel to deny those living in the UK this opportunity. Finally, I have been forced to source my Baricitinib from abroad, it was stressful and difficult. I was desperate, I forged ahead and it paid off. I am supported by a pragmatic and knowledgeable private consultant who monitors my bloods and advises accordingly. The thought of not being able to get hold of this treatment is unthinkable, and a constant worry. The experience of living how I did for those years has impacted my mental health deeply. My reaction to losing my hair again would be extreme and I will not allow myself to consider the outcome. **Composition of best supportive care** I agree with the final assertion that 'it concluded that there is wide variation in access to treatments, and that it is likely people would have limited pharmacological options and are more likely to use wigs and orthotics.' Dermatologists are not experts on autoimmune disease and it is not fair on them or their patients to expect them to have extensive knowledge on how to treat them. Patients should be referred to specialists in hair loss who are experts in their field. **Preferred assumptions** It is not really fair to compare the cost effectiveness of Baricitinib to the present costs incurred to the NHS. Currently there is no treatment that consistently works so people suffering from Alopecia stop trying. In my case I was given topical ointment and steroid	

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			injections into my head. Neither worked, the topical treatment was difficult to apply and irritated my skin, the injections were extremely painful and intrusive. After this my case was closed and I was only left with the option of trying to get wigs, this was difficult and the approved supplier had a limited range to try. So I stopped costing the NHS anything as they could offer me nothing. Does this mean we should never receive any help? as based on this assumption any new treatment coming along will be rejected as not cost effective compared to the current state of affairs.	
61	Web comment		**Has all of the relevant evidence been taken into account?** No **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No. Eczema and alopecia areata in clinical trials are related, it would seem right and proper to make Baricitinib available for both. In the measure of well being it would bring equal benefits to those in need of either treatment. It is not good practice to be using treatments on the present varied results prescriptions when the tests for Baricitinib show advantages. Cost of repeat unsuccessful visits to a dermatologist and medication need to be considered. **Are the recommendations sound and a suitable basis for guidance to the NHS?** Yes, these comments are forwarded on the basis of experience. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** No	The committee acknowledged that baricitinib is innovative (see section 3.18 of the FDG) and that there are uncaptured benefits (see section 3.18 of the FDG).

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62	Web comment	Parent of person with alopecia areata	I assume from people who Have accumulated this report and made the decision about this particular drug for the treatment of alopecia, have not got family members who have the condition, or go through the trauma of having a condition themselves or watching love one go through the trauma of having alopecia of any form. I have a family member, a daughter, who I have watched from the age of five battle through her journey of alopecia from a small patch on her, get any hair cut to cover the patches, different hairstyles to cover the patches and as she got older, we had to Look at alternatives. Ages 10 she chose to shave her hair because she was waking up to clumps of hair on her pillow, clumps of hair falling out in the shower. No, 10-year-old should ever have to face that things didn't stop there. It's only got progressively worse as she's got older and hit high school, she was different, but she was made to feel different. People knew she was different . My daughter has no friends at school no friends outside of school. She's currently waiting to see a psychiatrist because she wants to take her own life because she hates the way she looks the way she sees herself and the fact she doesn't feel like she belongs in life. I can buy all the wigs in the world, the eyelashes and the eyebrows, but if there's a chance that there is a drug that can be provided on the NHS for the treatment of alopecia, why would you not allow this drug to be given to people with alopecia men and women children, teenagers. Treatment is given to various conditions, some which are more important than others. I fully understand but alopecia is up there with the serious cases because it's a huge confidence blow. If you're reading this and you have children, put yourself in somebody else's shoes with alopecia and how would you feel if you had no hair no eyebrows no eyelashes your family member had it? What would you do? What length would you go to what fight would you take to make sure there is a drug available on the NHS to help potentially combat alopecia if your answer is exactly what we're doing then, maybe the decision shouldn't be a no to this drug now or in the future maybe it should be a yes this drug is a good idea because it will change so many lives. I don't want to wake up one day and not have a daughter because she can't cope with the world. The amount that Jack inhibitor costs compared to how much you pay out on wigs, per person per year. I am sure the drug is cheaper in the long run because you will save on Wigs and also mental health side of the NHS. It will relieve some pressures from the mental health capacity on the NHS. Please don't decline this look on the NHS, make it	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).

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			available for them and make it an option. Make them the confident people that they so desperately want to be again. Let's get these people back out in the world where they belong.	
63	Web comment	Spouse of person with alopecia areata	**Has all of the relevant evidence been taken into account?** No I don't believe all the evidence has been taken into account. As a husband of someone who has Alopecia the disease that impacts my wife everyday of her life physically and mentally also impacts family members. Firstly financially the options that are currently available to treat Alopecia aren't available in all postcodes and would require private consultation or products bought without prescription support. The impact on work is also another consideration, my wife can not always mentally be prepared which also impacts us as a family despite the love and support we continue to provide. In addition to clarify wigs are not made available to all and to obtain a reasonable wig which will need replacing yearly costs around £1000 per year, either make these available or provide some financial support. Mentally this doesn't only impact the Alopecia suffere it directly impacts family members, i have been on prescribed medication to support, however my wife is still waiting for counciling after 24 months, and this has also affected one of my children which is another drain on the NHS where it may not need to be. Unfortunately the evidence NICE have looked at isn't the big picture and the costs and support for people that surround that person also need to be considered, and the facts that the current treatments are a postcode lottery. Also consider every time a treatment doesn't work this also has a negative impact and even more so knowing there is a drug available that will help a lot of families get back their life! Please live a day in our shoes it impacts every aspect of every day life for all of us! **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** As above cost effectiveness needs to look at the bigger picture and consider the impacts of the disease relating to costs for additional medication and therapy to support mental health issues linked to this and time of NHS supporting with treatments that are less effective. Also consider depressions	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the wide variation in practice both in terms of pharmacological options and wig provision in the NHS (see section 3.2 of the FDG). It acknowledged the uncaptured benefits such as the impact on family and personal relationships (see section 3.18 of the FDG). In accordance with the NICE health technology evaluations manual 2022, costs relate to NHS and PSS in the reference case.

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			has a negative impact on keeping healthy which leads to other issues which directly anre an on-cost to NHS. Also look at samples of impacts to a family rather than an individual. **Are the recommendations sound and a suitable basis for guidance to the NHS?** The recommendation should provide anyone with severe and life changing impacts from Alopecia the option to try this treatment plan. This should not be a postcode lottery! **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** The current treatments available discriminates against postcodes and financial status.	
64	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** No I don't believe all the relevant evidence has been taken in to account. I do not believe that a large enough cross section of people living with Alopecia was studied to give a true insight in to the reality of living with this life debilitating condition. A larger cross section and more varied amount of patients should have been considered and monitored. I also believe that more patients living with the reality of Alopecia on a day to day basis should have been present at the committee hearing and heard. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** I passionately believe that they are not reasonable interpretations. My life has completely changed after the sudden complete loss of my hair 4 years ago in a period of just 3 weeks. There has been no consideration to the cost incurred due to the mental health impact and the financial life style changes made as a result of its impact. I have taken numerous GP appointments, seen counsellors, spent a fortune on lotions, potions, herbal, shampoos, vitamins anything that offered a glimmer of hope. Alopecia impacts me on a daily basis. I have changed from someone that would be the most confident,	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the uncaptured benefits such as the impact on family and personal relationships (see section 3.18 of the FDG). It considered equality issues in section 3.17 of the FDG.

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			active and outgoing person in a social group to a person that shy's away and stands back. I have avoided numerous social events purely because I can't work out how to cover my head in a way I will feel comfortable both physically and mentally. Having worked full time for over 35 years I no longer work as it is just too stressful. I haven't looked in the mirror for 4 years and liked what I've seen, I don't even recognise the reflection looking back at me. Every time I have to leave the house I have the anxiety and discomfort of covering my head. What will I look like? Will people stare? How will it feel? Every time I am invited somewhere my first thought is how will I deal with covering my head and sometimes there isn't a solution that works for me so I won't go. I have completely changed my life to try and remove any root cause. I resigned from my successful career in Sales as it was at times a very stressful challenging role. It was one I really enjoyed and actually excelled at but I had to put my health and hair first. This has meant my husband and I have had to downsize from a house we loved and had spent 7 years renovating to a smaller property but again we had to reflect, take stock and prioritise what was important in life. I felt cheated and angry, how could this be happening to me. This condition has impacted my professional life and career, my social life and my personal relationship with my husband all in a deeply negative way. Something which wasn't a result of any poor lifestyle choice. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No I firmly believe that the recommendations are not sound and are in no way a suitable basis for guidance to the NHS. Having the option to try Baricitinib would be the opportunity to try a life changing drug for me. To have my hair back would be life changing - the sentence Alopecia isn't life threatening but it is life changing is so true. I really can not stress enough how much I am impacted daily by this awful condition. Every time I have to answer the door or leave the house I am faced with dilemmas that aren't always solvable. To have hair would enable me to live a carefree life again. I would be able to make impulsive decisions and choices. I haven't been on holiday for 4 years as I simply cannot face having to deal with how I can hide and cover my head in a comfortable way. When the USA and Europe recognise how important and beneficial this drug could be to the treatment of Alopecia and the improvement of a sufferers life	

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			how can the UK get its interpretation and guidance so wrong? **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** It would appear having read much documentation and observations from the committee discussion that male sufferers of the condition were not given the same amount of consideration as females and I consider this unfair. Even though it is socially more acceptable in society for a male to be seen bald the mental health impact at the loss of ones identity is still the same and has the same deep mental health impact as women.	
65	Web comment		It is extremely puzzling that it is acknowledged here that hair loss causes severe psychological distress but not concluded that therefore regrowing this hair would improve quality of life. Hair regrowth would reduce psychological distress and therefore clearly improve quality of life. Speaking from personal experience, I can confirm this to be the case. In terms of the "range of medicines" offered by dermatologists, this implies that there are other treatment options. None of these options have good response rates for severe alopecia areata, nor are many of them available in every geographical area even if they did have good response rates. Therefore, in my experience and opinion as an alopecia sufferer, they are not reasonable alternatives. The approximately 50% regrowth rates offered by Baricitinib are a huge step forward in this area, if even half of people could be spared the severe misery and pain of this condition, it would be a massive improvement. Personally I have been obtaining a JAK inhibitor outside the NHS (which I am struggling to afford, and should not have to source independently as I contribute towards the NHS through taxation and national insurance contributions) for 6 months and have experienced significant regrowth. Prior to this I had exhausted all options offered by the NHS in my area and none had induced any regrowth at all. I acknowledge my privilege in being able to	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It acknowledged the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			access these medications independently, but worry that there will come a point when I am unable to. This medication has been nothing short of a miracle and should be available to all, regardless of their financial position. Furthermore, my private dermatology consultant has experienced regrowth rates of far higher than 50%. Regarding the reference to wig prescriptions, this varies between locations, with some localities offering very little provision at all. Offering only synthetic hair is not reasonable as it does not adequately resemble human hair. Nor are the wig options sufficient for men (which some could argue is discriminatory) or often for children. Should patients be offered human hair wigs then the NHS would find that the cost of providing this would be massive, which would therefore influence considerations on the cost effectiveness of Baricitinib. It is also worth noting that being given a wig prescription still requires a large financial contribution from the patient towards the prescription (I believe in the area of £70) which is not affordable to some (again, this could be seen to be discriminatory). Accessing a wig prescription also does not address the difficulties posed by having no eyebrows or eyelashes. Again, although false eyelashes and microbladed eyebrows are available, these are expensive and so not affordable to all, and are not included in your cost calculations. Furthermore, many of these options are not appropriate for men or children. In my experience, the wearing of false eyelashes has also resulted in multiple eye infections and inflammatory reactions, costing the NHS in terms of GP appointments and topical medications. It is also worth noting the not insignificant cost of medications to address the severe anxiety and depression caused by this condition. Plus the cost of psychological therapies. Again, psychological therapies are something which I have fortunately been able to access independently of the NHS, as the waiting times within the NHS are astronomical. At the time of accessing therapy, following (and necessitated by) my second experience of alopecia	

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			universalis, I was measured to be experiencing severe depression and moderate anxiety. It is egregiously unfair to attempt to calculate the cost effectiveness of this drug whilst excluding the huge financial burden that patients are having to shoulder themselves. Comparing the cost of Baricitinib to the cost of best supportive care does not come close to demonstrating the actual financial cost of this disease. As mentioned, best supportive care does not cater for human hair wigs, prescription contribution costs, microblading of eyebrows or other cosmetics, false eyelashes, psychological therapies or antidepressant (and similar) medication. In addition to this, alternative treatments such as topical immunotherapy require a huge contribution from the patient in terms of regular attendance at hospital and the associated costs of time off work, transport to and from hospital etc. There are also the costs of seeking private consultations due to extensive dermatology waiting list times, and the aforementioned costs of medications for related conditions. In conclusion, the fact that the NHS does not currently adequately support alopecia patients, and requires them to shoulder almost all of the financial burden themselves, should not be allowed to influence whether or not baricitinib should be approved. Were the NHS covering all these costs, then the cost of baricitinib would not be too large in comparison. The fact that most patients are not receiving active treatment is because most patients are told that there are no treatments, which will continue to be the case if you refuse to approve new treatments. It really is infuriating that many health conditions which are avoidable (such as those associated with smoking or drinking) are treated on the NHS, yet an alopecia treatment is being denied on the basis of its cost. As mentioned at the start of this comment, this decision cannot be based on quality of life considerations, as it is obvious that this drug would make, and is making, massive improvements in this area. If this was not the case, people would not be pursuing access to it. It is maddening that psychological pain is being deemed less important than physical pain, given that other JAK	

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			Inhibitors have been approved for conditions such as arthritis. Lastly I would just like to reiterate the impact that the regrowth I am experiencing through accessing these medications independently is having on my life. I had lost all hope of regrowth. I never want to experience the severe depression I was diagnosed with ever again, and I fear that this is what will happen should my access to this medication be revoked. There have been documented suicides related to alopecia, surely that alone should be enough evidence to satisfy quality of life considerations. I would ask the members of the committee to consider how they would feel facing the world having no hair, eyelashes or eyebrows and then to consider whether they think an opportunity to reverse this would impact their quality of life. Lets not forget that throughout history the shaving of heads has been administered as a punishment. Additionally, hair loss is a major concern for cancer patients, despite already facing a life threatening illness. I hope this adequately demonstrates the impact JAK Inhibitors may have. **Has all of the relevant evidence been taken into account?** No- please see my comment. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No- please see my comment. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No- please see my comment. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Yes- please see my comment. Plus additional concerns regarding socioeconomic discrimination.	
66	Web	Person with	I am a 60 year old woman with Alopecia Universalis. I lost my hair 3 years	The committee acknowledged the

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	comment	alopecia areata	ago. very quickly and suddenly . Before that I was a healthy happy person with a successful career and family life. I was looking forward to retirement and spending more time with close ones. After a private appointment with a dermatologist where it was explained there was no treatment for the condition and coping with the sudden loss would be hard I fell apart. I did not know Alopecia was an auto immune condition and like the majority of people I thought it was stressed related. The impact on losing all my hair has been devastating . I no longer work , I don't want to leave home and really don't want to socialise. The condition has effected my family life as its so difficult for them to see me not coping with the condition. To read there was a drug that already existed could treat my condition was wonderful and brought for the first time some hope. **Recommendations** Whilst I appreciate NICE evaluating the use of baricitinib I would question how can the cost effectiveness be evaluated when as in my case I was not offered any treatment . What is there to compare?	psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the wide variation in practice both in terms of pharmacological options and wig provision in the NHS (see section 3.2 of the FDG).
67	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** The impact of alopecia is not something that can easily be measured and this is evident throughout the guidance so no, I do not believe that the recommendation is based of sound evidence. The committee does not seem to have a good representation of experts in the area of Alopecia. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** There is high level of uncertainty on the cost effectiveness which likely comes from a lack of understanding or empathy on the true impact that alopecia has on someone so I struggle to understand how the recommendation was concluded. The fact that the trials showed great success is enough to make be believe this treatment would be very cost effective. It could potentially change the lives of many people suffering with alopecia, myself included.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It acknowledged that baricitinib is innovative (see section 3.18 of the FDG).

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			Are the recommendations sound and a suitable basis for guidance to the NHS? The recommendation made is very disappointing. I am a 30year old female who has suffered with Alopecia for the majority of my life. I have tried many other available treatments with no success. I was very excited when I heard Baricitinib had received approval and to now find out I will not be able to receive this potentially life changing treatment through the NHS is extremely disheartening. I feel the cost of wigs and other non successful treatments I have had over the years would far exceed the cost of Baricitinib. I don't believe this guidance truly captures the impact that alopecia has on an individual.	
68	Web comment	Person with alopecia areata/NHS professional	I am an NHS midwife with Alopecia Areata. I have followed this review closely because it's something that means a lot to me. Finally there is an opportunity to help patients with alopecia. I feel like the huge psychological impact that alopecia has on people has not been regarded as important enough in your review. I understand that this is an expensive drug, but I do not feel that a cost benefit analysis can be put on peoples mental health. Just as an example - I had to take 6 months off of work when I first got diagnosed. This was 6 months full pay by the NHS. I was told by numerous GPs that I should minimise stress. How can you minimise stress when you are watching your identity fade in-front of your own eyes? The worst is that after trying numerous treatments, paying privately for tests, investigations. Paying for nutritionists, acupuncture, reflexology to help with lifestyle and balance. After all this, there is still no hope that any medical professional can give you. I got told on numerous occasions by a GP that it was 'just hair'. I bought 2 wigs over the last 5 years which have cost in total 10,000. I feel like I'm walking around hiding a big secret and inside I am deeply unhappy. The support on the NHS is currently terrible. Because there are limited treatments, once all of these have been trialed you are left alone to deal with the fact that there is no hope. Please consider offering this drug on the NHS.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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69	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** No it has not. There is a vast amount of direct evidence across the USA and EU as well as the UK to demonstrate the positive effectiveness of Baricitinib for treating Alopecia, and subsequently the mental health impact of this disease by enabling people to feel like a normal human being. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No they are not, as a sufferer of Alopecia Universalis my life as been devastated by this disease for which there is no existing effective medical treatment. The mental health impact of this "apparently just cosmetic" issue has been completely undervalued. Given the emphasis on mental health in the last few years how can anyone say that Alopecia is just cosmetic when people commit suicide, don't leave the house, don't work, withdraw from friends, family and society as a result of Alopecia? Why is hair loss treatment and support for cancer sufferers even considered if this is truly the case? You cannot put a price on mental health. The clinical interpretations represented are inadequate. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No, please tell me what alternative I have on the NHS? The NHS gave me prozac to help with anxiety but nothing to fix the Alopecia which causes the anxiety. Fortunately as a UK resident and UK taxpayer I am buying this medicine from India directly for less than the price of 4 wigs a year. I get no help with wigs, eyebrow tattoo treatment or anything. In 4 months I have had FULL regrowth using this medicine, it is not the price that is the issue for me as it is super cheap to buy from abroad but the lack of NHS support is despicable for me and many others, and now something is available the evidence is being watered down and dismissed. Alopecia is an auto-immune disease, an inflammatory condition that can lead to other diseases, you are only considering the physical aspects and given the extensive list of nonsense treatments the NHS do fund it is a huge insult to say people like me do not matter. If I do get adverse effects from Baricitinib from the indian treatment I	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			am sourcing personally, the NHS will have to sort that out and many people are ignoring all the routine recommended blood tests etc to ensure they do not suffer serious side effects because they are desperate for their hair to grow back. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** No	
70	Web comment	Person with alopecia areata	I began losing my hair around a year ago which has led to losing my hair all over my body completely and has since had a detrimental affect on my life where I've been having days off work struggling mentally and also not seeing friends or family since July of last year and never ever going out anywhere as I am too embarrassed of what I have become and have seriously questioned my very existence, and hearing about this drug gave me some hope that something could be done and I wouldn't be like this forever as much as I know it is not guaranteed it was an option and some hope which is something rare when it comes to treating alopecia so the fact it has been rejected is extremely disappointing, especially as I have been referred to a dermatologist since July and have still a long way to go before even getting an appointment so whilst something could be happening to bell treat this it's not possible because of the ridiculously long waiting times to even just see a dermatologist. I noticed you talk about the cost effectiveness and basically doesn't impact a persons living standard well let me tell you until you have experienced it you can't imagine what it does to your mental health. To talk about the cost is ridiculous I feel because the NHS are prepared to pay for treatments for problems that people inflict on there own body through there own doing such as obesity, alcoholics needing transplants, smokers needing treatments for many issues, drug users and all there problems that's all fine to find money but something which has happened to me and others that is completely out of our control you refuse a drug which could potentially help a big deal. I've even just read that you have recently approved a drug for obese people to help them lose weight how much is that going to cost considering how much money obesity is already costing the NHS and without being funny	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			but surely the most cost effective thing to do which would cost absolutely nothing would be to tell them to stop eating and start exercising but again money is found for that. I would just strongly urge you to change your decision and at least give people who are suffering from this at least some hope and a chance of regaining our life because none of us have asked for this it is beyond our control and it really is detrimental to both of our physical and mental health.	
71	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** I can only comment on my personal experience. Over the past year, I have been treated on the NHS in the East Midlands with Baricitinib for atopic dermatitis. I also suffer from severe alopecia areata. Within three months, my hair had begun to regrow. I am now a year into treatment, properly monitored by a consultant and with routine blood tests. I am currently symptom free. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** In terms of cost effectiveness, being treated with Baricitinib on the NHS has meant coming off anti-anxiety and insomnia medication, topical medications and steroid injections. I also do not need my wig prescription and have not needed to access NHS counselling sessions. In the past, I have experienced a nervous breakdown and hospitalisation associated with alopecia areata, all of which have costs to the NHS. The truth is that with the lack of treatment on the NHS I am one among many sufferers who have spent a personal fortune on alternative treatments including from private consultants, trichologists, nutritional therapists, herbalists and nutritional supplements. None of these worked. The lack of treatment leaves us vulnerable to those in the medical profession and beyond who are happy to exploit us. It includes the extra anxiety experienced by those who are currently sourcing baricitinib off-label from overseas and take the medication without proper	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			medical supervision. The lack of treatment adds to the cruelty of our experience of the disease and the anxiety it causes. This associated burden could be avoided by the NHS providing this effective treatment for all sufferers.	
72	Web comment		I am disappointment in the decision from NICE to reject the use of Baricitinib for alopecia. There is clear evidence for the effectiveness in patients with alopecia. NICE have overlooked the severe psychological distress caused by alopecia. Clearly, improvement of hair growth in this distressing condition would improve quality of life. I ask that NICE urgently reconsider it's decision.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
73	Web comment		The report does not take into account the impact on mental health of sufferers. This is an omission which should be corrected. **Has all of the relevant evidence been taken into account?** Fails to take account of the mental impact on sufferers. Evidence shows a strong causal link between sufferers and negative mental health outcomes. This should be corrected. Patient impact statements and reports should shine a light on the physiological impact. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** The drug has a high success rate (and NICE have approved drugs with lower success rates in the past). Given this is an under resourced and under appreciated area it seems wise to approved such effective drugs for use. **Are the recommendations sound and a suitable basis for guidance to the NHS?** It goes against the key pillars of the NHS to prevent the use of this drug. It must be stressed that the impact on individuals is acute. It would be wise to	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG). The committee considered equality issues in section 3.17 of the FDG.

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			reconsider the initial recommendation for rejection. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** The EA 2010 must be considered here for its impact on those with a disability (as sufferers could arguably be caught under the act). Regard should also be had to the potential grounds for discrimination on the basis of sex given the higher negative impact of hair loss on women than men.	
74	Web comment	Person with alopecia areata	I wanted to comment on the effect of alopecia on quality of life. I've had alopecia for almost two years, and the impact of this condition on my mental health has been profound. My anxiety around people has meant I've avoided seeing family and friends, neglected meeting new people since moving to a new town, and had issues with social anxiety when mixing in public. I had been looking after my daughter until September when she started school, at which point for my family finances I needed to find work. Due to my social anxiety I've found it incredibly hard to put myself out there and as a result I haven't found employment in 6 months. As a young male, aspiring to help his family but unable to, I have had periods of depression that have taken away enjoyment from activities I used to enjoy and only able to do the most necessary tasks. Any treatment that may encourage hair growth being available would have stopped this spiral towards depression and social anxiety, but instead I'm using the NHS for ineffective treatments and to put plasters over the problems caused as a result of it.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
75	Web comment	Parent of person with alopecia areata	**Has all of the relevant evidence been taken into account?** I believe that all of the relevant evidence has not been taken into account. Some of the evidence that you have used and refer to is too minimal. The Adelphi study recruiting only 117 people through dermatologists in the UK is not an accurate study and should be disregarded in the decision making process. The fact that only 117 people were actually recruited is a true reflection of the minimal amount of people in the UK with alopecia that are actually under a dermatologist...most have either exhausted the minimal	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) The committee acknowledged the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and

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			options that a UK dermatologist is willing to provide or are still waiting to see a dermatologist. NICE estimate that there are approx 100,000 people in the UK with alopecia. Placing significant importance on only 117 of these people is unrealistic and non reflective for appropriate use as evidence. On this score you are using evidence from a source with only 0.117% of estimated people in the UK at any one time with alopecia. Also I would like to assume that the full breakdown of the patients sex, ages, length of time with alopecia, severity at the time of taking part in the Adelphi study was presented to the technology appraisal committee for it to have been used as valid evidence and also full details from the other Adelphi studies in all countries that took part in this study ....not only the UK with it's 0.117% representation of people with alopecia. USA initially and then Europe have given approval for Baricitinib in the treatment of alopecia. There must be a larger volume of evidence for this to have been granted. Why has this not been been presented as relevant evidence. The 2 clinical expert dermatologists at the technology appraisal meeting are exactly that....experts ...most NHS dermatologists in the UK are NOT experts in the treatment of alopecia. Dr Matthew Harries is a Consultant Dermatologist at Salford Royal Hospital and has focused on hair loss conditions during his medical career. Dr Harries is a member of Alopecia UK's Research Committee. Dr Abby Macbeth is a Consultant Dermatologist at the Norfolk and Norwich University Hospitals Trust. Abby has a clinical and research interest in hair disorders, in particular Alopecia areata (AA). She was Co-Champion and Data lead for the Hair Loss Priority Setting Partnership funded by Alopecia UK. Evidence provided by both Dr Harries and Dr Macbeth, again did not represent the majority of dermatology experience for patients nor outcomes for alopecia. My son was only ever offered scalp solution and steroid injections and no further treatment or follow up after this.	the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).

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			Evidence to represent patient perspective from [redacted] (Alopecia UK Trustee) and [redacted] (Alopecia UK CEO) was not enough evidence to provide a full picture of patient perspective from different demographics (age, sex for example). I was a public observer at this meeting. [redacted] and [redacted] did detail quality of life and mentioned suicide once as an end result of alopecia. For example they did not/could not give an accurate representation regarding quality of life of a male living with alopecia, nor a teenager going through puberty. There should have been a male representative. There should have also been at least 2 (one male/one female representatives that were not representatives from Alopecia UK). Alopecia UK aim to promote a positive approach to living and dealing with alopecia, which unfortunately is NOT the experience that thousands and thousands of people are having with their own alopecia. Key evidence that would influence a final decision at the meeting came from the 2 clinical expert dermatologists and the 2 representatives for the patients perspective. I have detailed above why this was a poor source of complete evidence to be presented at the technology appraisal committee. I am not surprised from the evidence provided by these select 4 that the potential outcome is going to be denial of Baricitinib by NICE. I am outraged at the limited scope of evidence. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** To a partial degree BUT the cost effectiveness was compared to treatments that included wigs - price over a lifetime etc. There was no comparison to the cost of dealing with the mental health impact of having to live a life with alopecia - or the socio-economic cost ... For example my son is 18 now. During the past 4 years of losing all of his hair - scalp, facial, eyelashes, eyebrows and all body hair (every bit of hair on his body) he now lives in his bedroom at home and does not go out - from ages 14 - 18 his life has become smaller and smaller due to the lack of self esteem he has from his visible difference. He had to leave school and college because of the stress and negativity he felt about his appearance at such a	

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			crucial time in a young persons life. He has recently attempted to commit suicide as he can't see future for himself. - he has been to see his GP over the 4 years at least 30 times - he has contacted CAMHS service 8 times - he has had NHS health psychology 5 times - he has had private counselling at £60 per session because CAMHS said they could not help - he had to leave school as he became too ill to do his GCSE's because of his self loathing - he has not been able to stay at college and now has no A levels, despite being an A* predicted student at age 14 before he developed alopecia - he does not go out, lives in his bedroom - he has recently attempted to kill himself - The NHS mental health crisis team have made 14 visits to our home - he has just been referred on to the NHS community mental health team My son's life has been destroyed by alopecia, this is a case where Baricitnib treatment would have been a suitable option. He has severe alopecia. Baricitinib could save his life and help him to move forward in life. My son's story is not an unusual story of a teenager living with alopecia. There is a vast array of evidence of similar cases on multiple Alopecia Facebook groups. Thousands of parents with children wanting to take their own life as they can't see another solution. Thousands of adults of all ages, male and female who are living the life of a recluse. It is imperative that Baricitinib be granted by NICE for severe alopecia areata based on present quality of life for an individual patient with their personal/individual history of alopecia both psychologically and medically being a deciding factor. **Are the recommendations sound and a suitable basis for guidance to the NHS?** The recommendations are not based on an accurate cross section of evidence. Any recommendations for a sound and suitable basis for guidance to the NHS can only come from an accurate cross section of provided evidence. This, unfortunately has not been the case.	

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			Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? Yes. There has been unlawful discrimination against men. I was shocked that a member of the external assessment group (EAG) asked the representatives from the patients perspective ([redacted] and [redacted] from Alopecia UK) if she was right in thinking that it's not as bad for a man to have alopecia, that there wasn't such an impact due to you often seeing men without hair implying that a man's response to alopecia or their deterioration of quality of life would not be as severe as a females. Again this was evidence and discussion that contributed to the NICE recommendations ...evidence that came from a biased sexual discriminative stance from a member of the external assessment group. This instigated a conversation about wigs, where either [redacted] or [redacted] (I can't recall which one) explained that she does not leave the house without a wig. There was no discussion on the fact that it is practically impossible for a male to get a wig that would look like real hair. Men are very restricted due to having short hair in the remit of wigs available. A teenage boy would not be able to get a suitable wig and most men would also not be able to. Therefore the Modelling of Best Supportive Care in 3.10 stating that it is likely people would have limited pharmaceutical options and more likely to use wigs is in fact inaccurate, particularly in the case of men. It appears evidence from males on this score has not been sourced. There was a female bias regarding wigs as wigs were only discussed in the technology appraisal meeting in relation to women...I feel that assumptions regarding wigs as a whole to anyone with alopecia (male or female) were incorrectly concluded by the committee as a result of this. In 3.11 the EAG's assumption that people who's condition had not responded to treatment in both arms would only have wigs and orthotics is inaccurate..females are more likely to access wigs than males.	

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			In 3.14 include only wigs and orthotics in best supportive care ...again biased towards female The EAG considered it unlikely that people would be willing to try more pharmaceutical treatments that have limited effect over a lifetime horizon after all other options have been exhausted. This is a massive assumption based on the evidence and discussions had during the technology appraisal meeting and the way the conversations repeatedly were steered back to wigs by the EAG members. The evidence was biased and discriminative to men. No male representation of patient experts were present at all.	
76	Web comment	Person with alopecia areata	It's is important Baricitinib is available to those suffering from one of lives truly cruel diseases, Alopecia. I've suffered from it since I was 18 and now 36. It has affected every part of my life, relationships, careers, self-esteem, dating, trying to fit into society, feeling and looking different. Quality of life has suffered massively yet time and time again I'm reminded it won't kill me and it's 'only cosmetic' and to put a wig on. I can't imagine suffering from this all my life with no hope and have felt extremely suicidal. Thankfully I have sourced baricitinib overseas for 8 months now and am responding well. This drug works! My bloods have been fine. Help stop the pain and suffering of the unheard alopecia community.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
77	Web comment	Person with alopecia areata	To whom this may concern, I am a 26 year old single woman, with Alopecia Totalis. I developed this when I was 24, buying my first wig (at my own expense) for £1,100 in August 2021. I am still yet to receive any NHS support for a wig, and have spent £5,000 so far in the last two years on wigs.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective

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			My father has Rheumatoid Arthritis, and has been prescribed a JAK inhibitor for 4 years now. Having seen the vast improvement in his condition as well as his overall well being and outlook on life, it is very hard to watch while struggling myself. I strongly believe that JAK inhibitors will give me a better quality of life, and a much more positive outlook. Having suffered with periods of depression and suicidal thoughts due to my condition, to be denied a treatment or promised treatments that have incredibly low success rates such as Methotrexate and Ciclosporin will be costing the NHS more money on providing me mental health support. I look forward to seeing the outcome of this. Yours faithfully,	treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
78	Web comment	Person with alopecia areata	I am so utterly disappointed that the recommendation is for this not to be approved to treat alopecia. I lost all of my hair 6 years ago. The NHS dermatologist I saw had no treatment available and I was prescribed a wig which was useless as I could only use it with a certain provider who were unhelpful. They offered limited choice and the prescription barely met the cost anyway. I ended up purchasing online and never used the prescription. The NHS dermatologist lacked empathy and signed me off their caseload as soon as they could. I've had to navigate almost 2 years of depression brought on by a sudden change in my appearance. Do you understand the psychological impact from an unwanted loss of self identity? It has affected me socially. I retreated into myself. The psychological impact on my life has been huge. I didn't want to leave the house. I've lost friends. I almost lost my marriage because I was depressed and felt sexually unattractive. It has stopped me having a fulfilling family life as I avoided activities with my children e.g swimming, going on holiday. It has halted any career progression as I feel self-conscious. It's not just a case of sticking on a wig and some false eyelashes and all is ok - it's a complete loss of self-identity. I felt bereft, isolated and worthless. Do you know how difficult it is to get into a swimsuit with a bald head, no eyebrows, no eyelashes - you feel like a freak.	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			I have now resorted to purchasing the medication from abroad and I am seeing regrowth within a relatively short space of time. It's unbelievable you can obtain treatment to treat other cosmetic issues eg acne or get breast enhancement on the NHS but nothing for alopecia. Or not through my trust provider anyway - it depends on where you live I guess. I'm sick of hearing it's just a cosmetic issue. My body has a disorder whereby it is rejecting my hair. It is not a cosmetic problem!!! I am been lucky to have joined alopecia support groups and gained knowledge and information from them as the support on the NHS was zero. At the same time I have had to read many encounters of individuals feeling suicidal from the loss of their hair and I am angry it's still not being taken seriously and brushed under the carpet. This report has just reinforced the total lack of empathy and understanding there is towards alopecia sufferers.	
79	Web comment	Person with alopecia areata	I do not agree with the decision made by NICE as part of this document. The decision about the cost compared to treatments now is not inclusive of all the relevant factors. The current treatments hardly work, so the cost effectiveness is probably quite low in comparison to this. Furthermore, lots of people with alopecia stop bothering to get treatment because it doesn't work and there aren't any new treatments, so if your economic case considered these individuals in the right way (rather than just accepting they are cost neutral to the NHS), this would be more cost effective. Referring to the wig allowance is also not really beneficial; the wig provision varies between trusts, and the financial support given is very minimal, meaning that most individuals have to get wigs privately, which also isn't in your figures. For me, in Sutton, I was told that I'd have to agree to pay £40 in advance just to visit the wig shop (Joseph's) that are the wig provider for my local trust (epsom and st helier), and from what I could see on the website there was little choice, and most of the wigs were aimed at elderly women. Similarly, your quality of life assessment is also lacking. The quality of life from my current treatment, DCP, means that I have to have my head in a hat for 24 hours and not wash my head for 48 hours. This means I can't exercise, I have to go to work with a hat on (regardless of the weather) and I feel like I have to explain to people why I'm wearing a hat. The clinic is also quite infrequent, because it's only one day a week, so I have to take time out of	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			work. I have also had the steroid injections - these are painful, they cause scar tissue around your skull and sometimes the marks remain for a long time, as well as bleeding. It is quite painful for many hours afterwards. Regardless of all this, having alopecia in general affects my confidence, self esteem and social anxiety, and the fact that there are hardly any treatments and a lack of research makes it worse. If NICe doesn't approve these sorts of treatments, you're strengthening the signal given to the pharmaceutical and life sciences industries that alopecia isn't a condition that's worth treating as it's purely cosmetic.	
80	Web comment	Person with alopecia areata	**Recommendations** Wait times to see a dermatologist are long and not all dermatologists understand the physiological effect .Wigs are not widely available on the NHS and are certainly not prescribed by every health trust. **Treatment options** “They also offer immunosuppressant medicines and wigs on prescription.“ This is incorrect wig prescriptions are a postcode lottery **Health-related quality of life measures** I feel this is an unfair assumption as many people with alopecia receive no care or offers of trials. Specialist dermatology appointments can take years to happen (8 in my case). Using people already receiving help is not a true reflection of the full impact of those affected. Quality of Life Assessment tool – EQ-5D – that has measures the impact of a health condition with dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression, this is not the most appropriate tool for measuring the impact of alopecia areata on quality of life. **Acceptable ICER** Alopecia currently costs the NHS little in terms of treatment as there is no set process in place . Not all treatments are widely a available on the NHS, some drugs mentioned are blocked by some healthcare trusts so despite being prescribed are only available privately	The committee acknowledged the psychosocial impact of severe alopecia areata on a person’s quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			Has all of the relevant evidence been taken into account? No. I do not feel that the full effect of alopecia in Every day life has been considered. The full impact on mental health has not been considered **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** Alopecia has hugely affected my quality of life in every single aspect. It has affected my ability to enjoy lots of everyday activities. My relationships have suffered , my working life has suffered and my ability to just live a normal functioning adult life has diminished. Current financial burdens placed on patients are not considered My confidence has been hugely effected . I receive no wig prescriptions and therefore I have also suffered financially as wigs and their care are not cheap Are the recommendations sound and a suitable basis for guidance to the NHS? I do not believe they are, baricitinib Is a proven drug that works in lots of other dermatological conditions and has shown it does work in alopecia. A treatment that is show to work and be available in n the nhs would be a huge improvement to current options offered. The quality of life assessment tool used does not seem to be completely appropriate for a person with alopecia areata	
81	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** Yes. From the evidence you can see the high success that JAKs has on a patient with severe alopecia. Eyelashes , eyebrows and scalp growth vastly improves from the SALT score. It is the most successful treatment for alopecia areata at the moment, in comparison to other immunosuppresants offered. **Are the summaries of clinical and cost effectiveness reasonable**	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of

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			interpretations of the evidence? Alopecia has effected my quality of life for the last 2 years from when I was first diagnosed. It effected me attending any social events, causing me to stay indoors all the time, worrying to step outside and feeling extreme anxiety when I do have to (for example food shopping). This took a huge toll on my mental health resulting in me needing therapy via the NHS and this to still be on going due to such a traumatic experience to happen in my early 20's. My 2 year old toddler suffered also as I dont want to attend any baby groups with him, my marriage has taken a huge strain due to my lack of confidence and depression. Things that I used to love like going to the gym I can no longer do, as being in such a environment is scary and worrying meaning that my normal healthy lifestyle doesn't exist. I avoid meeting with friends, crying at any old photos I come across of my "old self" wishing I would do anything to be able to get my hair back. **Are the recommendations sound and a suitable basis for guidance to the NHS?** I think Baracitinib SHOULD be available under the NHS. The clinical trials show it is the most affective treatment for severe alopecia. Experts have first handedly stated it is much better than any other immunesuppresants being offered currently and steriods/injections cannot be sustained long term meaning the relapse rate for people with alopecia is certain. I myself have tried every treatment offered through the NHS including Steriod tablets, injections, methotrexate and ciclosporin. All of these failing to work or causing severe side effects to myself. Baricitinib is a great medication for treating severe Alopecia and people ARE accessing it without being monitored by a health care professional and from overseas due to it being so expensive privately, meaning they are taking a huge risk in a desperate bid to get their hair back. Who would have £1000 a monthly basis to spare on this treatment, not to mention the cost of living crisis we are all experiencing in todays current climate. JAKS are already funded on the NHS for arthritis, though patients who have arthritis don't go through the same amount of emotional and physical trauma to those with alopecia. I myself have considered taking my own life due to the disease and there is an opportunity to have the drug funded and be life changing for some of us. We spend thousands of pounds on wigs, private health care in order to get back some of our identity and	the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			theres finally a drug that can help with this and its not being considered as "cost effective" are these decisions being made with someone who still has their hair,eyelashes and eyebrows? Unless you have severe alopecia you have no idea how much this effects our quality of life. I am costing the NHS loads of money due to treatment needed for my mental health and physical health due to eye infections, nail infections, depression medication - this could all be saved if offered the opportunity to try Baracitinib under the NHS. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** I dont feel there is any unlawful discrimination.	
82	Web comment	Person with alopecia areata/NHS professional	**Has all of the relevant evidence been taken into account?** Has mental health issues been taken into account . It is not our fault we are hairless .it affects our identity and self esteem .ok a wig can disguise but they are hot and false . I have worked as an nhs Midwife until I was 69 .I paid taxes and N.I for 50 years .developed Covid then Alopecia universalis . I feel strongly we need to be offered treatment on the N.H.S .so many people with this condition do not live a normal life suffering agoraphobia anxiety and other health issues .please listen it's not just about hair . **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No they don't consider our illness .It may not be life threatening except suicide risk but certainly is life limiting . It isn't just hair ,it's our whole identity and changes our life and relationships . .the cost effectiveness does not consider mental health issues ,anxiety and agoraphobia and even suicide **Are the recommendations sound and a suitable basis for guidance to the NHS?** Recommendations need further exploration about mental health issues and impact of severe Alopecia Areata on men and women .It is not a condition that's covered by health insurance and it's wrong we have to look for drugs abroad for treatment and certainly unaffordable for many	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG). It considered equality issues in section 3.17 of the FDG.

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			Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? This condition effects all races and genders and can occur any age. As a female with no hair I look like a man .I'm sure the committee have not discriminated but they need to look at our feelings .Again it is not lifestyle or abuse that have caused this condition .we are innocent people with a horrible condition .Please please listen and support this drug . Other countries have approved Baricitinib .it is expensive I understand but would help so many people .PLEASE a listen and support	
83	Web comment	Person with alopecia areata	I feel Baricitinib should be recommended within its marketing authorisation, for treating severe alopecia areata in adults as clinical evidence shows it grows back hair in a proportion of patients with this condition and there is also an unmet clinical need for a safe, effective and licensed medication to treat severe AA. If we look at personal experiences and further clinical data from trials I am sure it is very easy to conclude Alopecia has a profound impact upon an individual experiencing hair loss of any extent but even more so with severe Alopecia Areata. The Alopecian community deserve a licensed treatment to treat this disease in which currently there isn't. I hope my own personal experiences living with Alopecia has made an impact on the overall outcome and will see Baricitinib available to try in clinic later this year. Just wanted to acknowledge I am a 44 year old adult currently with Alopecia Universalis(very severe Alopecia Areata) with 95-100% hair loss in all hair bearing areas such as scalp, lashes. eyebrows, facial and body hair. No treatment to date has been successful in growing my hair back so I hope Baricitinib is approved as it would likely regrow my hair and as of result improve the quality of my life greatly. **Has all of the relevant evidence been taken into account?** No, I don't think all the relevant evidence has been taken into account. More data from clinical trials and comments from personal experiences of living with Alopecia needs to be taken into account in order to reach a final decision	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG). The committee considered equality issues in section 3.17 of the FDG.

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			on whether to recommend Baricitinib for clinical NHS practice. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No, the summaries of clinical and cost effectiveness are not reasonable interpretations of the evidence. More clinical data and personal experiences need to be taken into account before a final decision can be made. Alopecia has had a profound impact on my physical and mental wellbeing which as a result has reduced my quality of life greatly in the following 2 ways: 1- On a physical level having no hair has meant I feel strange and unsightly. I don't feel attractive and feel different looking to other people. I did not recognise the person(loss of identity) looking back at me in the mirror when I started losing hair such as eyelashes and brows in particular which frightened me so much. I feel uncomfortable everywhere I go such as work and sometimes I avoid this through feeling embarrassed. I get no protection from the sun nor a sense of warmth from cold weather unless I put a hat on. My eyes get sore and I get cold more easily due to having no hair to warm me up so temperature regulation is difficult without body hair. My eyes get watery and irritated due to dust particles getting into them due to having no eyelashes. No nasal hair causes me to have often a runny nose as there are no hairs to trap the mucus. I also have got to the point now where I've reduced contact with relatives and just keep to close family due to feeling uncomfortable with my appearance. B-On a psychological/mental level the loss of hair has resulted in a decreased self-confidence. It has been a very traumatic and stressful experience losing hair in which I've cried daily. I have had profound anxiety when I've worried about when I was losing the hair and whether it would come back or not. I got very depressed and had a real psychosocial impact since I experienced difficulty socialising with others and withdrew from activities I once enjoyed such as dancing, swimming and cycling. I avoided mixing socially with other people as I felt afraid and had very low self esteem. I have felt frustrated/despair at not knowing the cause and a sheer lack of hope with treatments. The feeling of loss of masculinity(beard/body hair makes you feel an adult man) had impact on my social and physical well being and made it	

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			impossible to form relationships with woman. **Are the recommendations sound and a suitable basis for guidance to the NHS?** The recommendations are not sound and a suitable basis for guidance to the NHS because I think Baricitinib should be approved and made available on the NHS immediately to treat adults with severe Alopecia Areata. I feel Baricitinib would improve my quality of life greatly as it would likely regrow my hair back. I would no longer feel anxious, different and strange to other people. I would be much happier as a person(no longer depressed and I would interact with others better. With more self-confidence and a higher self-esteem I would be able to achieve more in terms of work, leisure and socially. I would feel like a man again and my mental health would be greatly improved. With no longer any anxiety about the way I looked it would mean I would see improvements in all areas of my life. I could return to activities like cycling, swimming and dancing I used to enjoy. I would feel comfortable and warm with having hair instead of giving me anxiety and the need to cover my head with a hat when faced with hot or cold weather. It would bring me finally a sense of hope/closure that a treatment has been licensed to treat this condition and has a good success rate. I would no longer feel guilty with having this different appearance as I would blend in more with how other people look and not feel so isolated/alienated to anyone. It wouldn't also reinforce/highlight the difference my Phenylketonuria metabolic condition impact has upon me with others(food restrictions) as I look normal with hair. I would no longer cry nor feel emotional/upset as with hair it will bring me back the joy, satisfaction and comfort it used to bring me. I can also have a haircut again which I've missed so much and that feeling of being revitalised and looking smart/attractive afterwards which you get from having your haircut. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Yes but on the grounds of disease duration of 8 years. I don't feel anyone	

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			should be excluded from being treated with Baricitinib in terms of their disease duration set at no greater than 8 years. I feel it should be widely available to those with severe Alopecia Areata regardless of how long they have had it for. From anecdotal evidence I have heard many people of disease duration greater than 8 years growing their hair back successfully to include eyebrows, eyelashes, facial, scalp and body hair. I also don't feel that in order to be treated with this medication you should have tried other powerful oral immunosuppressive drugs as the majority of patients in clinic would never have been given them already for their severe AA(I certainly haven't). In terms of age I would like it to be available from the age of 18 upwards. The only conditions set in order to be prescribed this medication is for only severe cases of Alopecia Areata and adults above the age of 18.	
84	Web comment	Person with alopecia areata/NHS professional	**Has all of the relevant evidence been taken into account?** No! Absolutely not. You have minimal evidence to support the denial of this drug. This is a severe autoimmune disease which is hugely under resourced and underfunded. You have used an extremely small proportion of the alopecia population resulting in inadequate and irrelevant evidence. It is plain to see that the JAK inhibitors work and are a simple yet effective way of improving peoples lives. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No! I personally have suffered from various types of alopecia for around 10 years. Over this time I have attended various GP appointments, NHS dermatology appointments, private dermatology appointments, trichologist appointments plus many more. Whilst doing so I have received a multitude of treatments which have been fully funded by the NHS such as topical steroids, steroid injections, phototherapy treatments in addition receiving four fully funded NHS wigs on a yearly basis. How can NICE guidelines state the use of JAK inhibitors wouldn't be cost effective?! Please rethink this ridiculous statement! **Are the recommendations sound and a suitable basis for guidance to the NHS?** No, absolutely not. The NHS must be led by suitable and sound guidance to help support people suffering this horrible disease. By denying the use of JAK	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			inhibitors you are preventing health care professionals in their duty of care to their patients. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Yes! As a victim of this horrible autoimmune disease I was absolutely devastated and somewhat offended at the information in the guidance. Stating that people suffering with eg arthritis may benefit more greatly from the JAK inhibitors due to pain etc. However, as a sufferer of alopecia the emotional pain is indescribable. Can you imagine waking up each morning and not even recognising yourself in the mirror? Horrified to see yourself in any reflection. Unable to open your blinds until later in the day when you can face putting on an itchy wig to cover up your differences. I was an extremely active person prior to my disease but alopecia has prevented me from remaining active. The pain faced by having no eyebrows or eyelashes whilst trying to exercise is so difficult it barely makes it worth it. I, along with the whole alopecia community feel extremely discriminated and under valued as human beings. I am an intensive care staff nurse and have worked within the NHS for 11 years, I work hard every day and value the NHS and think of it as a great service. You are not providing support or reliable guidance in the use of JAK inhibitors to allow me plus many others to continue with their lives. Please, please rethink this unjustified decision and allow/recommend the JAK inhibitors!	
85	Web comment		There is no appropriate evidence on the Impact on Quality of life. It is ludicrous and simplistic to use the quality-of-life assessment tool for alopecia as it only focuses on the physical aspect of illnesses. There are physical ramifications from having alopecia and these include difficulties with wearing wigs, and eye/nasal problems due to lack of protection from hair. Sports participation in and out of doors is very challenging and requires sheer determination. However, the tool does not acknowledge the devastating psychological effects. Alopecia affects patients every moment of every single day as it is impossible to forget about it. This is comparable to other illnesses; it is just more difficult to measure.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG).

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86	Web comment	Person with alopecia areata	I am very upset that Baracitinib may not be approved by NICE Let me give you abit of my history..after years of AA I became AU in2019,,to say I was devastated is an understatement...I considered taking my life Our local dermatology dept were not interested So I set about finding help myself So 3yrs later and at a huge financial cost to myself I found a consultant In Cheadle who would help But at £1,200per month for Baracitinib I could not afford this So I am now buying them from India and being monitored by the Consultant The medication has saved my life, as I now how full regrowth,eyelashes and eyebrows and believe me,it is not cosmetic,as without eyelashes I was suffering from eye infections.Also with out nasal hair I was suseptible to infection Alopecia is brutal,it zaps your confidence and steals your identity I am a retired nurse...the last 25yrs working in general practice...I had patients coming in with panic attacks I sometimes thought...pull yourself together,but a few years later after the death of my mum,I had panic attacks and realised you can't pull yourself together So I feel the decision makers on whether JAKS should be available for severe alopecia Areata should try living with AU I do not agree that it's 'cosmetic' we shouldn't be denied this treatment If we lost a leg due to smoking,we wouldn't be denied a prothesis because it's deemed 'cosmetic' I feel very strongly about this lack of care/understanding in our plight I have spent thousands of pounds over the last few years in my effort to get help i.e Consultations.wigs,microbladding,supplements and Jaks which I purchase myself.....I never thought I'd be spending my pension fund this way....so I ask.please,please consider all aspects of this horrid condition **Has all of the relevant evidence been taken into account?** No....you are not looking at the bigger picture,,,you are just seeing it as 'cosmetic' not the impact it has on your mental health and day to day living For example my son and his family (2 small grandsons) live in Ecuador and I haven't visited for a number of years as I couldn't contemplate doing a long haul flight wearing a wig...so that has not only impacted on my life but also my family **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No...I don't think you are looking at the cost of our mental health...I have been	The committee acknowledged the profound psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			on antidepresants since 2019 **Are the recommendations sound and a suitable basis for guidance to the NHS?** I realise these drugs are expensive but I'm sure many Alopecians wouldn't mind making a small contribution to the cost to get our lives back...believe me I wouldn't wish this condition on anyone **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** I feel we are being disciminated against IT IS NOT COSMETIC	
87	Web comment	Person with alopecia areata	**Recommendations** Limited focus was applied during trials on measuring improvement in baseline mental health and wellbeing. Baseline measures need to be improves and generally effort to obtain large samples of results need to be increased. Therefore, this data is not statistically significant or imply causation that their is no MH&W benefit. I operate and represent a MH&W group for Alopecia sufferers in a global organisation - Those in the US advocated the vast improvements in their baseline MH&W i.e. confidence, reduction in depression and reduction in thoughts of suicide. These are the measures that need to be more accurately assessed in trials. As a personal alopecia sufferer, I can advocate this sentiment is incorrect . JAK inhibitors offers hope to UK sufferers but if not effective also provides closure that medically everything has been attempted to resolve the condition. Allowing those to try and learn to live with the disease rather than contemplating "what if". Also, personally this condition has made feel suicidal at times and i have increased levels of anxiety/depression. This has effected my career and family life, their is limited measures to analyse the detrimental effects this	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It acknowledged the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			disease has on a patients family and career. **Effects on quality of life** Agreed - Patients pay their Taxes & National Insurance and should have a human right to access treatment for a condition they have. Not be denied it, it should be the patients decision also Agreed, those with alopecia are statistically significantly more likely to get other autoimmune conditions if not treated. Also, high levels of inflammation and dysfunctional immune system can significantly effect the quality of life a person has **Has all of the relevant evidence been taken into account?** No: 1. Effect on Patients Family MH&W and Career prospects 2. Effect on Patients social circle i.e. bullying and discrimination **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** If you considered all the expenditure incurred by patients on trialing so many different products and solutions externally due to limited effective treatment options on the NHS, it wouldn't seem so expensive. Additionally, alopecia patients will continue to be on no active treatment if they won't actually approve treatments that are proven to be effective. Their is limited treatment options	
88	Web comment	Parent of personwith alopecia areata	**Has all of the relevant evidence been taken into account?** We have an adopted child who has recently been diagnosed with Alopecia Areata. Having joined a number of support groups looking for information that will help reassure our child that they are not only are they not alone. But that there are treatments that are being developed, that may potentially be of benefit when they are older.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life. It acknowledged the wide variation in practice both in terms of pharmacological options and wig provision in the NHS (see section 3.2 of the FDG).

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			kind regards. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** AS our child is or school-age, we are worried not only about the impact her hair loss is having on her currently, as she is learning to process what this will mean for her now. But as she gets older, the impact that her hair loss will have as she moves into her teenage years, may be traumatic. Where appearance and fitting in become more important for her, and the negative impact her hair loss may have on her mental and physical well-being, at one of the most formative times of her life. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** I think the negative impact of hair loss, and it's impact, cannot be overstated. It would also be disappointing to see potential successful treatments denied. I have concerns that a person's socio-economic status, which can be tied directly to a person's ethnicity, will often negatively affect that persons' ability to afford and access treatments, that can be accessed outside the National Health service. A two-tier system for treatments that can be accessed by those with the means is discriminatory. I cannot see any consideration made for this aspect of quality of life in the NICE decision	
89	Web comment		**Has all of the relevant evidence been taken into account?** Difficult to say, but from what I understand the drug has been sucessful for many patients and on balance is postive for their QoL. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No. Clearly it's very expensive but surely the benefit to so many people should outweigh the cost, and perhaps cheaper sourcing of a generic can be explored. **Are there any aspects of the recommendations that need particular**	The committee acknowledged It recognised that baricitinib is innovative (see section 3.18 of the FDG).

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			consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? Pass	
90	Web comment		Have the best interests and mental health of people suffering with the long term effects of alopecia been fully considered, following the decisions to not allow baricitinib to be a recommended for them on the nhs? Alopecia can be a debilitating condition by affecting the patient with severe hair loss. This can go on to cause a number of problems with their mental health and self confidence, which can lead to secondary complications such as anxiety and depression. Awareness of the cost effectiveness as been taken into account regarding baricitinib, however surely further care should be taken in considering the potential benefits for people suffering with alopecia.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged that baricitinib is innovative and there are the uncaptured benefits (see section 3.18 of the FDG).
91	Web comment		**Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No. Treatments such as topical corticosteroids are not offered to people with Alopecia Universalis (total head and body hair loss) and wigs are not a medical treatment, they are a sticking plaster. They do not cure or treat the problem, they merely cover the symptom. So as it stands, there are no treatments available to people with total hair loss. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No. The health-related quality of life assessment is not appropriate for this health condition. Having alopecia causes complex and sometimes severe anxiety and depression, but this is unique to people with hair loss. Alopecia should be considered a disfiguring autoimmune condition and I don't think the quality of life assessment properly reflects that. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or**	The committee acknowledged the wide variation in practice both in terms of pharmacological options and wig provision in the NHS and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It recognised the issues of the EQ-5D in assessing health-related quality of life in alopecia areata (see sections 3.6, 3.13 and 4 of the FDG). It considered equality issues in section 3.17 of the FDG.

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			belief, sexual orientation, age, gender reassignment, pregnancy and maternity? Yes, although men do suffer with alopecia, it is predominantly women that suffer the most with mental health issues linked to their alopecia. Rejecting this medication could potentially be discriminating against any women. Especially when some women are told that alopecia is "just a cosmetic issue".	
92	Web comment	Parent of person with alopecia areata	My daughter has suffered from Alopecia since the age of 9- she is now almost 21. She is training to be a professional dancer and this disease has been devastating for her. She wears a wig which we have had to source at our own expense - NHS wigs (which she hasn't been offered in almost 3 years) can't be put into a tight ballet bun. The current wigs she wears cost almost £1000 and this has to be replaced every 9-12 months. Over the years we have tried steroid treatment, minoxidil (purchased by ourselves), vitamins, essential oils, faith healers, creams, shampoos at great personal expense. This is only the financial side of it. She has been devastated by her hair loss from Alopecia Areata to Alopecia Totalis. She is depressed, suffers from anxiety and her mental health is at an all time low. If she was a smoker and got lung cancer - the NHS would treat her with the appropriate drugs. If she was an alcoholic and had liver cirrhosis- the NHS would treat her with the appropriate drugs. If she was obese and developed Type 2 diabetes - the NHS would treat her with the appropriate drugs. If she had inflicted a disease like these on herself she would be given the appropriate treatment. But no - she has Alopecia - that she has not brought on herself through poor lifestyle choices and yet she is being denied the only treatment that may indeed help her - 'it's only hair' -she is told. I just wonder if anyone on the NICE committee making decisions based on cost of drugs has had to deal with hair loss? Would they feel that oh it's ok - it's only my hair? How would they feel if the first chance they had of hope of treatment in years was snatched away from them because it is too expensive? They'd be devastated like every single person suffering from this dreadful disease. I urge you to reconsider this decision. The chance to make everyone with this	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			disease feel better about themselves will in the long run mean that less money will be needed for mental health treatment. Everyone deserves the right to treatment in a way that will improve their quality of life. Please give all Alopecians that chance. Thank you for taking the time to consider my views.	
93	Web comment	Person with alopecia areata	Firstly, thank you for allowing me to comment on the draft guidance. I am a 52 year old, professional, white male, I experienced reoccurring Alopecia Areata over a period of 3 years which progressively became worse until I experienced permanent full hair loss, Alopecia Universalis, in 2021. I am fortunate to have private medical insurance through my employer, so I was able to see a consultant dermatologist promptly throughout my hair loss episodes. I was prescribed topical & oral steroids, all with limited, temporary success. I would describe myself as extremely pro-active with my own personal healthcare, by virtue of being a commercial airline pilot whose health is monitored by the Civil Aviation Authority, however I very quickly exhausted all treatments available from the NHS. I extensively researched treatments for Alopecia Universalis and came across Baricitinib, having read about the trials completed in the UK. At this point, I was becoming very despondent at the lack of treatment available for my condition and my mental health was suffering as a direct result, which included extended absences from my job. In January 2022 I started a course of 4mg Baricitinib daily, whilst the hair regrowth was initially very slow, it has steadily increased to now be classified as Alopecia Areata. I now have significant scalp hair (approximately 75%), body hair, beard hair, eyebrows and eyelashes, but most importantly of all I have regained my identity and self-confidence, which in itself is priceless. In order to fund Baricitinib private prescriptions, my family and I have made significant financial sacrifices, however the results have made these sacrifices worthwhile. This is not simply a case of male pattern baldness.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			Baricitinib has worked for me personally, yes it does take time for results to appear, however the wait has been worth it. The committee recognises the stress that severe Alopecia can cause, it also recognises the benefits that Baricitinib can bring to some patients, however unless you have personally experienced the physiological stress of losing your identity, having to explain your condition constantly to friends, work colleagues, family and losing your self-confidence, then I think that it is very hard to put a price on Baricitinib for the treatment of Alopecia. I would be happy to speak in person to the committee about my experiences as a non drug trial patient. Until another credible alternative treatment becomes available, I would hope that Baricitinib is approved for the treatment of Alopecia on the NHS, all other treatments for Alopecia do not work, yet still cost the NHS considerable amounts of money. The associated physiological costs alone should make this drug available for the treatment of Alopecia. Thank you for taking the time to read my comments. Kind regards, [redacted]	
94	Web comment	Person with alopecia areata	I was very sad to hear that this was not approved. I have been on this medication for 12 months and from having hardly no hair left due to alopecia I have now almost full regrowth. I paid £700/month for the medication at first but could not afford this for long so now I have to buy it from Bangladesh. The impact alopecia has had on mental health and my life in general is immense and I really hope you will reconsider your decision. Many thanks,	The committee acknowledged that baricitinib is innovative (see section 3.18 of the FDG).
95	Web comment	Person with alopecia areata	**Has all of the relevant evidence been taken into account?** As a sufferer of recent complete hair loss, it does not appear that the impact that alopecia areata has on quality of life has been taken into account so far by this consultation. On diagnosis of this condition, many alopecians battle with a significant decline in mental health, depression and the inability to perform at their best in a work/ university capacity. These impacts are likely to be putting an even greater strain on other NHS resources (therapy etc).	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the issues of the EQ-5D in assessing health-related quality of life in alopecia areata

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			Are the recommendations sound and a suitable basis for guidance to the NHS? The initial recommendations are deeply disappointing and need to be reviewed in particular with regards to quality of life. If individuals were able to access this drug and it proves successful, the mental health impact are likely to be very significant.	(see sections 3.6, 3.13 and 4 of the FDG).
96	Web comment	Parent of person with alopecia areata	I would sincerely ask NICE to reconsider their initial outcome re bariticinib for severe alopecia areata. My degree is BSc Hons Pharmacy, I can read and understand scientific papers and the subsequent analysis. I truly believe NICE is wrong in its initial judgement. Any hair regrowth even if only partial, not complete, will be hugely valuable. It does not have to reach a SALT score of under 20 to make a significantly positive impact on the life of someone suffering from Alopecia areata. My daughter is 20, consider the devastating loss of hair is to a young adult, especially a female. It has become so bad that she is now on an immune suppressant medication that is unlicensed for alopecia. Bartiticinib is licensed and effective. If it's not allowed on the NHS she will need to continue to be given off licence drugs, is that what NICE are endorsing? Consider the cost of the psychological support, loss of paid income, loss of social life, loss of self esteem, loss of confidence, loss of actually living a life. She is at university studying Physiotherapy, she wants to work for the NHS on graduating. Alopecia is having such a profound impact on her that she is considering withdrawing from university, stopping her part time job coaching gymnastics to children, ceasing having a social life (which is already very limited due to how bad alopecia makes her feel) and has already resulted in her stopping sports participation. The cost of the drug could very well give her back her life and allow her to make a positive difference to the lives of others.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG). The committee considered equality issues in section 3.17 of the FDG.

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			For some, tragically, alopecia results in considering taking their own life. As a Mum that is a very big fear I have. Alopecia is not as a result of poor lifestyle choices, no-one can prevent themselves getting it. Please see the people and how horrendously it impacts them and grant approval for a safe and licensed medication to be used. **Has all of the relevant evidence been taken into account?** The evidence relating to partial hair regrowth has not been fully appreciated. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No, the impact of hair loss has not been accurately captured. And there has not been sufficient consideration of the benefit to quality of life that some, even if not complete, hair brings. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No, bariticinib is safe, effective and used for other conditions. What makes its use for eczema allowable and not for alopecia? **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Yes, under disability discrimination. Disability is defined in the UK as ‘under the Equality Act 2010 if you have a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on your ability to do normal daily activities.’ Alopecia is a physical condition that has the detrimental impact on mental condition and stops sufferers being able to do daily activities. In not allowing access to a drug that could relieve this, then people are being kept as disabled rather than freed.	
97	Web	Person with	**Has all of the relevant evidence been taken into account?**	The committee acknowledged the

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	comment	alopecia areata	It is of my opinion from reading the consultation report that there is insufficient quantitative and qualitative evidence / data of the psychological impact from severe alopecia areata. There is currently limited effective treatments for this condition provided by the NHS. Recent studies of longer-term use of Baricitinib have not been included in this report for which in two recent phase 3 trials of this treatment, the efficacy of baricitinib for severe alopecia areata continued to improve over 52 weeks and from this it was observed as potential for long-term treatment of severe alopecia areata. As a patient with this condition and speaking on behalf of other patients, we live in hope that this observed effective treatment is made available through the NHS. As an employed psychological therapist working within the NHS and as a patient with severe alopecia I am able to speak personally of the psychological, socio-economic impact this condition has had for myself and for those who I may support in clinical practice. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** It is of my opinion that cost effectiveness of this treatment vs longer-term socio-economic/financial impact of this condition has not been fully captured within this report. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No, I refer to my answers related to 'all evidence being taken into account'. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** No	psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
98	Web comment	Person with alopecia	**Has all of the relevant evidence been taken into account?** From the evidence provided, it is true that the measurement of the quality of	The committee acknowledged the psychosocial impact of severe

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		areata	life lacks indicators for the psychosocial impact and effects on patients with alopecia areata. It is essential to use other tools to measure the sense of well-being and psychological conditions of patients. From my experience as a patient with severe alopecia areata (more than 30 years), the current treatment options are also very limited and have many side effects. For example, intralesional steroid injection could be effective on a specific area, but it still has side effects, such as soreness at the injection spots. Additionally, the current treatment options available are not very effective for patients with severe alopecia areata, and recurrence of hair loss is common. This is also the reason why many patients do not seek treatment. In section 3.10 of the draft guidance consultation, the use of wigs is suggested as an alternative to pharmacological treatments. However, as a patient, I do not agree with this suggestion because wigs cannot compare to real hair. The psychological impact of wearing a wig can be significant, and it can negatively affect the patient's sense of well-being and quality of life. Therefore, I strongly recommend that pharmacological treatments that have been proven to be effective should be considered the primary option for treating severe alopecia areata. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** As a patient with severe alopecia areata, I appreciate the effort that NICE has put into developing guidance for the treatment of this condition. However, I would like to offer my feedback on the cost-effectiveness of Baricitinib and the importance of patient access to this treatment option. Regarding the cost-effectiveness of Baricitinib, I believe that NICE may consider commissioning it in the NHS for treating severe alopecia areata to monitor its efficacy in proving its effectiveness. It is crucial to evaluate the effectiveness of this treatment option thoroughly to provide patients with the best possible care. In the meantime, I would like to encourage Eli Lilly to continue the discussion with NICE and offer a discounted price to NHS to increase the cost-	alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			effectiveness at the initial roll-out stage. This would enable more patients to have access to this treatment option and improve their quality of life. Finally, I would like to stress that living with severe alopecia areata is much more than the cost-effectiveness of treatments. This condition can have a severe psychosocial impact on patients and affect their sense of well-being. Therefore, it is essential to provide patients with effective treatment options to help them manage the condition and improve their quality of life. Thank you for considering my feedback. **Are the recommendations sound and a suitable basis for guidance to the NHS?** Based on the information provided, I believe that the recommendations for Baricitinib as a treatment option for severe alopecia areata are sound and a suitable basis for guidance to the NHS. The trials of Baricitinib have demonstrated its efficacy in treating alopecia areata, and it has already received registration with MHRA in the UK, EMA across Europe, and FDA in the USA. This shows that Baricitinib is a well-established treatment option for alopecia areata. Moreover, severe alopecia areata patients currently do not have any effective treatment options, which may lead to other psychological conditions that require resources from NHS and may cause personality problems such as absenteeism from work due to devastating psychosocial impacts. This could result in far higher costs than providing access to Baricitinib. Therefore, I strongly believe that the access to Baricitinib is not just giving one more treatment option to patients, but it can also be a cost-effective solution in the long term. Therefore, I support the recommendations for Baricitinib as a suitable basis for guidance to the NHS for treating severe alopecia areata.	
99	Web comment	Person with alopecia areata	I'm commenting because I wanted to share my experience with Alopecia and the importance of Baricitinib within my community. In 2021 I lost all my body hair in a span of 6 months.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of

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			No doctor could help me via the NHS, let alone understand what was happening to my body. After months of research I discovered that I needed support from a dermatologist, who taught me about JAK Inhibitors. Since July I have been on JAKS and not only is my hair starting to regrow, but I am slowly getting my life back. To have this medication available via the NHS would mean stability, security, hope and faith restored within the system, and an opportunity for many who suffer from Alopecia a chance to regain their identity and life. My mental health has suffered greatly due to Alopecia. I have dealt with weight gain, and depression but I was fortunate to keep living my day-to-day. I know many who can't leave their homes and suffer from poor mental health because of Alopecia. This isn't just about having this approved, it's about recognising and registering the fact this disease needs further support and needs to be taken seriously. Thank you,	the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
99	Web comment	Parent of person with alopecia areata	As a layperson reading this document, it appears that the main reason for not recommending this medication is cost and, the measure used to assess this is based on an assessment which the document admits is probably not reflective of the reality of a person suffering from Alopecia. As the parent of a child diagnosed with Alopecia at age 11, I witness the terrible impact of this disease on her and on our family every day. Every day, I read heartbreaking stories from people struggling to live with this disease. However, this impact is not recorded officially because the sufferers of Alopecia are a long forgotten and neglected group which eventually gives up on the NHS as a source of help. Personally, I have also incurred considerable	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section

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			personal expense to try and treat my child and give them cosmetic options to cope at a critical time in their development. It is frustrating that the document recognises all of the negative impacts of the disease but still can't recommend a medication to alleviate that suffering. Every day I read about JAK Inhibitor treatments being used in other countries to amazing effect and it is so frustrating to be offered the various treatments mentioned in this document, knowing that there are much better proven options available. My child is in the vicious circle of constant loss and re-growth which is as debilitating at full hair loss in my opinion. I have been offered Immunotherapy and Immunosuppressants but I can't put my daughter through these treatments when I know and, my dermatologist admits, that JAK Inhibitors are a far superior option. Baricitinib is only one of these medications, but it's rejection as the first one does not bode well for future applications.	3.18 of the FDG).
100	Web comment		**Has all of the relevant evidence been taken into account?** No, I don't believe enough work has been done to speak to people with the condition to assess how it affects them in their daily lives. If it had then I think the outcome would have been very different. Can you show some statistics showing how many people with Alopecia you spoke to please? **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No. What will happen behind the scenes, which is what is happening already, is that people are buying these drugs from the likes of Bangladesh and have no idea if they are regulated or anything. People also don't realise that they have to be monitored by a doctor when taking these drugs to monitor their kidney and liver function. Does the NHS want lives put at risk because they don't want to incur these costs? **Are the recommendations sound and a suitable basis for guidance to the NHS?** No **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any**	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? The NHS must listen to thoughts and feelings of people actually affected by this condition and not just to the people who manager the purse strings!	
101	Web comment	Relative of person with alopecia areata	**Has all of the relevant evidence been taken into account?** In my opinion, there is insufficient information here and particularly fails to address the full impact on mental health and wellbeing. Surely, this is something we have been placing far more emphasis on post-COVID. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** Flawed and unreasonable in tone. Surely a 50% success rate is a considerable outcome, which is far higher than in most other cases, some of which are also more expensive. This makes it more cost-effective. **Are the recommendations sound and a suitable basis for guidance to the NHS?** Whilst appreciating the enormous and increasing strain on the NHS, especially in the current climate, with numerous demands being placed upon a limited service, I disagree that this initial recommendation is "sound and suitable". It is very easy to overlook individual stories, such as my niece, who works as an intensive care nurse in the NHS. She has dedicated herself fully to apply all the principles and demonstrate the values on which the NHS is based in her daily contacts with the patients she has responsibility for. To deny her, and others like her, the life-changing opportunity to benefit from this innovative treatment contradicts the whole vision of the NHS. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** The initial decision can most certainly be viewed as being in opposition to the disability section of the Equality Act and would be considered to be discriminatory, likely to result in a successful prosecution.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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102	Web comment		**Has all of the relevant evidence been taken into account?** No **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No **Are the recommendations sound and a suitable basis for guidance to the NHS?** No **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** No	Thank you for your comments.
103	Web comment	Person with alopecia areata	I have suffered with Alopecia since I was seven years of age. It has been the odd patch here and there but a few years ago after the death of a friend, which I believe triggered a stress response. Over half of my hair fell out over 3 years, small patches joined to be one large patches. At time I became very despondent, I was constantly anxious and it took its toll. I stopped going out and have relationships of any kind. I did not go on holiday or any social place. The anxiety of Summer coming where I could not get away with wearing a hat and hiding indoors, really hit me hard. Throughout the last 35 years I have tried every and all remedy that the Dermatologists have suggested. So during this, what I would call alopecia attack, I went through the process of seeing a specialist with zero hope of help as usual. However I happened to meet Dr [redacted], who works privately as well as for the nhs, and has been an advocate for the Barcitinib Jak inhibitor. He explained I was the right candidate but to be level headed and be tentative with my hopes. I decided to go ahead but the costs were so so much. I had to borrow money and sell my	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).

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			car to try this drug out as I was so desperate and my quality of life had become so poor. I took this drug for 10 months and all my hair which had been disappearing over 3/4 years by now, started to grow back. I had tufts of hair everywhere which I had to endure to grow out....but I had hair again. I was so grateful and so so hopeful that it would be approved this April. I am absolutely devastated to learn that you have rejected the drug. A drug that has been approved in Europe and America. Why on earth not here? We all suffer no matter what country we are in. These countries deem our suffering valid and worth treating. You do not know as you are not in my position. And if it was you or a loved one you would realise fist hand how psychologically, socially, emotionally and mentally damaging it can be to have most of your hair fall out in ugly patches. It's affected my health, I put on weight from being too anxious to leave the house, I became depressed, I really struggled to go to work. I avoided any social situation where there could be a risk of my 'exposing' myself. 4 years plus the 9 months it took to grow back have been the worst years of my life. I was unwell not just physically, but mentally. I am currently suffering with some bald patches right now. I'm dealing with it as best I can but it's starting to get worse, and it's starting to affect my well being and mental health. I have been praying and hoping that this April 2023 there could finally be a remedy, encase my hair does have an attack again, and that other severe alopecia sufferers would finally get help I was hopeful that the NHS will look after me. So like I said I am devastated to hear about your decision. I am not in a position to buy these pills again and I'm starting to worry and have sleepless nights again thinking that there is no end and no available remedy this time. Its not available not this time, because no remedy has been discovered, but this time due to your decision. Finally there is a re.edy but we can't have it. Barcitinib truly changed my life for the better. I am not articulate enough to truly explain how the quality of my life has improved in so many ways, and it	

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			has given me hope and a new lease of life, which is hard to write about as this gratitude goes beyond words. Please please please review your decision to permit this miracle drug to be accessible through the NHS. Please help alopecia sufferers, help them like this drug helped me and maje a huge difference to their quality of life.. There's been no solution up until now. Even the research has been lacking until now as it was not deemed worthy. But I promise you you will be changing lives and you truly have the power to do this. Please please reconsider. Kind regards, [redacted]	
104	Web comment	Parent of person with alopecia areata	This is extremely disappointing and frankly a disgrace that this drug has not been recommended for use in the NHS. My 32 year old daughter has severe alopecia and has has for many years, she has fought physically and mentally with this disease . I have had to pull her back from the brink of suicide a number of times , she feels like her life is never going to improve and this was a chink of light at the end of a tunnel. I feel that alopecia sufferers have been disrespected as their suffering has been ignored and sneered at by medical professionals and the public in general that do not understand how it feels to have no hope, or help available to them . This drug needs to be passed by the NHS for use on a huge number of forgotten and ignored alopecia suffers in the UK !	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is innovative and there are uncaptured benefits (see section 3.18 of the FDG).
105	Web comment		It takes an extraordinary amount of time eg years,to get alopecia taken seriously enough to even consider treatment. Then treatment available varies accross the UK. In our local area, there is next to no treatment so the statement of high costs is skewed. When you come from an area that offers nothing, of course any treatment is going to be at a significant cost compared to zero. There is a big emphasis on psychological impact of alopecia. The studies do not go far enough to fairly represent UK patients. There is undoubtedly a huge, long term effect on mental health for alopecia sufferers but not specifically attibuted to cosmetic appearance. The constant	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG). It acknowledged that baricitinib is

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			assumption that loss of hair due to treatment, say for cancer, the implication that it is 'just' alopecia, that 'it be worse'. The fitting of a wig can be seen as a path to recovery in cancer patients. There is no recovery without treatment for those who suffer with alopecia. There is not enough emphasis about the impact of loss of facial hair, nasal hair, eyebrows, eye lashes causes actual physical side effects, sore eyes, watering eyes, sore nostrils, where the natural 'filters' no longer exist. The person suffers great, daily chronic discomfort with this in addition to sensitive scalp. The possibility of alopecia treatments needs urgent review to address this long term chronic illness do that those who suffer may have access to treatment and a good chance of lessening their symptoms and distress. **Has all of the relevant evidence been taken into account?** No. The research is not representative of uk patients. **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?** No, the study is not representative of the UK, the physical and psychological effects of this disease, the lack of long term support and where an area provides zero/little treatment is not reasonable to interpret the cost as high when the existing cost is next to nothing. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No. The studies are not wide enough to make a reasonable interpretation of the evidence. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Unsure	innovative and there are uncaptured benefits (see section 3.18 of the FDG).
106	Web comment	Person with alopecia areata/NHS	Dear NICE Committee Chairman and members I understand consultation closed at 5 pm today.	The committee acknowledged the psychosocial impact of severe alopecia areata on a person's

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		professional	I am therefore sending an informal email to tell you what it is like for me to scratch my head constantly, be woken up or not sleep at night for the itching, have people stare when I go out unless I always wear a hat- and that is of itself bizarre in a cafe or restaurant so I just don't go . Avoid meeting people whether I know them or not, so don't have the social life that kept me afloat from depression. No longer swim in a public swimming pool , we have communal mixed sex open showers in our local pool and a swim hat gets so hot and dreadfully itchy. I've worked in the NHS most of my life, and social services emergency work before that, and I do feel that now I need help to avoid the social isolation, depression and sheer avoidable misery of constant scratching, it should be there for me. Please contact me if any further information would be of use,'	quality of life (see section 3.1 of the FDG) and the unmet need for safe and effective treatments for severe alopecia areata (see section 3.2 of the FDG).

NICE National Institute for Health and Care Excellence

Baricitinib for treating severe alopecia areata [ID3979]

Draft guidance comments form

Consultation on the draft guidance document – deadline for comments 5pm on Monday 20 March 2023. Please submit via NICE Docs.

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. The Appraisal Committee is interested in receiving comments on the following: • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? 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 preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example 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 provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Eli Lilly & Company Ltd
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	N/A

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Name of commentator person completing form:	[redacted]
Comment number	**Comments** Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	**Executive Summary** Lilly is disappointed with the draft decision not to recommend baricitinib for the treatment of patients with severe alopecia areata (AA), especially considering that NICE has recognised that there is an unmet need for safe and effective treatments in this indication, and given that "*clinical experts considered baricitinib to be a step-change in managing severe alopecia areata for which there are limited licensed treatment options*" (Section 3.16). Lilly is particularly concerned that the committee conclusion on the choice of utility values implies that the committee does not believe that there is any meaningful value for the NHS in treating this disease. Nevertheless, Lilly is grateful for the opportunity to respond to the draft guidance document (DGD) with a focus on the key areas of uncertainty that were discussed in the appraisal committee meeting (ACM). These include: • The use of the Adelphi Disease-Specific Programme (DSP) study to inform the cost-effectiveness model (CEM) utilities • Source of data informing the composition of best supportive care (BSC) • Differential use of BSC following loss of response • The impact of the uncertainties in this indication on the willingness-to-pay (WTP) threshold • The face validity of the Committee-preferred assumptions in the CEM
2	**Use of the Adelphi DSP study to inform the CEM utilities:** **Summary points:** • Severe AA has a significant impact on patient's health-related quality of life (HRQoL), especially those seeking treatment, but this was not adequately captured in the BRAVE-AA trials; utilities generated from these data therefore lack face validity and ultimately imply that

	treatment of severe AA is not of value to the healthcare service when used in the CEM • The Company consider that the preference for the use of the BRAVE-AA trial utilities in the CEM directly contradicts many of the earlier conclusions made by the Committee regarding the HRQoL impact of severe AA • The Company maintain their position that the Adelphi DSP is a more appropriate source of utilities for use in the CEM given that these data have greater face validity, and represent a robust, objective, and impartial source of evidence that is aligned with the NICE reference case[1] **Limitations of the BRAVE-AA trial utilities** The Company welcomes many of the key conclusions made by the Committee regarding the HRQoL impact of severe AA on patients. In Section 3.1, the Committee concludes that "*severe alopecia areata can have a profound psychosocial impact on a person's quality of life".* The Company considers that this closely aligns with the evidence presented throughout the duration of this appraisal, in which patients with severe AA consistently report an impairment in their HRQoL, and negative consequences on their daily activities, relationships and careers.[2-5] In Section 3.6, the Committee also acknowledge that this profound impact on quality of life is "*not shown in overall baseline EQ-5D scores for people taking part in the BRAVE trials*". Finally, the Committee acknowledge in Section 3.7 that "*hair regrowth can have a profound impact on improving a person's quality of life*", again aligning closely with the evidence presented by the Company, whereby controls and patients with mild disease frequently report greater HRQoL relative to those with severe hair loss.[2-4, 6] Importantly, the Committee's conclusions above exemplify the lack of face validity of the EQ-5D data from the BRAVE-AA trials for the population of relevance for this appraisal – individuals with severe AA who would become eligible for treatment with baricitinib (in secondary care) if recommended by NICE: • Firstly, use of the BRAVE-AA trial EQ-5D trial data would imply that [redacted] of this population have perfect health ([redacted]). This, by definition, appears to contradict the fact that these patients are considered to have a **severe disease** and that **they are actively engaging with the healthcare system** as a result of their condition. The Company would like to emphasise that those patients (if any) who do not experience an impairment in their HRQoL would be unlikely to

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	engage with the healthcare system, and therefore would not receive baricitinib in secondary care. • Use of these BRAVE-AA trial EQ-5D data would also suggest that [redacted] of these patients experience little to no anxiety and/or depression as a result of their disease (EQ-5D scores of 1 or 2 in the anxiety/depression domain). This is in contrast to clinical expert input received during the ACM, whereby it was noted that "***high levels*** *of anxiety and depression are common, occurring in about* ***1 in 3 people****"* (Section 3.6). • Finally, due to this ceiling effect, use of these data would suggest that significant hair regrowth does not result in any significant improvement in HRQoL. In fact, the Committee-preferred assumptions (including use of the trial utilities) suggest that additional hair regrowth (to Severity of Alopecia Tool [SALT]≤20) from the introduction of baricitinib would result in only [redacted] in full health per patient treated across their lifetime on average, relative to receiving 'no active treatment' (based on the [redacted] incremental quality-adjusted life years [QALYs] produced by the CEM when using the Committee-preferred assumptions). Considering this lack of face validity, the preference towards the BRAVE-AA trial utilities outlined in Section 3.14 directly contradicts the previous conclusions made by the Committee regarding the HRQoL impact of severe AA on patients. The Company would like to emphasise that preference towards the BRAVE-AA trial utilities implies that, contrary to the evidence presented throughout the ACM by the patient and clinical experts, severe AA does not have a significant impact on individuals, and hair regrowth would not result in any significant improvement in HRQoL among those responding to treatment (those achieving SALT≤20). As such, use of these trial data in the CEM ultimately implies that treatment of severe AA is not of value to the healthcare system. **Suitability of the independent Adelphi DSP real world evidence study utilities** Based on Section 3.12, it appears that the key driver behind the preference towards the trial utilities is the view that the BRAVE-AA trial data are "*more robust"* than the independent Adelphi DSP real world evidence (RWE) study. However, the Company consider that this conclusion ought to be heavily caveated by the lack of face validity associated with the trial utility data. While the independent Adelphi DSP RWE study is not a randomised controlled trial (RCT) and provides only one data point from each patient, these factors are greatly outweighed by the fact that the independent Adelphi DSP RWE study data more realistically reflect the evidence presented by the patient and clinical experts and the previous

	conclusions made by the Committee regarding the HRQoL impact of severe AA on patients. The Company would also like to clarify that contrary to Section 3.12, which suggests the sample size of the BRAVE-AA trials is "*more than 4 times that of the Adelphi study*", the independent Adelphi DSP RWE study included [redacted] patients in the mild group (used as a proxy for the HRQoL change from baseline) which is [redacted] of the population achieving SALT≤20 in the BRAVE-AA trials ([redacted]) – the population that would inform utility change from baseline in the CEM. It should also be noted that the collection and analysis of the Adelphi DSP RWE study data was conducted independently, with data collected only on the endpoints specified in the RWE study protocol. Furthermore, while Lilly contributed (by purchasing access) to the funding of the independent Adelphi DSP RWE study and collaborated on the data of relevance to be collected, the raw data do not belong to Lilly and can be, and have been, purchased and published by others. Moreover, the Company would like to emphasise that the independent Adelphi DSP RWE study for AA should be considered as suitable for decision-making as the BRAVE-AA trials, given that it represents a highly robust, objective, and impartial data source that aligns with the NICE reference case.[1, 7, 8] While not discussed during the ACM, Adelphi DSP RWE studies are an established method for investigating current treatment practices, and are designed to capture a cross-section of robust real-world data. They are conducted using specific procedures to reduce bias, which, "*in the context of observational research and real-world data collection, are considered at least as robust as those used in RCTs*".[8] As such, they have been conducted in over 30 different disease areas, and the results from many of these studies have been published at international meetings and in peer-reviewed journals, highlighting the robustness and validity of their findings.[7, 8] It should also be noted that Adelphi DSPs or similar evidence types (chart reviews/market research/treatment pattern studies) have been accepted in previous technology appraisals. As highlighted by the Medicines and Healthcare products Regulatory Agency (MHRA), "*evidence derived from real-world data may also be more representative of the true effects of a treatment in the community and more generalisable than data from the standardised setting of a traditional clinical trial*".[9] Moreover, the independent Adelphi DSP RWE study provides a real-world reflection of clinical practice in the **relevant presenting population**, i.e. patients in secondary care.[8] The Company therefore consider that the independent Adelphi DSP RWE study for AA is likely to provide a more accurate picture of the HRQoL impact of severe AA

(and the subsequent utility gain associated with treatment response) due to the following reasons:

- Contrary to the arguments presented by the EAG during Technical Engagement (TE), the independent Adelphi DSP RWE study is more representative of the population of patients who would receive baricitinib if it was licensed, given that the independent Adelphi DSP RWE study in AA was conducted among patients seeking treatment from their dermatologist in secondary care (i.e. those that would become eligible for treatment with baricitinib if recommended by NICE).
- BRAVE-AA participants were recruited based on their willingness to participate in an experimental medication trial and may therefore not representative of all patients with severe AA in clinical practice.[8]
- As noted by the patient expert in Section 3.6, people who were more psychologically impacted by their condition may not have been eligible to take part in the trials due to the exclusion of patients with severe neuropsychiatric disorder, and therefore not put forward for screening for trial entry, leading to overestimates of the baseline utility of patients with severe AA.
- As noted by the patient expert in Section 3.6, "*people who were enrolled into the BRAVE-AA trials may have had lower rates of anxiety than would be expected in the NHS, because people in trials have hope of being treated".*
- During TE, the EAG highlight that the ALLEGRO-LT trial also demonstrated [redacted].[10] The EAG suggests this supports the accuracy of the BRAVE-AA trial utilities whereas the Company consider that this is in fact a reflection of the challenges and complexities associated with capturing HRQoL in this disease area within a clinical trial setting using generic instruments such as EQ-5D.

Overall, the Company maintain that the Adelphi DSP represents a better source of evidence for the utilities used in the CEM, as these data are likely to be more representative of patients in real-world clinical practice (in a disease area where this may be particularly valuable), were collected using robust methodology and have greater face validity when considering the evidence presented throughout the ACM. The utilities from the BRAVE-AA studies and the Adelphi DSP are presented in **Error! Reference source not found.** and **Error! Reference source not found.**, respectively, for reference.

Table 1. Utility values from the BRAVE-AA trials informing CEM

Baseline utility	CfB among responders at Week 36

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	[redacted] | [redacted] **Table 2. Utility values from the independent Adelphi DSP RWE study informing CEM** **Severe/very severe group – proxy for baseline utility** | **Mild group – proxy for CfB among responders at Week 36** [redacted] | [redacted]
3	**<u>Source of data informing the composition of BSC</u>** **Summary points** • The arguments put forward by the EAG are of limited relevance to the current appraisal, since they focus on a situation in which "*all treatment options have been exhausted"* rather than considering the wider population of patients with severe AA who receive 'no active treatment' • Based on robust evidence of treatment patterns for severe AA in the population of relevance for this appraisal from the independent Adelphi DSP RWE study, the company maintain that these data should inform the composition of the BSC basket in the CEM **Critique of the EAG's arguments** In Section 3.10, it is noted that most people in the independent Adelphi DSP RWE study were treatment-experienced, having already tried many previous treatments. The EAG suggest that this is likely to mean that people would be less willing to try further pharmacological treatments that have limited effectiveness "*after all other options had been exhausted*" and subsequently argue that BSC should therefore only include wigs and orthotics. In response to this argument, the Company would like to emphasise that the relevant comparator for this appraisal (as accepted by the Committee in Section 3.14) is 'no active treatment'. Accordingly, in the CEM, patients receive 'no active treatment' (or baricitinib) for 36 weeks, at which point they may transition to BSC if they fail to respond (SALT≤20). This comparator reflects the fact that patients often initially receive no active treatment for their disease in the hope that their AA will spontaneously regrow, as well as the extended wait times for secondary care.[11] In this context, the Company consider that the arguments put forward by the EAG to be of limited relevance to the economic analysis underpinning this appraisal, since they focus on a situation in which "*all other treatment options had been exhausted"* rather than a situation in which more people are "*likely to be treatment-naïve"* (Section 3.10), having been referred to secondary care following receipt of

	'no active treatment'. Indeed, the Company acknowledge that there is likely to be a proportion of prevalent patients who *are* highly treatment-experienced, but who would likely receive baricitinib if it is licensed. However, it would be expected that over time the proportion of prevalent patients receiving baricitinib would gradually decrease, as baricitinib would become the first-line option for people with severe AA. **Composition and time horizon of BSC use** Focussing on the population of relevance for this appraisal, the Company would like to re-iterate the robustness and relevance of the independent Adelphi DSP RWE study, given that it was conducted amongst patients under the care of a dermatologist in secondary care. It should therefore be considered that these data, in which [redacted] were on BSC treatments (in a population were most patients were treatment experienced), provide robust and accurate data informing the composition of BSC in the model. Furthermore, as mentioned previously, independent Adelphi DSP RWE studies are an established method for investigating treatment patterns in real-world clinical practice, and this type of evidence (sometimes referred to as chart reviews/market research/treatment pattern studies) has also been accepted in previous technology appraisals for informing treatment patterns. As such, the Company consider that the use of only wigs and orthotics in the Committee-preferred base case following non-response in unrealistic and unreflective of current treatment practices within secondary care within the population of relevance for this appraisal. While the Company maintain that the independent Adelphi DSP RWE study should inform the composition of the BSC basket, Lilly acknowledges that it is unlikely that [redacted] of patients would on average remain on BSC drug treatments (and therefore incur BSC treatment costs) over the full lifetime time horizon of the model. Lilly have therefore provided an updated CEM alongside these responses, in which they have explored the effect of limiting the application of BSC drug costs only to a 10-year time horizon within the model, rather than over the full lifetime time horizon of the model, as presented in **Error! Reference source not found.**. This BSC drug cost time horizon was considered the most realistic time horizon over which to apply BSC treatment costs for the following reasons: • In the Adelphi DSP, [redacted] of patients were on current treatment, despite [redacted] being pre-treated. Moreover, of all the participants in the Adelphi DSP, [redacted] had previously received 1 line of therapy, [redacted] had received 2 lines of therapy, [redacted] received 3 lines of therapy and [redacted] had received

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	4 lines of therapy. These data demonstrate that patients with severe AA frequently cycle through multiple treatments, likely over an extended period. • In addition, as patients in the model are assumed to start treatment at 37.5 years (aligned with the baseline characteristics in the BRAVE-AA trials), the Company consider that it is likely that patients would continue to seek treatment for their severe AA until at least the age of 47.5 years, as during this time the potential impact of age-related hair loss is less pronounced and the incidence of comorbidities that would contraindicate some of the BSC drugs likely remains low.
4	**<u>Differential use of BSC following loss of response</u>** **Summary points** • The Company maintain that it is likely that patients who have lost response after treatment with the only treatment licensed for severe AA, baricitinib, would be less likely to engage with BSC treatments compared with those receiving 'no active treatment', and would emphasise that clinical and patient expert opinion may particularly help to resolve this issue in the second ACM • The Company have proposed a revised base case and two scenarios each based on a reduction in BSC use following baricitinib as well as incorporating the limitation of BSC drug costs to a 10-year time horizon, as discussed above. **Extent of BSC use following non-response to baricitinib versus no active treatment** In the scenarios presented in **Error! Reference source not found.**, the Company has also further explored the impact of reducing the extent of BSC use within the baricitinib arm versus the 'no active treatment arm' following non-response. This is because the Company maintain that, compared to someone who had received baricitinib – a licensed treatment with proven efficacy and a tolerable safety profile – a patient who had received 'no active treatment' would be more willing to experiment with off-label treatments after failing to respond. This is because these patients would likely still feel hopeful that an off-label, low efficacy treatment could work if all they had received up to that point was a similar or poorer alternative ('no active treatment' and maybe other off-label treatments prior to this). Therefore, these patients would be more likely to engage with off-label treatments that have

	painful and/or uncomfortable side effects as there would be some justification for doing so (i.e. the hope of response). Using the same rationale, patients who had received baricitinib would likely feel less hopeful for subsequent treatment success with BSC, given the most effective and tolerable option had already failed. Prescribing dermatologists would similarly become less willing and/or confident in prescribing these poorly tolerated and low efficacy treatments if the best available option (baricitinib) had already failed. Within the economic analysis, this concept is captured by assuming that the introduction of baricitinib would reduce BSC use compared to current treatment practices (as modelled in the comparator arm) if a patient were to fail to respond to baricitinib (Table 3). Due to the forward-looking nature of this issue, the Company would like to note that it is not feasible to gather any supporting quantitative data for the qualitative arguments made above. Clinical and patient expert opinion on this topic may therefore be particularly valuable during the second ACM, especially given that discussion of this issue was limited in the public portion of the first ACM and that this issue is a key driver of the cost-effectiveness analysis for baricitinib in this indication. **Revised base case** For the reasons above, Lilly has proposed a revised base case, and two additional scenarios for the Committee to consider, highlighted in Table 3 below. In the first scenario, the Company have assumed that [redacted] of patients in the model receive BSC treatments (using evidence on the proportion of patients receiving BSC treatments in the independent Adelphi DSP RWE study) following non-response to 'no active treatment'. Consistent with the Company base case post-TE, this scenario includes a [redacted] reduction in BSC use after baricitinib, relative to BSC use after 'no active treatment'. However, this scenario now includes a **10-year time horizon** for BSC drug costs, resulting in a more conservative ICER than the Company base case post-TE. The second analysis in Table 3 presents the revised Company base case post-DGD, in which [redacted] of patients in the model receive BSC treatments over a 10-year period (using evidence on the proportion of patients receiving BSC treatments in the independent Adelphi DSP RWE study) following non-response to 'no active treatment'. The Company's revised base case then assumes that there would only

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be a [redacted] relative reduction in BSC use following the introduction of baricitinib versus current treatment practices, which is a significantly more conservative assumption than proposed post-TE, and also represents only a small reduction when considering the anticipated step change that baricitinib will offer in the treatment of severe AA.

The final scenario presented retains the committee-preferred assumption of no BSC use following baricitinib discontinuation, but rejects this assumption following 'no active treatment' and instead applies an assumed 30% BSC drug cost for such patients over a 10-year period. This scenario represents an even more conservative option when considering the RWE presented, but may help to reduce the decision uncertainty as to whether baricitinib should be considered a cost-effective use of NHS resources.

It should be noted that in all cases the analyses below incorporate the 10-year time horizon on BSC drug costs only, as discussed above, while continuing to model a lifetime time horizon in all other respects.

Table 3. Revised base case and additional scenarios applying a 10-year time horizon for BSC drug costs within the overall model lifetime time horizon

Utilities	Extent of BSC use after failure on baricitinib	Extent of BSC use after failure on 'no active treatment'	ICER
Adelphi DSP	[redacted]%*	[redacted]%†	Dominant
Adelphi DSP	**[redacted]%***	**[redacted]%†**	**£12,403‡**
Adelphi DSP	0%	30%	£20,088

Footnotes: * Represents 50% reduction and 25% reduction in BSC use following the introduction of baricitinib for treatment of severe AA, respectively;
† Based on the proportion of patients in the Adelphi DSP study currently on treatment;
‡ This result reflects the company's preferred base case following Draft Guidance Consultation

The Company would request that the Committee explicitly consider the feasibility of the assumptions within this revised base case, and particularly whether the use of baricitinib would reduce engagement with BSC after treatment failure compared to current treatment practices, given that a small difference in this regard is potentially a major driver of the decision as to whether baricitinib is a cost-effective use of NHS resource.

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5	**<u>The impact of the uncertainties in this indication on the WTP threshold</u>** **Summary points** • The Company note that several of the uncertainties listed by the Committee in Section 3.13 are actually in favour of accepting an incremental cost-effectiveness ratio (ICER) on the upper end of the range considered a cost-effective use of NHS resources, rather than on the lower end and request that this distinction be recognised • The lack of a standardised treatment pathway for severe AA in the NHS at the present time should not hinder access to baricitinib given that the introduction of baricitinib would resolve this uncertainty • Underestimation of the effectiveness and quality-adjusted life year (QALY) gains associated with baricitinib treatment in the BRAVE-AA trials produces a conservative ICER that should favour the use of a higher WTP threshold, not a lower one In Section 3.13, the acceptable ICER for this appraisal is discussed, and it is noted that due to the uncertainty around various aspects of this appraisal "*an acceptable ICER would be towards the lower end of the range normally considered a cost-effective use of NHS resources*". As part of this discussion, a list of uncertainties is provided. However, the Company would like to note that, contrary to the way it is framed, several of the uncertainties listed would indicate that, if anything, the higher end of the WTP threshold range would be more suitable for baricitinib: **"*no clear consensus on standard of care*"** Although the Company agree that there is no standardised treatment pathway in this indication, the Company strongly disagree that this uncertainty should contribute towards a lower WTP threshold. This is because, if granted marketing authorisation in this indication, baricitinib could become the standard of care for patients with severe AA, and would therefore ultimately resolve this uncertainty in the current treatment pathway. Baricitinib may also resolve the 'postcode lottery' currently associated with treatment of AA in the NHS, since baricitinib would become widely available across all secondary care settings. The Company therefore consider that this uncertainty should not hinder access to baricitinib, particularly given that the lack of clear consensus on the standard of care has thus far, contributed to the significant burden associated with the disease (Section 3.1). **"*the evidence of baricitinib's effectiveness in the treatment-naive population is uncertain but likely to be underestimated based on BRAVE outcomes*"**

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	The Company would like to emphasise that an underestimation of the effectiveness of baricitinib in clinical practice within the CEM will lead to a conservative ICER, and subsequently should contribute to a higher WTP threshold, not a lower one. ***"the QALY gains with treatment may be underestimated in the BRAVE trials"*** Similarly to the underestimation of the effectiveness of baricitinib that is discussed above, the Company consider than this uncertainty should contribute toward a higher WTP threshold, rather than one closer to £20,000 per QALY gained. While this would in part be resolved by acceptance of the Adelphi DSP utilities (see above), it is likely that even the DSP data still represent a conservative estimate of the utility gain associated with response to baricitinib treatment, given the challenges of accurately capturing the impact of AA on HRQoL using EQ-5D as an instrument. The uncertainty that the "long term safety of baricitinib is unknown" is discussed below.
6	**<u>The long-term safety of baricitinib</u>** • Baricitinib has been authorised since February 2017 and it is estimated that approximately [redacted] patients (representing [redacted] patient-years of exposure) have received baricitinib worldwide post-approval within rheumatoid arthritis (RA), atopic dermatitis (AD), and alopecia areata (AA) indications • Based on post-approval reports, suspected adverse drug reactions remain low and are consistent with either the known safety profile of baricitinib • The long-term safety profile of baricitinib should not be considered a key area of concern or uncertainty, and should therefore not contribute to a lower WTP threshold. Within Section 3.8, the long-term safety of baricitinib was suggested to be an uncertainty. However, the Company would like to point out that this issue is not discussed within the DGD, and was also not highlighted as a concern during the public portion of the first ACM. The Company would note that baricitinib has been authorised (in other indications) since February 2017, with marketing authorisations in 76 countries for RA, 64 countries for AD and 31 countries for AA. In a clinical trial setting, [redacted]patients have received baricitinib for the treatment of RA, AD, and AA. Moreover, as of 31st July 2022, cumulatively, it is estimated that approximately [redacted]patients

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	(representing [redacted] patient-years of exposure) have received baricitinib worldwide in post-approval (non-clinical trial) settings for the treatment of RA, AD and AA. Importantly, based on post-approval reports, suspected adverse drug reactions remain low and are consistent with either the known safety profile of baricitinib or are non-specific symptoms that can occur due to multiple causes.[12] The Company would also like to highlight the existence of several published long-term safety datasets following treatment with baricitinib in AA, RA and AD: • In the RA dataset, the mean age of patients at baseline was 53 years and exposure lasted up to 9.3 years, with a median exposure of 4.6 years, for a total of 14,744 person-years of exposure (PYE).[13] • The AD dataset includes exposure up to 3.9 years with a median exposure of 1.6 years, for a total of 4,628 PYE with a mean age of patients at baseline of 37 years.[14] • As the most recently-approved indication for baricitinib, published data from the AA dataset includes a median follow-up period of 1.5 years (maximum 3.1 years), for a total of 1,868 PYE with mean age of patients at baseline of 38 years.[15] However, the updated dataset for this population, with exposure up to 3.6 years (2,217.9 PYE), will be disclosed at the March 2023 American Academy of Dermatology Association Annual meeting. This updated safety analysis in patients with severe AA enrolled in the BRAVE-AA trials is consistent with previous observations. Given these data, the Company would like to highlight that the long-term safety profile of baricitinib should not be considered a key area of concern or uncertainty, and should therefore not contribute to a lower WTP threshold.
7	**<u>Validity of the Committee-preferred assumptions in the CEM</u>** In conclusion, Lilly is disappointed with the Committee-preferred assumptions for the source of utilities and the composition and extent of BSC use following non-response. The implications of these assumptions are that treatment of severe AA is not of value to the healthcare service, and that these patients should continue to endure their disease and limited treatment options simply because of the nature of the condition and a methodological preference for utility values that lack face validity and directly contradict the Committee's prior conclusions on HRQoL in severe AA. Lilly also considers that lowering the acceptable ICER threshold in this appraisal does not reflect the considerable unmet need in this indication and the step-change that baricitinib could offer as a novel and innovative treatment.

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	The above points are exemplified by the fact that when the Committee-preferred assumptions are employed in the CEM, **baricitinib would still not be considered cost-effective at the Committee-preferred WTP threshold** (~£20,000 per QALY gained) **if it were made available at no cost**. While this is not an unknown scenario in appraisals for treatments that extend life (where the extra life incurs significant ongoing costs), this is not the case with baricitinib. In this case, the Committee have explicitly recognised that baricitinib "*is clinically effective"* in allowing hair regrowth; such hair regrowth does not incur any additional costs for the NHS, instead the benefits of hair regrowth have simply been considered (through the choice of utility inputs which lack face validity) to be of almost no value to the NHS. The Company therefore considers that these results point to the inadequacy of the modelling assumptions preferred by the Committee in terms of valuing the treatment of severe AA within the NHS. As such, the Company urges the Committee to consider the wider implications and meaning of their conclusions for any effective therapy, and would invite the Committee to reconsider their assumptions in the context of the responses presented above.

Insert extra rows as needed

Checklist for submitting comments

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- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information, and separately highlight information that is [redacted] and information that is [redacted]. If confidential information is submitted, please submit a second version of your comments form with that information replaced with the following text: 'academic / commercial in confidence information removed'. See the NICE Health Technology Evaluation Manual (section 5.4) for more information.
- Do not include medical information about yourself or another person from which you or the person could be identified.
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Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations 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 comments we received, and are not endorsed by NICE, its officers or advisory committees.

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Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Alopecia UK
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**None**
Name of commentator person completing form:	Lynn Wilks – Trustee with Alopecia UK

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Comment number	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that ……..
1	**1.Alopecia UK – Summary:** We are disappointed to see that The National Institute for Health and Care Excellence (NICE) could not recommend baricitinib for routine commissioning in the NHS for treating severe alopecia areata in adults. The NICE committee noted the lack of licenced, effective treatments for severe alopecia areata and hence the unmet medical need for an effective and safe treatment such as baricitinib. The committee discussed the lack of clarity of a 'best standard of care' and acknowledged the regional differences in treatment of patients with severe alopecia areata. Despite this, the committee could not recommend baricitinib for routine commissioning in the NHS. The fact that the committee discuss 'no active treatment' as a 'comparator' just shows that there are currently no real effective treatments available for people with severe alopecia areata. We are disappointed and concerned by the numerous people we hear from suffering from this lifelong, incurable, auto-immune condition (many of whom have other concurrent auto-immune conditions). We believe people with severe alopecia areata deserve the opportunity to have a treatment that can enable hair regrowth. With no licensed and very few effective treatments for alopecia areata, long waiting lists for dermatology appointments and a post code lottery for access to treatments, baricitinib offers real hope as an effective treatment to enable hair regrowth and not having to endure a lifelong condition of a visible difference, and the very real struggles that come along with that. While NICE have reviewed the direct cost-effectiveness of baricitinib in the treatment of severe alopecia areata, they have failed to account for the direct NHS costs involved in treating conditions secondary to alopecia including depression, anxiety, substance abuse/addiction and the increased prevalence of dementia (which is theorised to result from the social isolation that is frequent among those suffering alopecia). At Alopecia UK, we also see the cost to individuals, and wider society, of absenteeism from education, work, and the reduction in social activities. In addition, there is also the financial burden to individuals and their families of the costs of wigs, eyebrow microblading, camouflage clothing and private counselling. You really cannot imagine the psychosocial impact of having severe alopecia areata and the weight that every social interaction carries, hence why anxiety,

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	depression and agoraphobia are so common, which result in absenteeism from work, education, and social interactions. Even during this first committee process we heard from two mothers with young adult sons who were unable to continue their studies, were suffering severe anxiety and depression, and had both contemplated suicide. We hear of the suicides due to people with severe alopecia areata unable to cope with the condition and the associated stigma. How do you think those mothers and young adults feel seeing that baricitinib has not been recommended for commissioning in the NHS, and part of the reason seems to be that hair regrowth does not seem to improve a persons quality of life enough? It appears that the trials and data Eli Lilly presented to NICE did not show enough improvement in quality of life (QoL) for it to be assessed as cost-effective for the NHS. We certainly hear the absolute opposite from the alopecia community and those that have been fortunate enough to access JAK inhibitor treatment privately frequently claim that they have 'gotten their life back' because of the regrowth of hair. We ask that the NICE committee look at further 'real life' data around the positive changes in QoL from hair regrowth. We really hope that Eli Lilly can submit some further data to demonstrate that baricitinib is 'cost-effective' for NICE parameters, and that, along with comments from Alopecia UK, clinical and patient experts, we can persuade NICE to approve Baricitinib for use in the NHS.
2	**2.Has all of the relevant evidence been taken into account** **We ask the committee to consider a wider evidence pool to substantiate the negative quality of life impact of severe alopecia areata; as through our patient research, social media groups and support calls, we hear and we understand the true impact of alopecia areata. Additionally, we believe there are several peer-reviewed publications in reputable journals that report a higher prevalence of depression, anxiety and suicidal ideation and suicides within this community. While anecdotal, we also see and hear how hair re-growth resulting from privately accessed baricitinib treatment has substantially improved peoples' QoL.** o A meta-analysis conducted by Okhovat et al. (2019) of 6,010 patients found that AA patients are at greater risk of both anxiety and depression. o One study in the review by Okhovat et al. (2019) assessed suicidality in patients with alopecia areata and demonstrated that patients with AA were at higher risk of suicide and self-harm (Singam et al., 2018) o One study has reported rates of mental health challenges as high as 47.5% in people with alopecia, 35.5% anxiety and 29% depression. The study was predominantly AA (82.6%) (Montgomery et al., 2017) o For newly diagnosed patients with AA studies suggest that people are more likely to develop depression and anxiety disorders (Macbeth et al., 2022) 'academic in confidence information removed'

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	• Section 3.1: The comments made by Alopecia UK and the patient experts on the psychosocial impacts and negative effects on quality of life were noted. 'The committee concluded that severe alopecia areata can have profound psychosocial impact on a person's quality of life and that people with the condition would welcome new effective treatment options' • Section 3.7: We at Alopecia UK are disappointed to see comments from the committee as 'but based on the data from the BRAVE trials, the extent of this improvement on quality of life is uncertain' yet just in the paragraph earlier the comment was ' The EAG acknowledged that there is likely to be a group of people for whom severe alopecia areata can have a large negative impact on QOL and for whom treatment with baricitinib may results in large improvements in quality of life' <u>References</u> o Okhovat JP, Marks DH, Manatis-Lornell A, Hagigeorges D, Locascio JJ, Senna MM. Association between alopecia areata, anxiety, and depression: a systematic review and meta-analysis. Journal of the American Academy of Dermatology. 2019 Jun 1. o Singam V, Patel KR, Lee HH, Rastogi S, Silverberg JI. Association of alopecia areata with 57 hospitalization for mental health disorders in US adults. J Am Acad Dermatol. 2018 Aug. o Montgomery K, White C, Thompson A. A mixed methods survey of social anxiety, anxiety, depression and wig use in alopecia. BMJ open. 2017 Apr 1;7(4):e015468. o Macbeth AE, Holmes S, Harries M, Chiu WS, Tziotzios C, de Lusignan S, Messenger AG, Thompson AR. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. British Journal of Dermatology. 2022 Jul 1;187(1):73-81.
	<u>3. Are the summaries of clinical and cost-effectiveness reasonable interpretations of the evidence</u> **Overall, we feel that the summaries of clinical and cost-effectiveness demonstrate how the severe alopecia areata population are currently totally neglected by the NHS. We ask the committee to reconsider the following key points, which are substantiated below:** o **The use of more true-to-life QoL scores, using a QoL tool other than EQ5D that is more appropriate for measuring the effects of AA, particularly its psychosocial impacts on QoL. In addition, a more**

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	equitable way of measuring change in QoL from baricitinib treatment and its resultant hair regrowth should be considered. o **We believe the 'no active treatment' comparator used to be a poor and in-equitable comparator for cost effective assessment.** o **What is the ideal Best Supportive Care (BSC) for people with severe AA? The scenario used for BSC overlooks key aspects of the true real-world situation for people with severe AA. Why should people with severe AA be denied what is really the 'first' effective treatment for this population?** o Section 3.2: 'The committee agreed that there is wide variation in practice in treating severe alopecia areata'; therefore, the committee have acknowledged that people suffering severe alopecia areata are frequently 'abandoned' by the NHS. Therefore, 'no active treatment' as a comparator is actively perpetuating the lack of treatment and lack of attention that patients are given. The NICE review for baricitinib in the treatment of severe eczema serves as an example of how alopecia is overlooked compared to other (non-life threatening) conditions. In this previous review two comparators were deemed appropriate: o An active comparator of dupilumab (in which the inequity compared to the alopecia review is evident) o Best supportive care (BSC) which included (but was not limited to) education, psychological support, topical corticosteroids and hospitalisation. All these aspects of BSC are also true for alopecia, so why are they being overlooked? In our experience, multiple members of the alopecia community access NHS mental health services and many individuals will access these services several times in their lifetime, so why are these not included in the active comparator? Additionally, hospitalisation due to suicide attempts should not be overlooked, and although no studies have been conducted to quantify this, suicide attempts and death by suicide, is something we are sadly aware of within the community. o Section 3.2: The committee concluded that 'there is an unmet need for safe and effective treatments for severe alopecia areata' yet do not recommend baricitinib, which has proven via the BRAVE trials to be effective and safe for the treatment of severe AA. o Section 3.3: We agree that use of SALT 20 or less for treatment response is appropriate. When considering head hair. But SALT does not consider eyebrow and eyelash regrowth - which also has massive impact on QoL. I.e. even if SALT<20 not achieved, eyebrow+eyelash + partial scalp regrowth may still be meaningful <u>We have considerable concerns about the reliance of the EQ-5D tool in the assessment of cost effectiveness:</u> • Section 3.6: We at Alopecia UK are concerned about the emphasis and reliance on EQ-5D from the BRAVE trials and do not think EQ-5D shows the true impact of the affect of alopecia areata on QoL and

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	hence question how this measure can be what is being used for the cost-effectiveness measure. 'The clinical experts noted that high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia areata. And even the committee comments: 'it considered whether EQ-5D may not be picking up important aspects of the condition or because the people in the trials are not representative of those with severe alopecia in terms of anxiety and depression'. We ask that you look beyond the BRAVE EQ-5D data and even beyond the Adelphi data, although that seems to show a more accurate reflection of reality. We have detailed below some additional comments about why the EQ-5D is an inappropriate measure: o Anxiety and depression are uniformly recognised by the committee, clinical experts and patient experts as the main secondary conditions of concern. However, the EQ-5D only has one of five domains that is specific to anxiety/depression (with the remaining four domains addressing mobility, self-care, usual activities and pain/discomfort). o 80% of the EQ-5D questionnaire is not relevant to the clinical presentation of alopecia. Therefore, inclusion of irrelevant domains very likely dilute the true negative mental health impacts of alopecia (and the associated mental health improvements with baricitinib-induced hair regrowth) More specific questionnaires that have mental health as their predominant focus would be more appropriate e.g. Skindex-16 Alopecia Areata, phq-9 and GAD-7. o Additionally, we ask NICE to consider the most appropriate tool to measure the effect of severe alopecia areata on mental health, considering that some reviews suggest it should be used in conjunction with condition specific measures (Brazier, 2010; Payakachat et al., 2015). o Section 3.6: as noted by us, the patient experts, the baseline QOL scores in BRAVE are not generalisable. This is due to the hope that participation in a clinical trial provides. There are frequent complaints within the alopecia community of loss of hope and concern that they will 'look like this forever'; therefore, a patient population that is somewhat alleviated of these concerns through clinical trial participation is not reflective of reality. There is also likely to be some form of initial elation within clinical trial participants who have likely spent 6 months to many years feeling they have been offered little to no helpful advice or treatment for a condition that is so often overlooked by the medical community. NICE should not underestimate the positive mental impact that is associated with engagement from medical professionals and validation that alopecia is a condition worthy of treatment (and not simply cosmetic). o The EQ5D is an effective measure but only where it has demonstrated effectiveness of responsiveness and to our knowledge this is not the case in AA. Where this is no evidence or mixed evidence of responsiveness researchers should consider using the EQ5D with other specific measures. This was not the case in this trial? In a systematic review of the EQ5D and its

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	ability to detect meaningful change, there was mixed evidence of responsiveness across 48% of the conditions included and 7% of the conditions the EQ5D was not responsive. Interestingly the EQ5D was not found to be responsive to health status change after limb reconstruction. The EQ5D did also not detect changes after different hearing interventions (Payakachat et al., 2015). o A further study examined if the patient experience is adequately captured by the EQ5D. Findings suggested that the EQ5D showed poor-moderate responsiveness to clinical change that did not adequately reflect the views of the patients (Tordrup et al., 2014). o Section 3.10: Discussion of Best Supportive Care – We are really disappointed by the comments around 'Best Supportive Care' and that the only consideration of this seems to be to test the health economic model. We are concerned that this could negatively affect the cost-effectiveness of baricitinib. o As the draft guidance comments 'best supportive care is uncertain' – can the committee not see that this reflects that patients with severe alopecia areata are currently neglected by the NHS – there is no cure, there are no licenced treatments readily available and yet a first licenced treatment in a new category of drugs, baricitinib has so far been rejected by NICE for availability on the NHS. We hear and see individual patients' stories to the full impact on QOL and the positive difference that baricitinib and hair regrowth can have on a patient with this auto-immune condition (And as per our comments to 3.2). o Section 3.12: While we as expert patients and the patient organisation stakeholder are lay people and do not fully understand the health economic modelling, we do understand how alopecia areata affects QoL. We do not feel that the BRAVE EQ-5D data is a true representation of the QoL effects on people with alopecia areata and therefore encourage NICE to pay attention to Eli Lilly, clinical experts and patient experts to consider the EQ-5D from its Adelphi study (as per our comments of section 3.6 above). **Areas where cost evidence is lacking altogether:** o Direct NHS costs that have not been considered: these include the treatment of conditions that are secondary to the development of alopecia such as depression, anxiety, substance abuse/addiction and the increased prevalence of dementia that has been published in a peer-reviewed journal (which is theorised to result from the social isolation that is frequent among those suffering alopecia). Additionally, people with alopecia frequently discuss withdrawing from exercise-based activities where, due to increased heat and sweating, it is difficult to wear the wigs or hats they rely on o Indirect costs to the NHS: although NICE do not often model the loss of GDP associated with a disease, we view this as a mistake. According to a study published in the British Journal of Dermatology, people with alopecia are significantly more likely to be issued with time off work certificates and to be recorded as unemployed (Macbeth, et al. 2022). We also have collected anecdotal evidence of people disengaging from work responsibilities due to

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	the associated shame of turning up to work and being visibly different to co-workers. The median average UK salary in 2022 was £32,300 which equates to £6,917 tax and national insurance. If you were to assume that the average UK citizen were afflicted with alopecia and were too depressed to work, there would be an annual loss of £6,917 plus the addition of any costs associated with Universal Credit claims. **<u>References</u>** o Brazier, J. (2010). Is the EQ–5D fit for purpose in mental health? *The British Journal of Psychiatry, 197*(5), 348-349. doi:10.1192/bjp.bp.110.082453 o Payakachat N, Ali MM, Tilford JM. Can The EQ-5D Detect Meaningful Change? A Systematic Review. Pharmacoeconomics. 2015 Nov;33(11):1137-54. doi: 10.1007/s40273-015-0295-6. PMID: 26040242; PMCID: PMC4609224. o Tordrup D, Mossman J, Kanavos P. Responsiveness of the EQ-5D to clinical change: is the patient experience adequately represented?. International journal of technology assessment in health care. 2014 Jan;30(1):10-9. o Macbeth AE, Holmes S, Harries M, Chiu WS, Tziotzios C, de Lusignan S, Messenger AG, Thompson AR. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. British Journal of Dermatology. 2022 Jul 1;187(1):73-81.
4	**4. <u>Are the recommendations sound and a suitable basis for guidance to the NHS</u>** **We do not consider the recommendations 'sound' and 'suitable' for guidance to the NHS** • **People with severe AA are currently neglected and abandoned by the NHS, as there is no cure and no effective long-term and longstanding (can be taken beyond 6months) treatment.** • **While there is really no 'Best Supportive Care', we do not consider 'no active treatment' as a fair comparator. Please consider what should be 'Best Supportive Care', and a fair 'active comparator when assessing cost effectiveness of baricitinib.** • **The clinical experts raised the % people suffering from anxiety, depression, negative psychosocial impact and suicidal ideation – hence people with severe AA do have a much lower QoL, and while anecdotal, we hear the difference that privately-accessed baricitinib**

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	treatment and the resulting hair regrowth makes. Please be open to appropriate QoL measures. • **We believe that other non-life threatening dermatological conditions e.g. severe eczema, have several treatment options approved on the NHS. If baricitinib is 'cost effective' for eczema, then why is it not cost effective for severe alopecia areata?** • Section 3.13 – We do not agree with the conclusions that NICE make in this section stating: 'the committee will be more cautious about recommending a technology if it is less certain about the ICERs presented'. The issues where the committee noted 'high levels of uncertainty' surely demonstrate that patients with severe alopecia areata are currently being let down by the NHS including: o We hope that Lilly can provide the data that NICE seemingly requires in order to demonstrate that baricitinib is cost-effective in line with NICE parameters. o We also hope that NICE can look beyond the uncertainties which Alopecia UK feel are down to the lack of effective standard of care at baseline. o Additionally, we implore NICE to really listen to the positive impacts on QoL of privately-accessed baricitinib treatment that Alopecia UK have observed in the real world.
5	**5. <u>Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination</u>** • Section 3.15 states that alopecia areata may be more common in those with lower socioeconomic status. Access to baricitinib in the UK is therefore only manageable for those who can afford prescription prices and private medical healthcare. Additionally, as stated previously, there are inconsistent wig provisions across the UK and patients frequently have to pay out of pocket for something that is often deemed as an absolute necessity to feel comfortable leaving the house. Therefore, there is a massive equity concern with alopecia areata and those with a lower socioeconomic status will be hit the hardest. To not actively treat alopecia is to discriminate against those who cannot afford the most basic of necessities that many with the condition rely on. • Those of Asian ethnicity, we believe, are three times more likely to experience AA (Harries et al) and 'academic in confidence information removed' Not prescribing would therefore potentially put them at a disadvantage

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	• Severe alopecia areata is associated with 'severe physical disfigurement' which is classed as a disability by the UK Disability and the Equality Act 2010; therefore we view it as a form of discrimination to individuals with alopecia to be denied an effective treatment that is available. ○ Additionally, baricitinib is available on the NHS to individuals with severe eczema and rheumatoid arthritis (both of which had active comparators in their NICE review and both of which have several other approved treatment options). To deny the same treatment to people suffering with severe alopecia areata is to overlook and de-prioritise the distress of their condition and therefore give higher priority to conditions that already have treatment options. References ○ Harries M, Macbeth AE, Holmes S, Chiu WS, Gallardo WR, Nijher M, de Lusignan S, Tziotzios C, Messenger AG. The epidemiology of alopecia areata: a population-based cohort study in UK primary care. British journal of dermatology. 2022 Feb 1;186(2):257-65.
6	

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- Do not include medical information about yourself or another person from which you or the person could be identified.
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	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. The Appraisal Committee is interested in receiving comments on the following: • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? 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 preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example 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 provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced**.**
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**British Association of Dermatologists (BAD)**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**None**
Name of commentator person completing form:	**[redacted], on behalf of the BAD's Therapy & Guidelines sub-committee, and [redacted], on behalf of the BAD guideline development group for alopecia areata and British Hair and Nail Society**

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Comment number	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	We are concerned that NICE TA committee A has failed to act fairly in making its decision not to recommend baricitinib for the treatment of severe alopecia areata. The preferred assumptions made by the committee in evaluating the cost effectiveness of the intervention are inconsistent with the recommendations made by clinical experts and patient representatives. Therefore, the economic modelling on which the decision is based is unsound and does not represent clinical practice in the NHS.
2	The NICE TA committee's preferences in considering only the cost of NHS wigs and orthotics as representative of best supportive care (BSC) is not consistent with the recommendations made by clinical experts, patient experts or the evidence presented by the company (Adelphi study). The EAG base case is an *exceptionally* conservative assumption and not supported by any underlying evidence (that BSC *only* includes costs of wigs and orthotics), and we are concerned that this scenario has been chosen as the preference by the NICE TA committee. The ACD/draft guidance states that this is an area of high uncertainty, and we agree – however, it seems perverse in a situation of high uncertainty to select a scenario with no evidential support over those with evidence. From the draft guidance, *"Treatments available on the NHS for severe alopecia areata include **topical corticosteroids, which are usually prescribed in primary care**. If they do not work, people may be referred to a dermatologist and offered a range of medicines many of which are not licensed for this condition, or a wig."* (p3), and *"The clinical experts explained that they would **use baricitinib** at the same position as contact immunotherapy and immunosuppressants, in a **secondary care** setting rather than tertiary care."* (p.7) Therefore, the likelihood of patients being treatment-naïve in real-world practice is highly unlikely. We present below evidence from a survey collected independently of this appraisal (collection period ended prior to ACM1, data released during consultation period) which supports the company base case data from the Adelphi study but was generated independently of the company and with no input from them. **These data have not been published yet and remain confidential.** On costs of wigs and hair pieces on NHS prescriptions – patients are entitled to one real hair item per year or two non-real-hair items per year. Many NHS Trusts require that prescriptions be renewed annually, and this can only be achieved in secondary care, and not primary care with its associated costs. https://www.nhs.uk/nhs-services/help-with-health-costs/wigs-and-fabric-supports-on-the-nhs/ Patients still require secondary care appointments for ongoing wig prescriptions and the frequency of this depends on each Trust. There is a huge discrepancy on accessibility of wig prescriptions and type of wigs for patients, and there is variability in how these are

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	funded in different regions. Some Trusts incur the cost, others are funded by CCGs. Therefore, patients and clinicians are facing several barriers in obtaining wigs. There is also issues around appropriate wigs for different types of hair based on ethnicity. Our Afro-textured hair patients and Asian patients can sometimes struggle to find appropriate wigs. Epidemiological studies have shown that alopecia areata can be more prevalent in Asian and African patients (Harries *et al.*, BJD 2022, 10.1111/bjd.20628; Feaster *et al.*, JAAD 2022, 10.1016/j.jaad.2022.01.033). This adds to the anxiety and mental health burden seen in these patients. Additionally, wigs will not be addressing eyebrow and eyelash loss which can have functional consequences such as eye irritation, etc. Nail disease can also be very symptomatic with brittle nails causing pain and impacting on patients' activities. Clinicians have limited treatment options, with the main treatments used being systemic agents.

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3	Survey results with figures A. [redacted] response rate. B. Lines of treatments: • First line: ○ [redacted] oral CS ○ TCS ○ intralesional CS • Second line: ○ [redacted] MTX ○ oral CS ○ DPCP • Third line: ○ [redacted] CiA ○ DPCP C. Best treatment (ranking): [redacted] D. Frequency of systemics use:

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	[redacted] E. Frequency of localised scalp treatments use: [redacted] F. Frequency of prosthetic prescription/recommendation:

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	[redacted]
4	We are concerned that the impact of AA on HRQoL has been significantly underestimated in the economic models, and that the committee's choice of BRAVE HRQoL data is a potentially unfair one. As acknowledged by the committee in the ACD, EQ5D results from BRAVE may lack face validity as model inputs (section 3.6). We would like to direct the NICE TA committee's attention to independent analysis of HRQoL in skin diseases for European patients, including those with AA, which showed a 10-point decrement in HRQoL due to AA compared with healthy controls. Although use of direct trial data is preferred in the methods manual, there is flexibility to use independent data sources where the data from the trial fails to match the clinical experience of experts, and therefore is potentially misleading. We would encourage the NICE TA committee to consider the wider body of evidence in this regard and recommend that scenario analysis with HRQoL inputs from independent RWE be conducted. We are concerned that the NICE TA committee's decision to choose the BRAVE EQ5D data over other sources which match clinical experience more closely (as expressed by the clinical experts, accepted by the committee in part 1, and confirmed by independently published data) primarily due to its convenience in populating an economic model is not a fair one. Balieva, F., Kupfer, J., Lien, L., Gieler, U., Finlay, A.Y., Tomás-Aragonés, L., Poot, F., Misery, L., Sampogna, F., van Middendorp, H., Halvorsen, J.A., Szepietowski, J.C., Lvov, A., Marrón, S.E., Salek, M.S. and Dalgard, F.J. (2017), The burden of common skin diseases assessed with the EQ5D™: a European multicentre study in 13 countries. *Br J Dermatol*, 176: 1170-1178. https://doi.org/10.1111/bjd.15280
5	We are concerned that there are NHS-related costs that have not been included in the company or EAG base cases, and which will influence the total costs of both BSC and baricitinib treatment. Significant numbers of patients with AA require referral for

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	psychological support, the cost for which did not appear to be included in the total cost of disease. A population-based study carried out in the UK has demonstrated that depression and anxiety were more prevalent in people diagnosed with AA than in controls (P < 0·001). People with AA were also more likely to subsequently develop new-onset depression and anxiety: adjusted hazard ratio (aHR) for recurrent depressive disorder 1·38 [95% confidence interval (CI) 1·13-1·69], depressive episodes aHR 1·30 (95% CI 1·04-1·62) and anxiety disorder aHR 1·33 (95% CI 1·09-1·63); to be issued time off work certificates (aHR 1·56, 95% CI 1·43-1·71); and to be recorded as unemployed (aHR 1·82, 95% CI 1·33-2·49). Higher rates of antidepressant prescribing were also seen in people with AA (Macbeth *et al.*, BJD 2022, https://doi.org/10.1111/bjd.21055) A UK-based study performed by Alopecia UK reviewed the impact of wig use on social anxiety, anxiety and depression. There were 313 participants commenting on the impact wigs has on their confidence with only 26% stating it would have a positive impact. However 43% of participants stated the wig would have a negative impact due to their concern about other people knowing they are wearing a wig or due to the discomfort caused by the wig or the wig not fitting and falling off. There were 33% of participants who felt the wig restricted their activities. (Montgomery *et al.*, BMJ Open 2017 http://dx.doi.org/10.1136/bmjopen-2016-015468). Patients have to resort to using wigs as a coping strategy. However, the wigs do not help alleviate the anxiety these patients experience from their condition. In certain cases, they have had extremely negative and traumatising experiences such as young patients who have had their wigs pulled off their heads on a night out or in a social setting.
6	We believe this treatment to be innovative, with significant uncaptured benefits which have not been included in the economic modelling of this appraisal. We recognise that NICE methods include NHS costs but not patient-borne ones, however, the NICE TA committee should be aware that wig and orthotic provision in the NHS result in lifetime costs >£10,000 per patient to each patient with the condition. Furthermore, the system impact of patients who are treated with broad immunosuppressive medication has not been fully considered (particularly, in view of the apparent preference to ignore pharmacological therapy for AA as detailed above). These medications require both costly (included in company base case) and burdensome monitoring with significant morbidity long-term from their use. Costs associated with adverse effects due to ciclosporin, methotrexate, etc. (including increased rates of cancers, renal and liver failure, and secondary infections) appear to have not been included, and the benefit of avoiding those remain uncaptured.

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NICE National Institute for Health and Care Excellence

Baricitinib for treating severe alopecia areata [ID3979]

Draft guidance comments form

Consultation on the draft guidance document – deadline for comments 5pm on Monday 20 March 2023. Please submit via NICE Docs.

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Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**none**
Name of commentator person completing form:	Dr Matthew Harries, Consultant Dermatologist & Honorary Senior Lecturer Clinical Expert

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Baricitinib for treating severe alopecia areata [ID3979]

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Comment number	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that ……..
1	I am concerned about the very conservative assumptions made in this appraisal regarding "best supportive care". These assumptions are not consistent with my experience of current clinical practice. Although I did caveat in the discussion of treatment options for AA in the original meeting that my experience is from a tertiary care viewpoint, I am concerned that my comments were misinterpreted. I still work in a large department alongside non-hair specialist dermatology colleagues and receive referrals from across the region. From these interactions there are clearly several treatments currently pursued, with variable success, for treating this condition outside specialist hair loss clinics. As outlined previously, we and other centres across the UK use topical immunotherapy for extensive AA in both adults and children. This position is supported by our evidence-based national AA treatment guidelines from the British Association of Dermatologists (BAD) that recommends topical immunotherapy for extensive AA [Messenger, A.G., et al., *British Association of Dermatologists' guidelines for the management of alopecia areata 2012.* Br J Dermatol, 2012. **166**(5): p. 916-26]. A significant proportion of referrals into my clinic is to access this topical immunotherapy option. Further, many general dermatologists who do not have access to topical immunotherapy will use a range of other options including topical and oral corticosteroids, and various immunosuppressant medications. It is not uncommon for patients to try multiple therapies over time. For example, we have previously looked at the records of 50 consecutive patients with *alopecia totalis* / *alopecia universalis* (i.e. SALT = 100) attending Salford Royal Hospital Hair Clinic; multiple treatments were usual in this population, with >50% receiving three or more secondary care therapies for their AA (MH unpublished data). These treatments may include courses of oral steroids, ciclosporin, mycophenolate and methotrexate, as well as topical immunotherapy. The cumulative costs of these frequently unsuccessful therapies, on top of the personal impact to the patient, are significant to the NHS. Drug monitoring is intensive for most standard immunosuppressants (i.e. baseline screening, weekly bloods initially and regular clinic appointments), and must always be initiated in secondary care, irrespective as to whether there is ultimately shared care monitoring options available once stabilised. Further, virtually all patients will require wig provision in addition and throughout the time of their hair loss, which may be lifelong for some. Unfortunately, those AA patients who do not receive appropriate advice or options to pursue available treatments highlights a significant health inequality but should not distract from what is being provided currently by many dermatologists across the UK and so it feels unfair not to take these used treatments into account for the economic model.
2	I appreciate that the two phase 3 studies did not demonstrate a significant improvement in EQ5D, and the potential reasons for this are discussed in the appraisal document. Importantly, these scores do not reflect my experience of the impact of extensive AA on my patients and using these data alone fails to capture the impact of the disease, and hence the potential benefits of baricitinib. Unfortunately, I am unaware of anyone routinely collecting EQ5D data in their UK clinical practice to inform this discussion [NB. EQ5D will be a measure collected as part of a prospective AA

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	disease register currently being built (due to start summer 2023) that is supported by the British Association of Dermatologists and funded by the British Skin Foundation so these data will be available moving forward]. The Adelphi data, despite its shortcomings, resonate better with my experiences and those shared by the patient representatives in the first meeting. When one looks at the wider literature there are several studies that support the marked emotional impact experienced by people with AA. A recent study suggests a bi-directional association between severe depression and AA, indicating that both conditions are independent risk factors for development of the other [Vallerand, I.A., et al., *Assessment of a Bidirectional Association Between Major Depressive Disorder and Alopecia Areata.* JAMA Dermatol, 2019. **155**(4): p. 475-479]. Biologically, systemic inflammation may contribute, with serum IL-22 and IL-17E levels correlating with depression symptoms [Bain, K.A., et al., *Alopecia areata is characterized by dysregulation in systemic type 17 and type 2 cytokines, which may contribute to disease-associated psychological morbidity.* Br J Dermatol, 2020. **182**(1): p. 130-137] These impacts are highlighted in a UK large primary care database study [Macbeth AE et al. The associated burden of mental health conditions in alopecia areata: a population-based study in UK primary care. Br J Dermatol. 2022; 187: 73-81]. Here, 5,435 people with newly diagnosed AA in UK primary care were identified from the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network database and matched to 21,740 controls. The results were as follows: "Depression and anxiety were more prevalent in people diagnosed with AA compared to controls (p<0.001). People with AA were also more likely to subsequently develop new onset depression and anxiety (adjusted hazard ratio [aHR] DE 1.38 [95%CI 1.13-1.69], RDD aHR 1.30 [95%CI 1.04-1.62], AD aHR 1.33 [95%CI 1.09-1.63]), be issued time-off work certificates (aHR 1.56, 95%CI 1.43-1.71), and be recorded as unemployed (aHR 1.82, 95%CI 1.33-2.49). Higher rates of antidepressant prescribing were also seen in people with AA." The impact of AA is further highlighted in the Global Burden of Disease 2010 estimates of years lost to disability, with mean age-adjusted Disability-Adjusted Life Years (DALYs) attributed to AA being 19.4 globally, where one DALY is equivalent to 1 year of healthy life lost. Alopecia areata was ranking 137th out of 176 diseases in terms of disability burden; ranking higher than psoriasis (144th) and melanoma (138th) [Hay, R.J., et al., *The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions.* J Invest Dermatol, 2014. **134**(6): p. 1527-1534. Karimkhani, C., et al., *The global burden of disease associated with alopecia areata.* Br J Dermatol, 2015. **172**(5): p. 1424-6. Korta, D.Z., et al., *Alopecia areata is a medical disease.* J Am Acad Dermatol, 2018. **78**(4): p. 832-834.] My direct experience comes from running the hair loss service at Salford Royal Hospital for over 10 years. Here we see the significant psychological impact every week in clinic, and these are routinely captured using other validated measures (DLQI / PHQ9 / GAD7). Data collected sequentially from all new AA patients (2017 -2019) into our clinic revealed the following results: Mean DLQI 8.62 with 64/168 (38%) DLQI >10 Mean PHQ9 6.81 with 46/168 (27%) PHQ9 >10 Mean GAD7 5.81 with 41/168 (24%) GAD7>10 Unfortunately, our analysis has not stratified these results by disease severity, so may further underestimate the impact of more severe disease. Strikingly, 10% expressed suicidal ideation because of their hair loss on the PHQ9 questionnaire [Asfour et al. The role of psychological interventions in hair loss patients. British Association of Dermatologist Annual meeting 2021 – abstract]. Finally, AA is one of the commonest reasons for clinical psychology referral from dermatology in our Trust (Psychology services, Salford Royal Hospital – unpublished data), and many more seeking advice outside the trust through their GP or local psychology services.

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	Together, these data show significant emotional and functional impacts of AA that are not captured in the clinical trial EQ5D data.
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Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
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- Do not include medical information about yourself or another person from which you or the person could be identified.
- Do not use abbreviations.
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
- If you have received agreement from NICE to submit additional evidence with your comments on the draft guidance document, please submit these separately.

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Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**Independent clinical expert**
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	Nil
Name of commentator person completing form:	Abby Macbeth

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1	**I am concerned that the use of wigs/orthotics as standard care does not represent the usual care provided by UK dermatologists.** Following my attendance at the committee meeting as an independent expert, I have reflected on the discussions of the day around the definition of standard care/ best supportive care. In my practice, for patients with severe or very severe alopecia areata (AA) of at least 6 months duration, I would offer methotrexate. My regimen for commencing methotrexate includes a 6-week tapered course of prednisolone (starting at 40mg) as per the trial protocol of Professor P Joly (Clinical trials Reg: NCT02037191- The Efficiency of The Methotrexate At Patients Affected By Grave Pelade.) The weekly dose of methotrexate required is often 20-25mg. Treatment would continue for 12-18 months before deciding that there is no treatment effect. The resultant trial, I believe, has not yet been published but preliminary data suggested approximately 1/3 of participants showed significant improvement. Whilst I understand that this may not be the practice of all dermatologists and represents my personal position, I have spoken to many tertiary specialists and many colleagues in secondary care over my years in practice, who will either use a systemic immunosuppressant themselves, or refer to me for consideration of a systemic immunosuppressant (usually Methotrexate), or for contact immunotherapy with DPCP. The use of wigs alone, or discharge back to primary care, tends to be a “last resort” as expressed by my patients who are most frequently seeking active treatment. Wigs are also used in addition to immunosuppressant therapies and DPCP, whilst the treatment begins to work, and so the two pathways are not mutually exclusive and costs of wigs for at least 6 months should also be included in any cost comparison of immunosuppression or DPCP.

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	Concealing the scalp from daylight, with the use of a wig liner and wig, can enhance the efficacy of DPCP contact immunotherapy. With the use of immunosuppression, patients will often also continue on potent or very potent topical steroids in addition. With the use of DPCP contact immunotherapy, Fexofenadine will frequently be co-prescribed as a daily dose to improve local adverse effects and improve concordance. These additions must also be considered within cost-efficacy comparisons, if the selection of best supportive care is substituted.
2	**I have concerns that the use of the EQ5D alone for alopecia areata will lead to significant uncaptured benefit during committee discussions.** I appeal to the committee to consider benefits not represented within the EQ5D, including the impact of improvement in visible difference with treatment on employment, relationships, and other social interactions. The mechanical impacts of alopecia including impaired temperature regulation and mechanical eye injury from grit/dirt in the eyes (from loss of eyebrows/eyelashes) are also not represented within this health utility assessment. In addition, for cost considerations, published epidemiological data demonstrated that those with alopecia areata consulted in Primary care at a greater rate than controls (4·32 (4·27–4·38) visits per year compared with 2·58 (2·56–2·60) in matched controls.)(*Harries et al. The epidemiology of alopecia areata: a population-based cohort study in UK primary care. Br J Dermatol 2022;* ***186:*** *257- 65.)* Wider cost implications for the NHS could include reduction in the cost of primary care consultations. Whilst I appreciate that population level employment data does not ordinarily guide the committee, there is also a population level impact of the potential for those with alopecia areata to return to work. Employment is significantly impacted by alopecia areata with those with AA being more likely to be issued time off work certificates (aHR 1·56, 95% CI 1·43–1·71); and to be recorded as unemployed (aHR 1·82, 95% CI 1·33–2·49).*(Macbeth et al. The associated burden of mental health conditions in alopecia areata: a population-based study in primary care. Br J Dermatol 2022;* ***187****: 73– 81.)* To reiterate the comments of the committee, it is a significant concern that participants are reporting perfect health as measured by the EQ5D in the BRAVE trial, when we know that people with AA are more likely to have depression and anxiety: adjusted hazard ratio

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	(aHR) for recurrent depressive disorder 1·38 [95% confidence interval (CI) 1·13–1·69], depressive episodes aHR 1·30 (95% CI 1·04–1·62) and anxiety disorder aHR 1·33 (95% CI 1·09–1·63) *(Macbeth et al. The associated burden of mental health conditions in alopecia areata: a population-based study in primary care. Br J Dermatol 2022; 187: 73–81.)* As briefly discussed, this likely represents selection bias in the trial population, but could also evidence the inability of the EQ5D to capture the impact of significant visible difference and hair loss, likely underestimating the impact and improvement after treatment with Baricitinib.
3	**I have concerns that the impact of financial costs for the patient of alopecia areata are underrepresented in the draft guidance and do not factor in cost-utility data.** Patient costs and out of pocket expenses are also difficult to quantify, and whilst I do recognise that these costs did factor in discussions, I worry that these may have been underrepresented. Costs include own wig costs, wig maintenance costs, scalp applications, supplements, over the counter treatments (e.g. Minoxidil), private trichology consultations, eyebrow/ eyeline/ scalp tattooing, eyelash prostheses, make-up for cosmetic camouflage, colour matched sprays, and also loss of earnings from social withdrawal and resultant depression and anxiety.
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Insert extra rows as needed

Checklist for submitting comments

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- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
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Single Technology Appraisal

Baricitinib for treating severe alopecia areata [ID3979]

Comments on the DG received from the public through the NICE website

Name	Text removed
Comments on the DG:	
I've suffered from alopecia for 2 years since I was 14, it started off as small bald patches. I felt disheartened initially, i had suicidal thoughts at 14 because of this disease and the isolation from covid was killing me. When school started back up again I was able to cover my patches for about a year and a half because I grew my hair out to cover the patches. Then came about the steriod injections which completely cured my alopecia by july 2022. Then, by october it started again... 1 patch grew into 2 and 2 to 3 and so on. Every small task i would do I would see hair everywhere, on my laptop, desk, textbook, when i ran my fingers through my hair bundles of hair would fall. By January I had lost all hair, scalp, eyebrows, eyelashes, pubic. I had lost all hope and was at an all time low with my head flooding with depression and suicidal thoughts everyday. But then i heard about a new drug called olumiant "could this possibly help me when I reach 18" i thought, I was given hope and the past 2 months i was actually feeling happy. I regularly check this website to see i anything had changed and when i found out olumiant was not reccommened by NICE i was shattered and the thoughts came back (although they really never left). reading an article from alopecia UK they stated that the commitee found that "hair regrowth can have a profound impact on improving a person's quality of life, but based on the data from the clinical trials, the extent of this improvement in quality of life is uncertain" and that the commitee uses a "cost-effectiveness" system. your probably wondering what my story has to do with me commenting. Well... I'm here to say [text removed], YOU PEOPLE DONT THINK WE'RE WORTH THE MONEY, "improvement in quality of life is uncertain" OF COURSE MY QUALITIY OF LIFE WOULD INCREASE, I WOULDN'T TO HAVE TO WEAR A HAT ALL THE TIME, I WOULDNT HAVE TO MAKE UP STUPID EXCUSES OF MY MY NAILS ARE SO [text removed], I WOULDN'T HAVE TO LOOK AT MYSELF AND WONDER WHY I'M SO [text removed] UGLY SO [text removed]	

Name	
Comments on the DG:	
I am a patient at York hospital who has been suffering from severe alopecia areata for around the last 6-7 years. I previously lost c.50% of the hair on my head in around 2009 as well and was treated then using diphencyprone (DPC) at a London hospital, where I lived at the time. This seemed to be successful and my hair regrew until it fell out again in around 2016. I had	

previously received oral steroids and steroid injections, which appeared to have no impact on my condition. My recent hair loss has been more extensive and over the past 6-7 years I have lost all the hair on my head, my eyebrows and some patches of hair elsewhere on my body. Currently I have zero hair on my head and patchy eyebrows, but my eyelashes and body hair are unaffected. I recently stopped the DPC treatment I had been receiving at York for around 5 years on and off, as whilst it had contributed to extensive regrowth, this ultimately always fell out again, causing a significant amount of distress and a belief that the treatment was a waste of time for everyone involved. I had been attending a weekly clinic and had also experienced severe discomfort on occasion, for example when the DPC accidentally got onto my eyelids, causing blistering. Following a recent consultation with the Dermatology consultants, I understood I had their support for treatment using baricitinib once it had been approved for use by NICE, and that it was considered a safe and effective treatment that was already in use for patients with severe eczema. Subject to being mindful of potential side effects, this made me feel positive for the future, having lived with this condition for such a long time. Now I am concerned that this door will be closed to me, which makes me feel rather hopeless.

Effects on quality of life

Having severe alopecia areata affects my daily activities and mental health. I am unable to leave the house (or even answer the door) without a wig or head covering. Swimming used to be something I enjoyed, but now I avoid it, as I do not feel comfortable wearing a swimming cap, and a fabric head scarf makes my head very cold. People sometimes approach me and ask me if I have cancer, and while I know they mean well, this makes me feel uncomfortable and disheartened. Wearing a wig can be itchy, hot and uncomfortable, but wearing a head scarf can lead to questions or comments - for example, I feel I have to wear a wig to work to avoid causing colleagues and clients to become confused or uncomfortable. My kids "use up" their birthday wishes, wishing for my hair to grow back. I am only grateful that I have a loving husband and family as I think if I had experienced hair loss as a young person that would have been very difficult for me indeed.

Treatment options

As noted in my general comments, I feel fortunate to have been able to access DPC treatment in both London and York. This has worked for me in the past, but unfortunately in recent years the hair has always started falling out again - even whilst the treatment is ongoing. Having previously tried oral steroids and injected steroids, as well as minoxidil, I believe I have exhausted existing treatment options. At my last appointment light therapy was mentioned, but it was felt this would be unlikely to work even as well as the DPC. I have never had a wig on prescription as my understanding was that only limited choices would be available to me. However, I do not see a wig as a 'treatment' as such anyway.

Positioning of baricitinib

I would be grateful for the opportunity to try baricitinib, as my clinicians are supportive of this in my circumstances. As noted above, apart from trying light therapy, I understand I have exhausted existing options. Light therapy would mean a return to weekly clinic visits with little confidence of success.

Conclusion
I understand that the NHS has finite resources but I want to conclude my comments by stressing that severe alopecia areata is a condition which I think is deserving of greater treatment options. I have seen what is available and it is limited. DPC was unlicensed and carried no guarantee of success. It worked for me to begin with but despite persevering with it, my later experience was a cycle of regrowth and further hair loss. This has had a significant impact on me and has caused me further stress and potentially exacerbated other stress-related conditions that I have. I don't think I should have to look forward to a future in which I am bald for the rest of my life and just have to cover my head with a wig or a head scarf. Thank you for reading and considering my input.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
Recent research published in
Acta Derm Venereol 2023 Jan 25;103:adv00855.
doi: 10.2340/actadv.v103.4536. Comparative Efficacy and Safety of Janus Kinase Inhibitors Used in Alopecia Areata: A Systematic Review and Meta-analysis by Farnam Barati Sedeh et al
Link available at 10.2340/actadv.v103.4536 clearly states that Alopecia Areata sufferers have a 66-74% lifetime prevalence of psychiatric disorders with a 38-39% lifetime prevalence of depression and a 39-62% prevalence of generalized anxiety disorder. The NHS are currently spending significant amounts on counselling, hospitalisation for mental health and medication for people with AA. Money would be better spent on effective medication such as Baricitinib that could help patients manage the condition. Many UK citizens, including myself, are having great success with Baricitinib that we buy from abroad under the supervision of private dermatalogists. In addition, these dermatalogists are predominantly working in the NHS and are frustrated by the lack of support for this medication. I believe AA is largely a hidden disease, I have not been to an NHS dermatologist for 20 years (I have Alopecia Universalis) as there was nothing further they could offer me. Therefore I am not in any of your statistics about the prevalence of Alopecia in this country. The studies highlighted were flawed in their assessment of mental health improvements, as noted by the dermatalogists who took part in the meeting. Hope that your hair will grow at the beginning of a trial obviously improves mental wellbeing. There was no evidence provided to the current cost of mental health services for Alopecia sufferers. Most sufferers require psychological and mental health support form the NHS. The fact that the USA have granted approval for Baricitinib and experts such as Dr King et al from the USA are reporting significant hair growth for alopecia sufferers was not mentioned. Also I do not believe that Alopecia UK should have been the only patient representatives, with two

members present. This organisation does not represent all UK sufferers and the failure to have other patient voices was unfair. The two members spoke well but their case lacked any real data that may have swayed the commitees decision.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
The cost effectiveness does not account for mental health treatments that are currently provided by the NHS. The poor use of wig prescibing is currently a farce. I have had one prescription in 20 years despite being Alpocia Universalis. The cost to the NHS to process requests is costly in itself and not fit for purpose. I spend at least £800 a year on a real hair wig as lots of alopecia sufferers also have eczema and nylon wigs are impossible to wear without causing a skin reaction. You have not calculated loss of earnings and therefore tax revenue for this country. Due to the effect on sufferers mental health most people have a significant period of time where they are not in the workforce and contributing to society. I count myself in this group.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No. Evidence from the alopecia community was severely lacking. No statistical evidence was provided regarding the costs of mental health services and the effectiveness of those of us using Baricitinib (which there are many). I have substantial regrowth after 4 months on Baricitinib after 20 years Alopecia Universalis. I now have eyelashes and eyebrows too. I have to pay a private dermatologist at significant expense. The recommendations don't take into account monies that are currently spent on treating Alopecia patients other associated autoimmune and mental health ailments. This money could be saved by the use of Baricitinib.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Yes. There has been discrimination in a number of areas. The implication that it is not as bad for men was ill-informed and discriminatory. Losing your head and facial hair completely strips you of your identity to the point where people no longer recognise you. There was no patient viewpoint from men or young people who have a massively different perspective from the middle aged women from Alopecia UK. The assumption that wigs would be a solution for a young male is ridiculous. Wearing a wig as an adult woman is humiliating enough.
I think there is also discrimination on older age groups with more research linking autoimmune disease with dementia surely the NHS has a duty of care to help us all have a better old age and live a full life. I see the NHS has funded an anti-obesity drug this week. I am not overweight, I've always lived a healthy lifestyle and through no fault of my own I have Alopecia Universalis. Is it not discriminatory to help one group of patients and not

another? And finally please try and empathise - put yourself in our shoes for a day and imagine the mental toll of having no hair. You never get used to it and a wig certainly does not compensate. Baricitinib is helping me in all areas of my health and with your support long may this continue. Thank you

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
Yes, I have read all of the evidence.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No, the summaries are not appropriate and reasonable interpretations of the evidence; they seem patriarchal and condescending to sufferers of alopecia. The cost of treatment as a sole determiner of whether or not a patient should receive the drug to remedy the problem is short sited. There are many hidden costs that occur with a person having alopecia that have not been included in the outcome. Providing money for a wig is not a solution to the problem. Also. the disease can also mean loss of eyebrows, eyelashes, etc. Physical appearance equates with mental well being. Having to operate in life, school, work, etc. can be excrutiatingor even unbearable for some with alopecia. Taking away the opportunity to rectify this issue can only hamper efforts for these people to live fully functioning lives and contribute completely to society.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No, the recommendations are not sound. A superficial idea of the costs involved for patients dealing with Alopecia is what is considered. Also, because women are effected by the side effects of alopecia more than men because of societal norms, the decision is a patriarchal and condescending one that doesn't fully consider the role of women in society and how important it is to look and feel one's best in order to contribute.

A generic form of the drug could be substituted for Eli Lilly's version, saving the NHS money.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
This initial decision is discriminatory towards women, claiming that protocols in use now are cheaper and satisfactory for patients, most of whom are women. This is not the case and could result in costing the NHS more in the long run as women patients have to deal with loss of work, depression, anxiety, etc. so much more than men who encounter a different standard for looks in our society.

Name	
Comments on the DG:	

My 21 year old son has alopecia universalis and has suffered for over two years. His GP didn't offer any type of treatment at all including any counselling, which we paid for privately in the end.

My son is studying drama at Falmouth University and I can't emphasise enough the impact this disease has had on his life and mental health. It has been severely stressful for him and for my mental health too as obviously I worry about him. About 18 months ago, he was having suicidal thoughts - thankfully his is coping better now.

The prospect of a treatment being available - i.e. the JAK inhibitors - that are readily available for other auto immune conditions has given us some hope. So to hear that NICE has not approved it in this first round is profoundly upsetting to say the least. Please can we implore you to approve this treatment for Alopecia suffers so at least it might work for some of them and give them back some semblance of a normal life. GP and treatment support needs to be radically improved.

Many thanks

[redacted]

Name	
Comments on the DG:	

The document talks about the psychological impacts of alopecia areata and that these are not improved with the use of Baricitinib. I am very surprised by this response. As a parent to a 15 year old boy who started with AA at 3 years of age and has had extensive >70% hair loss issues over the last 12 months I would be interested to see the research that shows that hair regrowth caused by this medication does not significantly improve mental health. My 15 year old wanted to take his own life due to his AA and we found little help from the NHS and were only offered topical treatments of which evidence shows has little effect with over 50% hair loss. He felt there was no hope wearing a wig at 15 years old offers no comfort at all.
We have been forced to access private health care at huge financial cost and have been using Baricitinib for 4 months with significant hair growth. The change in my sons mental health is huge he is attending school which for a lot of young people with this disease becomes not an option . I would urge NICE to look at figures on the percentage of young people with alopecia that are home schooled.
These drugs are used for rheumatoid arthritis and it seems that if you are in physical pain then NICE can justify the costs of Jak inhibitors as a treatment. But as alopecia is continually referred to as cosmetic the same courtesy is not applied. As a parent who has lived with a child suffering with this disease I can clearly state this I s not cosmetic and I would hope NiCE have worked closely with alopecia uk to look into the many factors of alopecia and its long term devastating effects.
As a health care professional it saddens me to see that this group of patients and their suffering is not validated by NICE. This drug makes hair grow back and the impact of this on individuals is life changing.
I hope the many views of alopecia sufferers are considered by NICE for these recommendations. Also looking at how these drugs have been recommended for AA treatment in both Europe and the USA. I hope the UK follow suit.

Has all of the relevant evidence been taken into account?
No I do not think so. When talking about alopecia suffers who have been questioned as no one in the alopecia community I am part of have answered any questionnaires.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No. As have the costs to mental healths services and private counsellors been factored in as many people have to access this due to the psychological impact of AA.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No as currently there are no options to AA sufferers for a treatment that can work potentially long term. There is clear evidence this is a treatment that has clear clinical benefits for the first time in AA.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
I don't think enough has been said about the true cost of severe alopecia areata. Those who as a result of their severe alopecia areata are not participating fully in society. Lost work days - how can you quantify that? It's hard but it is happening. The cost of those with alopecia areata accessing mental health services, antidepressants, wigs, various other treatments, dermatology appointments. I think the 'no active treatment' comparator is not relevant in itself.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
I am gravely concerned that 'no active treatment' was used as the comparator for cost-effectiveness! This is wholly unreasonable. Many people with severe alopecia areata are not on an active treatment because there aren't any other licensed treatments available. We don't have drug options! We are often dismissed without any treatment offered to us. Many people with severe alopecia areata are not choosing to be on no active treatment! It's not a fair comparator. Baricitinib offers true hope to patients with severe alopecia areata.

Are the recommendations sound and a suitable basis for guidance to the NHS?
I do not believe the recommendations to be sound. I have big concerns about the quality of life assessment tool that has been used. I do not believe that EQ5D measures the psychological impact of living with a visible difference. I know that people feel they are 'getting their lives back' when their hair comes back when taking this drug privately (at huge cost, or huge risk if purchasing from online overseas pharmacies and not getting appropriate supervision), so I do not understand how a conclusion has been reached that a significant improvement in QoL is not evident. More needs to be done on this.
This drug needs to be available via the NHS because too many people are taking this privately, with different attitudes to health risk and financial risk. Some are purchasing the drug and not putting in place adequate health-monitoring. Others are opting for private treatment as they are so desperate to get their life back that i've heard of people wracking up thousands of pounds of credit card debt, or even remortgaging their home!
If this very same drug can be approved for the treatment of atopic dermatitis and rheumatoid arthritis, I do not understand why NICE is not recommended for alopecia areata. I really hope there is not any 'it's just hair' bias creeping in to anyone's decision making. Alopecia areata is an autoimmune disease. It is something that causes huge amounts of emotional distress and leads to mental health impacts for so many of us with this condition. We really deserve to be able to have the option of a treatment.
I write this as a patient with severe alopecia areata. One who, herself, does not wish to take baricitinib. I have concerns about the lack of long-term safety data, and I have reached a place of acceptance with my hair loss.

Not everyone with severe alopecia areata will wish to take this drug. But it absolutely should be made an option for those who struggle EVERY SINGLE DAY to live rather than simply exist. That's what alopecia areata does for some people. It takes them from someone living life, participating in society, to someone who merely exists, perhaps not even going to work, education or having any form of social life.
If baricitinib can give some people their hair back, as the clinical trial data clearly shows it does, it should be recommended as a treatment option for those with severe alopecia areata to allow those who suddenly develop this autoimmune disease, often very quickly without warning, to have a chance of a normal life.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
People with severe alopecia areata would fall under the 'disability' group on the basis of 'severe disfugurement'. This is supported by many other visible difference groups and charities. I feel by not recommending this drug, this group of patients is once again being overlooked and dismissed. Whilst this might not be unlawful discrimination (I'm not a lawyer so unclear on what constitutes discrimination), I would be very interested to understand why this drug can be recommended for the treatment of two other medical conditions and not for severe alopecia areata. As i've alluded to earlier, I really hope there is no 'it's just hair' bias creeping in to any decision making as this would be hugely unfair and not recognise or understand the mental anguish that alopecia areata can cause.

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? Don’t feel that evidence from America studies by Brett king have been fully taken into account as these have good hair regrowth and much better efficacy than other treatments - these are first new treatments in over 15 years. **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** This treatment would have a huge psychological and social effect on people with alopecia universalis. This hasn’t been fully taken into account. AU can be life limiting and have mental health concerns attached. **Are the recommendations sound and a suitable basis for guidance to the NHS?** I don’t believe they are.	

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
The committee have heard evidence from the patient representatives and clinical experts of trauma, anxiety, depression, isolation and disrupted identity due to alopecia areata, with a major impact on a sufferer's ability to work, socialise and have intimate relationships. This is very much in line with my own experience as a person suffering from severe alopecia areata. Severe alopecia areata has had a life changing effect on me. I have total hair loss that has led to significant ongoing issues of anxiety and depression, for which I receive anti-depressant treatment on the NHS. I am also paying for private counselling because of difficulties accessing NHS mental health treatment. The mental health impact of my hair loss has been a very significant factor in me requiring 3 months sick leave from work and ultimately has led to the breakdown of my marriage.

The patient representatives' and clinical experts' evidence, as well as my own experiences of severe alopecia areata, is significantly at odds with the BRAVE health-related quality of life measures. This study has a baseline where almost half of people are classed as at full health. While the committee acknowledges that the health-related quality of life measures in the BRAVE study is likely to underestimate the impact of severe alopecia areata, I do not believe the committee have given sufficient weight to the evidence presented by the patient representatives and clinical experts.

The evidence of the patient representatives and clinical experts is qualitative in nature, based on their life or clinical experience, rather than the quantitative nature of that provided by the BRAVE trials. The more intangible nature of qualitative data makes it more challenging to use as a definitive numerical basis for cost-effectiveness. This results in a situation where it is acknowledged that the BRAVE study's health-related quality of life measures are flawed and not truly representative, but are still used as the basis of the assessment as there is no quantitative evidence available on the true impact of severe alopecia areata. The high baseline in the BRAVE study also means that there is difficulty in proving a statistically significant or clinically meaningful treatment response on mental health, further skewing the assessment of the cost effectiveness of the treatment. These issues are acknowledged by the committee and an attempt made to correct for this. However, for a truly effective appraisal of baricitinib for treatment of severe alopecia areata, in the absence of reliable quantitative data, greater weight must be given to the qualitative evidence of the patient representatives and clinical experts.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
The committee have concluded that baricitinib is clinically effective at improving hair regrowth, as demonstrated by the BRAVE study. The cost effectiveness of this treatment has been derived from health-related quality of life measures based on qualitative data from a large clinical trial (BRAVE). At face value, the source of the data for the health-related quality

of life measures appears more reliable than other possible data sources, but when the committee itself acknowledges that it underrepresents the impact of severe alopecia areata, it is still a flawed and a misrepresentative measure to use as the basis for cost effectiveness. The summary of the cost effectiveness cannot be a reasonable interpretation of the evidence.

Are the recommendations sound and a suitable basis for guidance to the NHS?
The contents of the draft guidance clearly highlights the disparate nature of treatment of alopecia areata on the NHS. The report concludes that there is little consistency on the current approach to treatments, with geographical limitation on access to these treatments. This is typified by the assumed best supportive care approach in the report being limited to wigs and orthotics at best. The people who are impacted by the current arrangement are the sufferers of severe alopecia areata. It is a condition that has a life changing affect on a person's wellbeing but is met with little to no support and treatment provided on the NHS. For a condition that itself is isolating for sufferers, this effect is further enhanced by the antipathy shown by the NHS.

Clinical experts have described baricitinib as a step-change in managing severe alopecia areata. The committee itself concludes that baricitinib is innovative and clinically effective at improving hair regrowth. This treatment could, for the first time, provide for those who wish to follow this path, the basis for a clear, consistent and effective treatment pathway for people who have suffered the most severe detrimental trauma/impact to their quality of life, through the psychosocial impact of hair loss.

The basis of the recommendations in the report are based on the cost effectiveness of the treatment being assessed using data that is acknowledged to underrepresent the true impact of severe alopecia areata. The recommendation cannot therefore be judged as sound and suitable.

Name	
Comments on the DG:	

Hi

Just wanted to share my experiences with Alopecia Universalis . I waited months for an appointment with an NHS dermatologist who have provided no help at all.

I was told I was a poor prognosis and that nothing could be done to help me and that I'd have to "live with it".

I first noticed a coin sized patch in my beard in 2019. I am a Cognitive Behaviour Therapist and work for the NHS. At the time I was under a lot of stress and pressure at work which I thought may have contributed towards the hair loss. The patch slowly started to get larger and in 2020 I noticed I was also getting patches in my hair.

In 2021, over the course of around a month, I lost all the hair on my head, including eyelashes and eyebrows. The following month I lost all the hair on my body. Adapting to such a dramatic change in appearance was not easy and is still tough. As a father of three young children, I have to try and deal with the impact such a dramatic change in my appearance has had.

Unless you have suffered with this condition you will never know the extent of the impact it has on you. I don't recognise myself anymore and I have to battle everyday with the sense of anxiety it evokes in me. Losing all the hair on your face, head and body has a dramatic impact on your mental health and I think it's disgusting that we are so far behind the USA in addressing this life changing condition.

Name	
Role	GP
Comments on the DG:	
As a GP I have seen several patients with alopecia and the devastating effects it has on their mental health. Alopecia is not a cosmetic condition! This condition should be treated as seriously as rheumatoid arthritis for which this drug is licensed. The cost to the health care system and the economy to treat mental health issues suffered by people with Alopecia is great and to deny sufferers this drug is unfair (given this is the only drug for which we have evidence of effectiveness).	

Name	
Comments on the DG:	
Dear Sir\Madam In November 2022 my entire life was turned upside down when my first bald patch appeared (roughly 5% hair loss) on my scalp. I telephoned for a GP appointment which wasn't given but instead a telephone call who sent me to a nurse for blood test (2 week wait for blood test). These tests showed inflammation in the body and I required further tests that needed to be taken 3 weeks apart. 3 weeks later the test came back all normal. I telephoned for another GP appointment due to even more loss (20% hair loss), again refused an appointment but a telephone call that basically said a large majority of people suffer hair loss and that mine was just severe and the NHS doesn't really treat it. I pushed and pushed to be referred to a dermatologist. 5th January 2023 received a letter from Aneurin Bevan University Health Board that stated that the Welsh Government had set targets of 36 weeks wait but they were nowhere near this target. When I phoned for more clarity, they said it could be up to 2 years! 16th January - I attended a private dermatologist and was diagnosed with Alopecia Areata and it's most probably one of the worst cases she seen since it only started in November, 50% hair loss at this point. They recommended Steroid Injections to the scalp but because of the severity it	

may require oral steroid on top. They administered the steroid injections and I was to return in 4 weeks for another set of Injection and a prescription for oral steroid.

15th February – Appointment with the private dermatologist who gave a second set of steroid injections and also prescribed oral steroids. My hair is now at 80% loss and they've told me that this will be my last set of treatment as they feel it's just prolonging the hair loss and I should prepare for total loss. They were quite surprised I still had eyebrows and eyelashes.

22nd February – I was declined the 2 free wigs on the NHS due to being diagnosed privately as only an NHS dermatologist can prescribe the wigs. I've now had to purchased one privately.

The last 3 months have been an absolute rollercoaster that has not only taken its toll mentally on myself but also my son and husband. The first 2 months my son would get up early in the morning to help conceal my bald patches with spray to give me the confidence to go to work. I would go to bed around 9pm each night but would lie awake for hours worrying how much hair was going to be on the pillow the next morning. You try and relax by having a nice hot bath but there's nothing relaxing about having hundreds of strands of hair just floating around in the water. You switch to a shower to try and get away from the anxiety of the bath but then the shower tray overflows because the hair has blocked the plug hole.

Socially I have withdrawn from everything, we didn't celebrate my birthday because I didn't want to be the freak sat in a restaurant with a hat on. My son plays for a rugby team and whilst I support him every match because it's winter, I can stand in the cold with a hat on but we don't go back to the club house anymore for food and celebrations afterwards. The only reason I drag myself out of bed each morning is because I need the wage to pay privately to treat my alopecia.

With regards to the decision to not approve Baricitinib for use on the NHS I find this decision absolutely appalling, especially as the treatment is given for other conditions. Whilst I agree that arthritis patients do suffer physical pain the mental impact for hair loss patients can out way any physical pain. For the trial to show that the drug was 50% effective for treating severe alopecia areata, that's 50% of people whose mental health has improved massively. In reality, hair loss patients are being forced to pay into an NHS which provides inadequate services and also inadequate medication.

This drug needs to be approved for use in the NHS. The NHS is FAILING people with hair loss!

Name	
Comments on the DG:	
It is utterly heartbreaking to see that the use of Baricitinib has been rejected in the UK for apparently just being too expensive. Can a cost be put on mental health? Children have literally killed themselves due to the effects of Alopecia and the impact it has on their life. It's not enough to say that counselling is available. It's not good enough. The board who have rejected this need to seek out more first hand experience of the utter devastation that Alopecia can cause on individuals and their families. As the parent of a 12 year old who has suffered from alopecia for 18 months in a constant cycle of loss, regrowth, loss, regrowth, loss I have seen first hand the physical and mental impacts it can have - not just on my child but also on the parents. Even our own dermatologist recognises that JAK inhibitors are the best option, and were we living in a host of other countries we would be able to access JAKs. I wonder whether the same outcome would have been reached if any of the board suffered from Alopecia? Baricitinib, and JAKs in general, are proven to work. They need to be approved. **Has all of the relevant evidence been taken into account?** No. **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** No. **Are the recommendations sound and a suitable basis for guidance to the NHS?** No.	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? There is no appropriate evidence on the Impact on Quality of life. It is ludicrous and simplistic to use the quality-of-life assessment tool for alopecia as it only focuses on the physical aspect of illnesses. There are physical ramifications from having alopecia and these include difficulties with wearing wigs, and eye/nasal problems due to lack of protection from hair. Sports participation in and out of doors is very challenging and requires sheer determination. However, the tool does not acknowledge the devastating psychological effects. Alopecia affects patients every moment of every single day as it is impossible to forget about it. This is comparable to other illnesses, it is just more difficult to measure. However, literature is full of evidence on this: https://pubmed.ncbi.nlm.nih.gov/23700152/	

“We found a high prevalence of comorbid conditions among individuals with AA presenting to academic medical centers in Boston.”

https://www.sciencedirect.com/science/article/abs/pii/S0190962219308904

“This study suggests that patients with AA are at higher risk of both anxiety and depression”.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8260215/

“AA has substantial psychosocial impact on patients and results in reduced health-related quality of life. Addressing this should be an active part of treatment”.

https://medicaljournalssweden.se/actadv/article/view/1622/3038

The results indicate that patients with alopecia areata had greater odds of subsequent depression within 2 years from alopecia areata diagnosis, and showed a steeper increase in cumulative probability of depression as time progressed (log-rank =336.38, $p < 0.001$), compared with the opposite trajectory. All patients with alopecia areata had comorbid depression within 10 years of alopecia areata, compared with 70% of depression patients receiving diagnoses of comorbid alopecia areata within the same time-frame.

https://dermnetnz.org/topics/psychological-effects-of-hair-loss

“These symptoms can have a severe impact on an individual’s mental health, ability to work or study, and well-being”.

I truly hope that NICE read every single patient experience report and take on board the massive impact this has on alopecia sufferers. Some alopecia sufferers may feel the psychological burden is too great to bear. To deny a trial of an effective treatment for alopecia is scientifically wrong and morally reprehensible.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
Baricitinib has been shown to work for many patients, with hair growth in around 50% of people with severe alopecia. It is a licenced treatment and NICE have made the decision not to approve this in the NHS due to cost effectiveness. As a doctor myself, I would like to argue this:

- This is an autoimmune disease which is hugely under resourced and underfunded, with support being a lottery in different regions. The current upfront current cost to the NHS is minimal due to the lack of licenced medications. There are however unseen costs which include time off work (my daughter works in the NHS), and counselling/CBT costs.
- NICE acknowledge that there is an unmet need for alopecia. It is therefore very unjust to look at the increased costs of prescribing Baricitinib

when it is acknowledged that there has been no effective treatment to date! This is surely how medical treatments progress. More and more treatments become available following research for many different illnesses, particularly in oncology.

- NICE have approved more expensive treatments with far less than a 50% chance of success in the past.
- NICE acknowledge that Baricitinib is an “innovative treatment”. The cost of private prescribing and monitoring is prohibitive to the vast majority of patients. This is likely to place further psychological and financial burden on alopecia sufferers.

Are the recommendations sound and a suitable basis for guidance to the NHS?

The NHS is a wonderful organisation albeit with limitations. Ultimately it is here to provide the best possible treatment possible for patients.

My beautiful 30-year-old daughter has been struggling with alopecia for more than 10 years, and with alopecia totalis for 3 years. It has been a heart-breaking journey for her and for all the people who love her. She is an active, outgoing, and sociable young woman and alopecia has hugely affected her everyday life and impacted on her confidence and mental health. She works as a nurse in intensive care and regularly receives wonderful feedback, which is not surprising as she is a hugely caring and empathetic person in and out of work. She slogged through the pandemic whilst coping with isolation and the devastating impact of her progressive alopecia. She has been incredibly proactive in learning about alopecia, joining alopecia UK and attending local meetings. She is lucky to have a very understanding and empathetic dermatologist locally who has given her scalp steroid injections. Unfortunately, this may have caused her to rupture her Achilles tendon and injections were stopped. She has been attending weekly sessions for phototherapy for more than six months, being determined to do all that she can to reverse her alopecia. Sadly, there has been no sustained response to this therapy.

I cannot begin to describe how difficult it is to watch my daughter going through this. She is very well informed about treatment options and is very realistic about these. To deny her and others the opportunity to try new innovative treatments goes against the whole ethos of the NHS.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

I believe that the disability provision of the equality act applies to severe alopecia. This is of course ultimately a legal decision. To argue this is not the case will leave NICE open to legal challenges. As per the definition of the disability provision of the Equality Act:

"'substantial' is more than minor or trivial, eg it takes much longer than it usually would to complete a daily task like getting dressed". It is clear that this applies to many daily tasks of daily living across the spectrum of normal life.

- Getting ready to go out/go to work is a daily battle. Alopecia totalis sufferers have no eyelashes or eyebrows in addition to managing the challenges of wearing a wig. Options are to go out with no eyelashes/eyebrows or spend a significant length of time applying false brows/lashes. Many people would struggle in a public facing role for these reasons. It is therefore possible that they limit work choices because of this. What adjustments would be possible in these types of roles to make the workplace a level playing field as per the Act?
- Social occasions are also challenging, and many sufferers becomes very anxious, leading to social isolation.
- Participation in sports is difficult. Having no nasal hair or eye lashes removes the natural defence which hair provides for filtering debris entering the nose and eyes in addition to secretions flowing rather than being slowed down by nasal hair. Sweat irritates the eyes due to removal of the barrier provided by hair.

"'long-term' means 12 months or more, eg a breathing condition that develops as a result of a lung infection". The majority of alopecia sufferers have difficulties ongoing for more than 12 months.

Name	
Comments on the DG:	

Effects on quality of life

My anxiety levels are 'through the roof' as I see no future ahead for me. I have anxiety and panic attacks when leaving the house and interacting with other people. I recently had an opticians appointment where I complained about a pricking sensation in my eyes and the clinician commented on the amount of debris that had accumulated underneath the skin of my eyelids which was causing the discomfort was caused by my lack of eyelashes so this is also another symptom of the condition which the optician could do nothing about. I used to be a confident female but that has all changed as this has all gone now. I cannot lead a normal life and this is not helped by repeated hospital appointments where no help can be offered. I find it very unfair that this treatment is now offered in the EU with Germany seeming to be leading the way. Also available in the US. This treatment has been approved for use so why is it not available? I wear a wig which is easily identified as one which makes me very anxious also extremely uncomfortable and hot and causes me constant headaches. I would urge a different decision at your next meeting as you have no idea how distressing this condition is. It has impacted my family immensely also.

Has all of the relevant evidence been taken into account?

As far as I can tell

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
What is the cost versus a persons life?

Are the recommendations sound and a suitable basis for guidance to the NHS?
I my opinion yes

Name	
Comments on the DG:	

I have lived with alopecia in various forms for 20 years and I have never been able to come to terms with this condition. We get very little sympathy as it's not life threatening as far as medical terms go but I can tell you it most certainly is life threatening. I have considered suicide several times because of how it has made me feel about myself I've seen at least 9 dermatologists and non of them have been helpful or sympathetic towards me. They just hand you a prescription for a wig and tell you to be on your way. I am on anti depression tablets and on a waiting list to see a psychologist for help but how much is that all costing the NHS?? when there seems to be a obvious cure out there why not let people like me try it? I hope that who ever reads this sees how easy it would be to make so many lives worth living. Thank you

Name	
Comments on the DG:	

Alopecia itself may not currently cost the NHS much in terms of funding, there is currently no treatment for Alopecia, so any form of treatment will be more costly. The implications of Alopecia, however, are most certainly costly to the NHS, in the form of antidepressants being prescribed for the depression it causes, self harm, counselling the is prescribed for those suffering from a lose of self identity. Treatment for self medication and binge eating disorders it triggers and the repercussions of those - for instance obesity, type 2 diabetes, liver disease.

The psychological impact of severe Alopecia has been completely disregarded and most certainly hugely under estimated in this recommendation. Severe Alopecia impacts every aspect of life, from your job - reluctance of going for interviews or promotions as you look different and perspective employers and colleagues may judge you negatively. Exercise / not being able to confidently undertake healthy pastimes such a swimming for fear of ridicule in a public setting. Romantic relationships suffer due to fear of rejection and intimacy inevitably suffers. These are just a few aspects of life that are affected and collectively these all have a huge impact on the mental and emotional health of those with severe Alopecia.

Has all of the relevant evidence been taken into account?
The psychological implications of severe Alopecia have been dramatically down played if not completely ignored. Severe Alopecia impacts every aspect of a persons life.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
There is currently no treatment for Alopecia, so of course it is not costly to the NHS, so any form of treatment will cost the NHS more than is currently does. Although Alopecia directly does not cost the NHS, the implications of certainly do. Antidepressants, counselling, treatment for self harm caused the by the depression it triggers. Treatment for self medication and eating disorders (leading to obesity or anorexia) that are triggered by the complete loss of identity and control.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No the recommendation is not sound or suitable, severe Alopecia is a life changing condition which huge mental health implications and also physical implications that have been completely disregarded in the recommendation.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Alopecia affects both men and women, however it is more socially accepted that men suffer with hair loss, female hair loss is a taboo subject the women feel they are forced to hide. A man with hair loss walking down the street would not receive any like the number of looks, or negative comments that a female with hair loss would.

Name	
Comments on the DG:	
Baricitinib not being approved by NICE for use on the NHS for the treatment of Alopecia is extremely devastating to me and my family. My mum has suffered with Alopecia on and off for many years and the impact it has had on me, her daughter is huge but nothing compared to the impact it has had on my poor mum. She is the strongest and bravest person I know and she fights with her mental health as a result of her Alopecia everyday. She remains a pillar of strength for our family and always puts everyone else first. She isn't the person she should be and is capable of being due to the stress and worry of having Alopecia. As a woman, hair is a huge part of feeling feminine and beautiful. To me & my family she is still the most beautiful person in the world but in hurts us so much that she can't see it due to her Alopecia. We love her so much and want nothing more than for her to be able to be happy. She's 70 next year and has worked so hard for her whole life! I want her to be able to enjoy her retirement like she deserves and be able to travel and socialise without the constant worry. She is also in constant discomfort, anyone who hasn't worn a hair piece day in day out has no idea how uncomfortable it is and how much it brings her down. The medication has been approved on the NHS for treatment of other	

autoimmune diseases and so this makes no sense to me. It has also been proven to be successful in the treatment of Alopecia privately and in other countries so this seems hugely unfair. The fact that Alopecia isn't taken seriously as a condition that needs this medication is an insult. Especially in this day and age when so much emphasis is being put on the importance of mental health.
Please help my lovely mum! She is one of the most important people in the world to me & I want nothing more than for her to be happy.

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? The Quality of Life Assessment tool EQ-5D is not a suitable tool for using against this condition. A separate assessment tool should be used. This tool is not a true reflection of an assessment of our quality of life and how it impacts us. The tool is totally inappropriate for measuring our daily life. I may not have a physical pain but it's an emotional pain.X **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** Alopecia universalis has been part of my life for 13 years. The trauma of losing my hair has been immeasurable. It causes me psychological pain with high levels of anxiety, depression and embarrassment. It's very damaging and causes emotional turmoil and suffering which has led to personal marital problems with intimacy, social phobia with paranoia that everyone is looking at me. I have lost my identity with feeling feminine, attractive and I feel ugly in my appearance. It has led to a total change in my personality to being withdrawn and a lack of self esteem. Panic attacks happen sometimes as it all becomes too much. Many times I have suicidal thoughts as there is no cure or treatment that lasts longer than 6 months. This disease I feel has robbed me of 13 years of my life. It has a considerable impact on my quality of life with this burden constantly with me on a daily basis. Dealing with windy days or considering leisure activities stops me because of the consequences just in case my wig comes off. I live in anticipation of the thought of this successful treatment on the horizon that can change everything for me and my life. I am not having any treatment and do not use prescriptions for wigs as I pay for them myself. This is not costing the NHS anything. I feel that this is about what it will cost and not about supporting my care as a human being and having a duty of care. I hope NICE will approve this drug and not continually not recommend other drugs as we are an easy option to save money. **Are the recommendations sound and a suitable basis for guidance to the NHS?** Many patients including myself with severe alopecia will want the opportunity to try Baricitinib. I recognise that not everyone will be willing or able to take the drug. All patients must be given the opportunity to be given	

this drug through the excellent care of the NHS and not privately. Why can't patients take Baricitinib on a 36 week basis to see if there is any growth and if tolerated?
I have waited for years patiently and with eagerness and hope for the development of Baricitinib to be given the chance this year to possibly change my life. The drug has been approved in USA, Europe and MHRA. To not have it as a recommended treatment in Uk, when there is not anything else is soul destroying for those suffering.
Baricitinib will give me the chance of getting back to a proper decent life with confidence and self esteem. You need to have compassion and give us hope.

Name	
Comments on the DG:	
I unfortunately suffer with severe alopecia areata and so far failed to respond to treatment available in my area . Alopecia areata has affected my life so much physically, mentally and emotionally. There is no standard of care which there should be and to be told by nhs gps its only hair is beyond a joke . We all deserve the right to fair treatment medically. The nhs provides wig prescriptions in my area but only to the value of just £112 each wig and only 2 wigs per year In my area which don't last with every day wear . Please feel free to check good quality wig prices and you will see just how little the NHS actually help us people with alopecia. I'm just lucky I have a large caring family to help me financially buy nice wigs but I shouldn't have to buy wigs just to feel & look like a normal female. I should be given the chance to decide and have decisions about treatments with the specialists that know & understand this horrible condition . I personally think the specialists should decide what treatments are appropriate for each individual.	

Name	
Comments on the DG:	
It is extremely disappointing that Baricitinib has not been recommended by NICE to treat the most severe forms of alopecia, considering it is approved for Rheumatoid arthritis and eczema sufferers. Since the age of twelve, I have had alopecia and I have tried the approved ways of treating it including, steroid injections in my scalp (which was a very painful experience) and oral steroids, these options had a short-term positive outcomes but then they did not work. I now suffer from alopecia universalis and this significantly impacts my day-to-day life. The synthetic wigs provided by the NHS cause daily pain and lead to my head becoming infected on a regular basis. I have open lesions on my scalp which are painful and I have to apply a steroid cream to treat the infections, this is an ongoing vicious circle. Due to my current situation I have had to leave my profession, as a secondary History teacher, this was due to the regular comments made by the students about my alopecia, calling me the bald teacher etc. Alopecia prevented me from taking part in sporting events and attending school trips. Standing outside the school on duty on a windy day would increase my anxiety because I was always worried the wig would blow off. The loss of my eyelashes has resulted in regular eye infections	

and sore eyes. When I exercise at home (I cannot exercise at the gym in a synthetic wig) I will obviously perspire, this goes straight into my eyes and stings because I no longer have eyebrows. Alopecia has affected my physical, and mental health, my profession and, social interactions. I find it hard to believe that 'baricitinib did not show a meaningful improvement in many of the health-related quality of life assessments'. For me, this drug offered hope and would be life-changing. I implore you to review and reconsider your recommendations.

The synthetic wigs that are offered by the NHS are extremely uncomfortable to wear. For example, I find they significantly rub on my head and dig in to my scalp causing lesions, which then lead to infections. My head weeps and this causes pain. The repetition of wearing the wig on a daily basis means that my scalp is never able to heal and I am in constant pain, and this impacts on my physical and mental wellbeing. I am a secondary teacher and it is very obvious to the students I am wearing a wig. This has led to the children commenting on the fact I am bald. It has destroyed my confidence and has led my to leave the profession which I am devastated about.

Hair loss can cause severe psychological distress, but baricitinib did not show a meaningful improvement in many of the health-related quality of life assessments undertaken in the trials compared with placebo.
Although I have not been a part of the clinical trial, as someone who suffers from alopecia universalis, I find it very difficult to believe that this medication and its positive outcomes of regrowth of hair, including eyelashes and eyebrows would not have a 'meaningful improvement' on peoples' lives. Wearing a wig on a daily basis causes my scalp to be irritated to the point where I have lesions on my head and these get infected. Having no eyelashes and eyebrows results in frequent eye infections and sore eyes. Having alopecia restricts the activities I can do, e.g. because the synthetic wig is not secured properly I cannot do certain activities which people living without alopecia would take for granted i.e. walking outside on a windy day because the wig could blow off. Having alopecia has even impacted me professionally. The constant pain and worry has significantly affected my confidence and mental well-being.

Name	
Comments on the DG:	
I feel that this document demonstrates how far resources for Alopecia has come on I have suffered from alopecia from age 11 on and off from loosing all my hair to patches and even part on one side. I feel this is positive I have now gotten to the point where I don't really go out unless it is absolutely necessary for me to do so I have blood work done and nothing. However you provide millions every year for a methadone programme which patients constantly relapse which costs millions every year where as a simple tablet for alopecia is going to provide a life time of hope and even a cure and may have a chance of relapse. This is coming from a NHS worker also. Just feel we need a bit of support from this and	

proof is there that it is working!

Please think of the positive effects this is going to have on one persons life maybe even millions. You do it for drug users so why not us.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
I think there should be a greater emphasis to look at the impact that alopecia has on self esteem, anxiety, depression, relationships and work attendance rather than focus on the more physical limitations scored by EQ 5.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
There are many patients who are not receiving active treatment due to low chance of success or potential toxicity and because we knew a better treatment may be available. The cost comparison for patients with severe disease should be against those on systemic immunosuppression - eg Combination of Prednisolone/Azathioprine or Ciclosporin. This needs to take into account 4 hospital visits and blood monitoring + wigs per year.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No. We have the first properly studied and effective treatment for Alopecia which is being potentially turned down because of cost effectiveness. The use of EQ5 is not helpful in appreciating the impact of this disease. Every committee member should consider themself as a patient, waking up one morning with 50% of their hair missing, no eyelashes, having to explain this to every person they meet, the impact it would have on their self esteem, identity etc

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
No

Hair loss can cause severe psychological distress, but baricitinib did not show a meaningful improvement in many of the health-related quality of life assessments undertaken in the trials compared with placebo.
Most quality of life scores underscore the psychological impact and QoL impact of this disease. There are no physical disabilities, messy treatments, symptoms etc however the impact on self identity, self esteem and knock on effect on anxiety and depression is really profound.

It concluded that the company's and EAG's comparison with no active treatment in their base cases is an acceptable comparator for decision making.

Whilst there is wide variation in the UK for treatment of severe AA, when considering alternatives if JAK inhibitors are not funded, one needs to compare to continuous use of systemic immunosuppression. Many patients are not on active treatment as we were all hopeful a better and safer treatment was on the horizon and what we have at present is unreliable and often toxic. However, if there is no funding for JAK inhibitors patients will be offered an alternative in my tertiary care clinic. This may include oral prednisolone, systemic azathioprine or methotrexate as a steroid sparing drug or cyclosporin as mono therapy. Patients will require a minimum of 4 hospital visits (4 x £150) per year and 4 x full blood counts, liver function tests, U&Es in additional to baseline testing (TPMT, Procollagen, HIV, Hep B, C, T spot etc). All of this has cost attached to it. Baricitinib cost per patient should therefore be compared to that and not to no treatment (= no cost). Patients will also have 3 x acrylic wigs and we subsidise this by £150 per wig so £450 per annum.

For example, some people may prefer to have a local treatment such as contact immunotherapy rather than a systemic medicine like baricitinib.

In my experience, contact immunotherapy works best for people with patchy disease < 50%. Immunotherapy should be more widely available in the UK and used for patients with less severe disease. JAK inhibitors should be used for more severe disease unresponsive to first line therapy eg topical or intralesional steroids. Once you have more than 30% hair loss it is very hard to disguise the loss. Patchy disease is often cosmetically more disfiguring that total loss. The only reason for setting the threshold for treatment at 50% is a financial one. I have had patients with 30-50% who respond at much higher rates that SALT 100 and achieve total regrowth and huge improvement in quality of life.

At baseline, almost half the people with severe or very severe alopecia areata in the trials had EQ-5D scores of full health

These general scoring tools are too blunt to detect the impact of alopecia areata.

Alopecia does not impact mobility, self care, does not cause pain and most people can do their usual activities. The only domain it will score for is anxiety and depression and this can be variable.

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? I do not feel that the mental impact of hair loss has been fully taken in to account. It is not a life threatening condition as such but can make you feel like ending your life and is certainly life changing. It impacts on everything that you do, it destroys relationships, causes stress, anxiety and depression. And places restrictions on everyday life e.g I regularly attended exercise classes previously but no longer do so for fear of wig falling off or	

embarrassment of wearing a head covering. I am grateful that my local authority offers support with synthetic wigs on prescription as lack of funds would cause an additional stress. I have put on weight due comfort eating. The lack of exercise, poor diet and low mood as a result of the alopecia has a detrimental effect to my health, potentially causing more cost to the nhs. I have seen some fantastic results from people purchasing these drugs from abroad but I am fearful at trying this method as I am concerned they may have not been properly regulated and would be unsure what I was purchasing.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
From the perspective of a young woman who suffered severe alopecia areata (AA) and who has since (privately) received effective treatment with baricitinib (achieving a Severity of Alopecia Tool [SALT] score of zero), I have outlined below the areas where evidence is lacking.

1. Sections 3.7 and 3.9: The measure of quality of life (QoL) should have contained a subgroup analysis that specifically compared treatment responders (SALT score ≤20) to placebo

- As noted in the draft guidance "only about 1 in 3 people having baricitinib had a treatment response". Any improvements in QoL scores are likely largely associated with hair regrowth. Therefore, the inclusion of 66% of patients that did not respond likely diluted the true positive QoL impact that hair regrowth causes.
- As a personal example, I was attending cognitive behavioural therapy (CBT) due to the psychological distress of hair loss, and noted a linear decrease in my PHQ-7 and GAD-7 scores as baricitinib-induced hair regrowth occurred over time. My PHQ-9 score decreased from 17 (moderately severe depression) to 2 (within the healthy range), and my GAD-7 score decreased from 21 (severe anxiety) to 6 (mild anxiety) with full hair regrowth.
- As noted in section 3.9, the economic model assumed that "no one can move from having a treatment non-response to a treatment response after the end of the 36 week induction period". Therefore, treatment non-responders are likely to discontinue treatment at the 36-week mark, reducing any further cost to the NHS. As such, more focus should be placed on the cost-effectiveness of baricitinib in the patient cohort that will receive long-term treatment. The QoL scores from this cohort may show a resultant reduction of cost per quality adjusted life year (QALY) and would be a more appropriate model input of utility to base NICE recommendations on.
- In conclusion, the psychological symptoms associated with severe AA are only likely to improve in treatment responders. A subgroup analysis should therefore be conducted using the QoL scores from responders versus placebo. This subgroup analysis should be applied to the economic model to gauge the real cost per QALY of long-term treatment with baricitinib.

2. Section 3.9: The economic model failed to account for additional direct and indirect costs that are associated with not effectively treating severe alopecia areata (AA)

- As stated in section 3.9, the economic model “assessed the cost-effectiveness of baricitinib 4 mg compared with no active treatment”. No active treatment assumes a cost of zero with no other associated costs. I have outlined in question 2 (‘Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?’) why this is an incorrect assumption for several reasons. In addition, there are some direct and indirect costs that did not get mentioned in the draft guidance.
- Direct NHS costs that have not been considered: these include the treatment of conditions that are secondary to the development of alopecia such as depression, anxiety, substance abuse/addiction,(1-8) and the increased prevalence of dementia that has been published in a peer-reviewed journal (which is theorised to result from the social isolation that is frequent among those suffering alopecia).(9) With the World Health Organisation (WHO) quoting depression as the leading cause of disability worldwide,(10) it is associated with a massive economic burden.(11, 12) Depression was reported to as the largest contributor to disability in the UK at 22.8% of the total burden with an estimated cost of £105.2 billion in England each year in 2011 (which is likely currently higher due to 12 years of inflation since the study was conducted).(12) The clinical experts noted in the draft guidance that “high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia”; thus NHS treatment of depression secondary to severe AA is likely associated with a high cost. Additionally, people with AA frequently discuss withdrawing from exercise-based activities where, due to increased heat and sweating, it is difficult to wear the wigs or hats they rely on; therefore, although not presently quantified in a peer-reviewed study, individuals are more likely to gain weight which can be associated with obesity, type 2 diabetes and cardiovascular issues, to name a few. All these secondary conditions are expensive for the NHS to treat; therefore, treating the hair loss associated with these conditions should be viewed as a preventative measure.
- Indirect costs to the NHS: people with alopecia are significantly more likely to be issued with time off work certificates and to be recorded as unemployed.(13-15) As a personal example, I quit my job 2 months after the onset of my AA as I could not cope with the distress of having a severe visible difference in the workplace. In that job role, I paid more in monthly income tax and national insurance than the listed monthly cost of baricitinib of “£805.56” in section 2.3. After a month out of work, I subsequently found a job that allowed me to work permanently from home without the need to switch my camera on during remote meetings. However, had I not found that job I would likely be claiming Universal Credit. Therefore, without effective treatment, there was a very real possibility of me going from a being financial asset to the UK economy to someone who depletes government resources.
- In conclusion, the costs of treating conditions secondary to the onset of severe AA combined with the indirect governmental costs associated (including time off work, unemployment and Universal Credit claims) are likely extensive. These costs should be considered in the economic model

to give an all-inclusive interpretation of the true financial cost of untreated severe AA. This will likely result in a reduction in the cost per QALY.

Overall conclusion: The QoL input to the cost-effectiveness analysis should apply data specifically from baricitinib responders versus placebo; as responders are the patients who will likely continue long-term treatment as opposed to non-responders who will not. There are also multiple costs that should be factored into the cost-effectiveness model as a non-treatment comparator. These include the direct NHS cost of treating conditions secondary to AA onset such as depression, anxiety, substance abuse/addiction, dementia and weight gain (and all associated conditions). Additionally, indirect NHS costs associated with AA onset including time off work, unemployment and Universal Credit claims should be factored into the cost-effectiveness model. The combined (probable) increase in QoL from baricitinib responders offset by the true costs associated with non-AA treatment will likely result in a substantial reduction of cost per QALY gained.

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Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
From the perspective of a young woman who suffered severe AA and who has since (privately) received effective treatment with baricitinib (achieving a SALT score of zero), I have outlined below the areas where NICE interpretations of clinical and cost-effectiveness evidence are lacking.

1. Section 3.7: The baseline QoL scores from patients in the BRAVE trial are not generalisable to those with AA that are likely to be treated with baricitinib

- As noted by the patient experts in section 3.6 “people who enrol into a trial may have lower rates of anxiety than would be expected in the NHS, because people in trials have hope of being treated”. Therefore, patients with AA who enter a clinical trial are likely to have higher baseline QoL scores due to the hope that is gained from clinical trial participation. This is because the treatment pathway for severe AA is so poor with no effective treatment options provided. As a young woman who has suffered with severe AA, and who has sought baricitinib treatment privately, I can attest that my hope and happiness surged when I found a dermatologist who was willing to explore this treatment option with me. Baricitinib, as a treatment option, allowed me to envision a future where I wouldn’t have to live the rest of my life with the associated shame of such a stark visible difference to other people.
- As I have only had AA for one year, this surge in hope is likely amplified for those with longer-standing AA who have endured extensive periods without effective treatment options. Indeed, the mean baseline

duration of the current episode of AA in BRAVE-AA1 and BRAVE-AA2 cohorts ranged from 3.5 to 4.7 years.

- Engagement of physicians and the associated validation that AA is a disease worth treating can have a profound positive mental health impact on patients. In my experience, my first visit to an NHS dermatologist made me feel more depressed and isolated when anti-depressants were the only treatment option offered for my severe AA. In contrast, my subsequent visit to a private dermatologist gave me life-changing hope with the discussion of several treatment options (including baricitinib). This hope was likely amplified due to how let down I had felt after my initial NHS appointment.
- Beyond personal anecdotal evidence, there have been several peer reviewed publications that report a higher prevalence of depression, anxiety and suicide ideation within those suffering AA.(1-7) The committee also acknowledged in section 3.1 and section 3.7 that "severe alopecia areata can have a profound psychosocial impact on a person's quality of life and that people with the condition would welcome new effective treatment options" and that "hair regrowth can have a profound impact on improving a person's quality of life".
- In conclusion, the QoL scores in the BRAVE-AA trials are unlikely to be reflective of the real world and thus assumptions made based on these scores should be treated with caution and skepticism.

2. Section 3.9: No active treatment is a poor and inequitable comparator for cost-effectiveness modelling

- In section 3.9, the economic model "assessed the cost-effectiveness of baricitinib 4 mg compared with no active treatment". As severe AA has historically had no effective treatment options, this is an exceedingly unfair comparator.
- No active treatment comparator will drastically skew the cost-effectiveness of baricitinib with the obvious conclusion that £0 is substantially less expensive than any active comparator. This will render even the cheapest of medical technology unlikely to meet NICE's cost-effectiveness threshold when applied to the economic model.
- In other conditions, the NICE review comparator applied to the economic model is usually an active treatment that provides, at minimal, some form of symptom alleviation from the disease in question. Therefore, this comparator is akin to actively stating that people suffering severe psychological distress, as well as pain and intense pruritis (which is often associated with AA and something I have had the misfortune of experiencing) do not need or deserve effective treatment.
- As a comparison, baricitinib is available on the NHS to individuals with severe eczema and rheumatoid arthritis. In both of these NICE reviews, there were active comparators in their cost-effectiveness models. Additionally, both conditions already have several other approved treatment options and therefore patients are not simply left to suffer.
- "No active treatment" as a comparator also discounts the multiple other (in my experience) sub-par treatment options that (often desperate) individuals with severe AA will likely try at least once if they are made available to them. Indeed, clinical experts state in the draft guidance that treatment options include "oral or locally injected corticosteroids, dithranol,

contact immunotherapy, minoxidil and immunosuppressive medicines such as oral azathioprine, ciclosporin, methotrexate and sulfasalazine". I have personally paid out-of-pocket for treatments including oral prednisolone, topical and oral minoxidil and plasma rich protein (PRP) injections before finally receiving effective (and privately sourced) treatment with baricitinib.

- In conclusion, no active comparator substantially skews the cost-effectiveness results. It is an unfair assumption that no disease or symptom alleviation is a sufficient comparator when most other diseases assessed in a NICE HTA reviews have an active comparator to the health technology in question. Additionally, where treatment options are actually provided for severe AA, patients will often try multiple treatment options as they tend to be desperate to escape the psychological distress associated with severe AA.

3. Sections 3.9–3.11: The best supportive care (BSC) applied to the economic model does not contain enough elements that correspond to BSC applied in the real world, and BSC should be a comparator rather than a health state in the economic model

- BSC, in the real world, extends far beyond wigs and orthotics for individuals with severe AA. Even if a patient has exhausted all treatment options available (which is unlikely, as few people suffering severe AA gain access to treatment on the NHS), they will likely require psychological support. As outlined above, the psychological distress of having a severe visible difference can be all-encompassing.
- As a comparison, the NICE review for baricitinib in the treatment of severe eczema (which gained approval) had BSC as one of its comparators. In the baricitinib/severe eczema review, BSC included (but was not limited to) education, psychological support, topical corticosteroids and hospitalisation. All these elements are also applicable to severe AA, and therefore should have been included in the draft guidance in addition to wigs and orthotics.
- As a personal example, I have suffered severe AA for less than a year. During that timeframe, I accessed NHS mental health services twice (counselling with six treatment sessions, and CBT with 12 treatment sessions). The need for these mental health services were as a direct result of the psychological distress that that severe hair loss caused. I only no longer require psychological support due to the immense relief that (privately accessed) baricitinib-induced regrowth has caused.
- The cost to the NHS of treating this psychological distress should not be ignored, particularly since NHS mental health services, such as counselling and CBT, are often accessible through self referral and (in my experience) there are no limits to the number of times a person can access each service.
- Additionally, suicide ideation and risk of suicide is reported in 13% of those with AA (with the prevalence unknown, but likely higher, in those with severe AA).(2) In my own experience of the disease, when my SALT score surpassed around 50, I contemplated suicide every single day and began self harming. The only thing that prevented me from attempting suicide was the hope that I gained from online research of JAK inhibitors and the subsequent treatment with baricitinib. When suffering severe AA, I

completely withdrew from all social activities and only left the house (in a hat) for necessities such as shopping and medical appointments. Social withdrawal as a result of AA has also been reported in peer-reviewed publications,(8, 9) with social isolation being a key risk factor for suicide.(10) As such, hospitalisation due to suicide attempts should be included as part of the BSC that is applied to the economic model.

- As outlined above, BSC will likely be accessed by many patients until sufficient hair regrowth, and subsequent alleviation of psychological distress occurs. Therefore, BSC should be applied as comparator to economic model, not a health state.
- In conclusion, real world BSC extends far beyond wigs and orthotics. Many of those suffering with severe AA experience intense psychological distress and will likely access mental health support through NHS services. As the QoL impact of severe AA is unlikely to disappear until significant hair regrowth occurs (SALT score of ≤20), BSC should be included as a comparator in the economic model, not a health state.

4. Sections 3.7 and 3.12: EQ-5D is a poorly chosen tool to measure QoL changes in patients with severe AA, as such the utility values applied to the economic model are inadequate

- The clinical experts noted that “high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia areata” and the committee noted that “hair loss can cause severe psychological distress” and that “severe alopecia areata can have a profound psychosocial impact on a person’s quality of life”. Therefore, psychosocial impacts including anxiety and depression were recognised as the main secondary conditions of concern.
- The EQ-5D only contains one of five domains that are specific to anxiety and depression (with the remaining four domains addressing mobility, self-care, usual activities and pain/discomfort). Inclusion of irrelevant domains likely dilute scores and therefore are unlikely to reflect the true baseline psychological distress that is felt. As such, any psychological improvement associated with baricitinib treatment and hair regrowth is likely to be overlooked.
- More specific questionnaires that have mental health as their predominant focus would be appropriate e.g. Skindex-16 Alopecia Areata, PHQ-9 and GAD-7. Indeed, “statistically significant improvements in the emotions and functioning domains Skindex-16 Alopecia Areata scores” are noted in section 3.7 of the draft guidance.
- As a comparison, the NICE review for baricitinib in the treatment of severe eczema used the dermatology life quality index (DLQI) tool to measure QoL. The DLQI tool is substantially more specific to aspects of severe eczema that impact QoL then the EQ-5D is to severe AA.
- As a personal example, I was attending CBT (due to the psychological distress of hair loss) and noted a linear decrease in my PHQ-7 and GAD-7 scores as baricitinib-induced hair regrowth occurred over time. My PHQ-9 score decreased from 17 (moderately severe depression) to 2 (within the healthy range), and my GAD-7 score decreased from 21 (severe anxiety) to 6 (mild anxiety) with full hair regrowth.

- In conclusion, the EQ-5D tool does not directly address the key secondary conditions of anxiety and depression that result from severe AA. Therefore, it is an inappropriate tool, and tools that more specifically address the psychological impact of severe AA would be more appropriate.

QoL/utility conclusion: A combination of issues with QoL measures has resulted in a (likely) poor/false interpretation of the true QoL impact of baricitinib-induced hair regrowth. These include: (1) not accounting for the increase in baseline QoL scores upon clinical trial entrance (due to increased hope of participants); (2) using EQ-5D to measure QoL which is a non-specific tool that does not properly address the depression/anxiety that are key secondary conditions associated with AA onset; (3) measuring QoL improvement in the full baricitinib-receiving cohort as opposed to specifically measuring QoL impact in the 34% of baricitinib responders (as discussed in response to question 1). Therefore, a combination of unusually high baseline QoL scores, a non-specific QoL tool, and QoL impact being measured in both responders (34%) and non-responders (66%) combined (vs placebo) has likely amounted to QoL results that are substantially diminish the true positive impact of baricitinib-induced hair regrowth. QoL scores are diluted by background noise, including the 64% non-responders, as well as the 80% of EQ-5D domains that are not applicable to AA.

Cost input conclusion: the cost inputs to the economic model were inequitable and fell short of the true costs of non-AA treatment. No active comparator equates to NICE/the NHS normalising and tolerating the severe psychological suffering that severe AA causes. I cannot fathom how a comparator that provides zero symptom alleviation and leaves patients depressed, anxious and suicidal is good practice. At the very least, BSC should be applied as a comparator which includes the cost of wigs/orthotics, mental health support (for anxiety and depression) and hospitalisation for suicide attempts. Active treatment options are also used within the NHS, but are unequally distributed. However, it is a failing of the NHS that these are not common practice and therefore should also be considered as a comparator. As a comparison, in the eczema/baricitinib review, both BSC and active treatment (dupilumab) were applied as comparators within the economic model; NICE should ensure that certain non-life threatening diseases are not treated more favourably than others. In this instance, it is evident that baricitinib treatment in severe eczema was tested with a substantially fairer economic model that was more reflective of the disease reality.

Overall conclusion: an accumulation of poor QoL measures and associated utility inputs, as well as an inappropriate cost comparator likely skewed the economic model toward a high cost per QALY. Application of QoL measures that better reflect the real world, combined with a fairer and more accurate cost comparator will likely result in a substantial reduction in cost per QALY.

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Are the recommendations sound and a suitable basis for guidance to the NHS?
From the perspective of a young woman who suffered severe AA and who has since (privately) received effective treatment with baricitinib (achieving a SALT score of zero), I have outlined below why I do not believe the recommendations to be “sound” or “suitable” for application to the NHS.

1. The recommendation contradicts the NHS value that “everyone counts”

- The NHS has no effective long-term treatments for longstanding (lasting beyond 6 months) severe AA. Any treatments available are largely inaccessible to the majority of patients, as clinical experts noted that “there is no standard care for severe alopecia areata and treatment options vary widely depending on geographic location, healthcare setting, availability and the person’s preference”. As I stated previously, the only treatment option I

was offered for 95% scalp hair loss was anti-depressants, with no wig provision provided (I had to spend £1,500 out-of-pocket on a wig for a sensitive scalp due to excessive scalp pruritus and pain associated with active AA — I still found the wig exacerbated the scalp symptoms, despite this expenditure).

- The clinical experts also noted that “high levels of anxiety and depression are common, occurring in about 1 in 3 people with severe alopecia areata”. Additionally, there are several peer-reviewed publications that report a higher prevalence of depression, anxiety and suicide ideation within those suffering AA.(1-7) Therefore, there remains a large unmet need within this patient population and only those who are not financially constrained can access baricitinib treatment through expensive private consultation, private blood monitoring and pharmaceutical expenditure. One of the six NHS values is that “everyone counts”. However, the outcome of the draft guidance translates to only those wealthy enough “count” when it comes to treating severe AA.
- Additionally, other non-life threatening dermatological conditions have several treatment options. For example, severe eczema has baricitinib as a treatment option available on the NHS. Severe eczema and severe AA have many similarities in that they can result in intense pruritis, pain and psychological distress. Severe AA also causes severe physical disfigurement (which is classed as a disability by the UK Disability and the Equality Act 2010).(8) Therefore, this appears as preferential treatment of other conditions and directly contradicts the NHS value of “everyone counts”. Due to its cosmetic nature, this can be translated to “those whose psychological distress is largely caused by a visible difference (among other symptoms) do not count”.

Overall conclusion: the 33.3% of people that suffer anxiety and depression as a result of severe AA are overlooked by this guidance and therefore it is not “sound” or suitable”. It directly contradicts the NHS value of “everyone counts”, with only those with the ‘right’ non-life threating condition, or with enough money being able to access baricitinib treatment.

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Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
From the perspective of a young woman who suffered severe alopecia areata (AA) and who has since (privately) received effective treatment with baricitinib (achieving a SALT score of zero), I have outlined below where I think recommendations verge into discriminatory territory.

1. Section 1.1: the fact that “baricitinib is not recommended” for treatment of severe AA shows that a condition that causes visible difference is of a lower priority than other non-life threatening conditions
- Severe AA is associated with ‘severe physical disfigurement’ which is classed as a disability by the UK Disability and the Equality Act 2010.(1) However, myself and other people suffering AA often state that psychological impact of a visible difference is often overlooked or downplayed by both the medical community and general public; this further adds to the distress of the disease.
- Baricitinib is available on the NHS to individuals with severe eczema (of which several other approved treatment options are also available). As outlined in my responses to question 2, the parameters applied to the economic model in the eczema/baricitinib NICE review were substantially more favourable and disease-specific, resulting in a much lower cost per QALY. In contrast, the parameters applied to the severe AA/baricitinib review were non-specific to the disease and failed to account for many of the additional NHS costs associated with not effectively treating patients (as outlined in my responses to question 2).
- Parameters in the eczema/baricitinib review included the more specific DLQI QoL tool vs the non-specific EQ-5D tool applied to the AA/baricitinib review. Additionally, the treatment comparators in the eczema/baricitinib review included BSC and dupilumab whilst the AA/baricitinib review had no active comparator; this translates to severe eczema being viewed as deserving of symptom alleviation whilst severe AA is not. The BSC for severe eczema also included several elements that are

applicable to AA that were not included for the BSC in the AA/baricitinib review (which was applied as a health state to the economic model). Namely, the BSC in the eczema model factored in mental health treatment which was not factored into the AA/baricitinib review. It is frequently acknowledged in the draft guidance that AA is associated with severe psychological suffering; therefore, lack of inclusion of mental health support in the BSC is perplexing and makes it appear as though the treatment of eczema is thought to be of higher importance than that severe AA. Overall, the eczema/baricitinib review was subject to a much fairer, more balanced cost-effectiveness analysis than that of the AA/baricitinib. A potential explanation for this ill-thought-out review is that people often fail to recognise the true detrimental QoL impact of a visible difference. As, myself and others suffering AA can attest, the psychological impact is frequently overlooked or downplayed by the medical community

- In conclusion, to deny those suffering severe AA the only effective treatment option, is to overlook and de-prioritise the distress of their condition. In doing so, other non-life threatening conditions (that are not visible diseases) are given higher priority. This is particularly unfair when these diseases already have multiple treatment options available on the NHS.

2. Section 3.15: Those with lower socioeconomic status suffer disproportionately as a result of severe AA and the associated cost of treatment and/or tools for symptom management (wigs and orthotics)

- Section 3.15 states that AA may be more common in those with “lower socioeconomic status”. Access to baricitinib in the UK is therefore only manageable for those who can afford the cost of prescription, private medical consultation and private blood monitoring.
- Additionally, as stated in section 3.2, there are inconsistent wig provisions across the UK and patients frequently have to pay out-of-pocket. When I had not received baricitinib treatment, my wig was something that I deemed as an absolute necessity to feel comfortable when I (rarely) attended anything that involved socialising; as one patient expert noted (in section 3.2) “about 75% of people with severe alopecia areata wear a wig most of the time”.
- As AA has such a poor and inconsistent treatment pathway within the UK, it often comes with a huge personal expense to those suffering. I have personally spent close to £10,000 in less than one year of suffering with AA (including a wig and various private treatments).
- One study reported that patients with AA were “seriously (25.2%) or moderately (31.7%) affected by the financial burden”. Additionally, in a willingness-to-pay analysis of 40 adult patients (aged 18 and older), it was found that individuals were willing to pay 12%–20% of their monthly income for a permanent AA cure, with those experiencing severe disease willing to pay more. This emphasizes the desperation people feel when it comes to finding a treatment for AA.(2)
- Therefore, there is a massive equity concern with AA and those with a lower socioeconomic status will be hit the hardest. To not recommend the only effective treatment option for severe AA is to discriminate against those who, not only cannot afford the treatment privately, but also cannot afford

the most basic of necessities that many rely on to manage the psychological distress and ‘hide’ their visible difference.

- In conclusion, the treatment of severe AA in the UK is poor and inconsistent and as such many people suffering bear a significant financial burden. Those with lower socioeconomic status are more likely to suffer AA and have greater difficulty funding treatment options for severe AA. The approval of baricitinib within the NHS would remove treatment access barriers and give those with a lower socioeconomic status a fairer chance at hair regrowth and improved QoL.

3. Certain religions prohibit hair cuts or the removal of facial hair, such as Orthodox Judaism, Rastafarianism, and Sikhism. This may result in people with AA being ostracised from their cultural community

- Hair has a substantial social significance in most cultures and societies. In certain religions, hair is even viewed as sacred or a gift from God. As such, extensive hair loss can be particularly distressful for people within these communities and may lead to them being excluded or ostracized.
- NICE have failed to account for the cultural and religious significance of hair in the draft guidance. As a viable treatment option is available that could alleviate this burden for members of certain religions, NICE have discriminated with their lack of recommendation. This may result in the continued persecution of those suffering severe AA within certain religions, which could have been avoided had these people gained access to the only known effective and approved (in certain countries) treatment for severe AA.

Overall conclusion: the lack of recommendation is discriminatory in the sense that it favours a non-visible non-life threatening disease (severe eczema) over a visible one (severe AA). Baricitinib is approved for the treatment of severe eczema whose NICE review had more favourable, disease-specific inputs in the cost-effectiveness analysis than the inputs applied within the baricitinib/AA review. Additionally, those with lower socioeconomic status have a higher prevalence of AA. As the NHS provides few to no treatment options for severe AA (depending on your postcode), those with less money are left to pay for expensive wigs that are deemed as an absolute necessity for most (and barely address the root problem/unmet need). Effective treatment is therefore only accessible to those who can afford it. As such, those with a lower socioeconomic status suffer the double blow of increased AA prevalence coupled with the inability to afford treatment options that are not provided on the NHS. Furthermore, with baricitinib not currently recommended for the treatment of severe AA, NICE may be continuing to allow the ostracism of members of certain religious communities. This is because certain religions place great importance on hair and prohibit hair cuts or the removal of facial hair. Thus, involuntary severe hair loss may result in exclusion from a religious community, which otherwise may not occur if people with severe AA had access to baricitinib.

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Name	
Comments on the DG:	
I was unhappy to hear that Barictinib has not been improved in the first consultation period but I am hopeful that it will be in the future. I have Alopecia Universalis, my hair loss occurred over a 6month period whilst I was studying for my nursing degree. I have always made a conscious effort to not let my hair loss prevent me from doing the things I have wanted and have worked as a theatre nurse for 10years and have been able to travel the world. However, to do this comfortably and feeling secure, I have had to spend £1000's of my own money to buy wigs which look realistic, are comfortable and will not move on my head (or blow off in the wind). It is these wigs which have provided me this opportunity and this is not an option for many who do not have the opportunity to have realistic comfortable wigs provided by the NHS. I have never had a NHS wig as my area only allows synthetic wigs which don't suit my lifestyle or work (they get damaged easily under a theatre hat). If I had the opportunity to take this medication I would. I understand Alopecia at present doesn't cost the NHS much money (this is partly due to the appalling poor wig provisions offered) however cost of antidepressant medications and therapy's must also be taken into account aswell as increasing costs to the individuals.	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? I feel there are some questions regarding the way information has been collated for the impact on quality of life. In my experience, my quality of life was massively affected. This condition pushed me into disordered, dysmorphic, OCD type behaviour. A combination of the lack of medical support, lack of general understanding of the condition and lack of effective treatments means that i had to develop my own coping mechanisms. I changed my diet and developed strict rituals and routines to try and gain some control, the condition consumed me and eventually resulted in...basically a breakdown. I was unable to eat, sleep, look after my children, go to work etc. I eventually started taking sertraline, got a diagnosis of PTSD and started treatment for this. Im not sure the evidence you have access to really covers these nuances	

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
Frustratingly i can see that this condition does not currently cost the NHS very much. However with regards the the previous answer have the knock on conditions been taken into consideration.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
It is widely accepted that a person can straighten their teeth, have gender reassignment, access reconstructive procedures, receive fertility treatment etc on the NHS. I would like to see evidence that autoimmune hairloss has the same credence as some of these better supported differences. Severe alopecia is a disfigurement and in my opinion, when severe, the mental implications are in fact a hidden disability.
Consideration of these points should be made

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
Possibly

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
I do not believe so, the costs somewhat underestimate the true cost of treating alopecia, it is not simply the cost of a wig, it is the costs of numerous visits, numerous treatments and lost productivity across a wide range of people, mainly females. The stress levels and anxiety of many of these suffers has not been fully acknowledged.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No, this seems very biased against alopecia suffers and in no way is there a balance between alopecia suffers and those people with other diseases.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
In my humble opinion the recommendation is very much an anti female decision and discriminates against strongly against females. It in many ways underestimates the true impact of this disease and makes somewhat belittling statements about this disease as being trivial compared to other diseases. The mental health aspects of alopecia are not really addressed from a medical and general perspective and are clearly not factored into the appalling conclusion about making this treatment not available to sufferers.

To not make this available to alopecia sufferers denies them hope that they may be cured, the NHS is supposed to look after sufferers and not to deny them at least a chance of being cured.

Name	
Comments on the DG:	
I would like to express how disheartening it is to know how little alopecia is taken seriously. Your first point of the lack of people taking up treatment is down to the ridiculous waiting list for a referral (1-2 years) and by that time we are told there is nothing they can do once all the hair has fallen out. Secondly, your point about the quality of life shows how severely uneducated you are. Since being diagnosed with alopecia my quality of life has been significantly impacted. My mental health is rock bottom because it has been so distressing losing myself. Furthermore, there are physical impacts such as severely irritated scalp, painful eyes due to losing eyelashes and the list goes on. I have seen the incredible things Jak inhibiters have done for people, and the fact you're denying people the right to treatment at an affordable price is disgusting! I really hope you put yourself in our shoes and actually emphasise how desperate we are to get an affordable treatment to end our pain and suffering. Please listen to the people, we need our voices heard!	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? Evidence relating to quality of life is poor. Markers used are not relevant to the harm caused by alopecia. For example it would be more useful to consider impact on self esteem than domains considered in EQ5D like mobility. **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** No they are not as the evidence to look at quality of life is insufficient. I have witnessed a friend of mine who has started this medication 6 weeks ago and had early signs of re growth. This has been very beneficial for her quality of life.	

Name	
Comments on the DG:	
Having read the document relating to the use of baricitinib to treat alopecia and NICE position on it's use within the NHS in England I felt compelled to contribute to the comments. I was diagnosed with alopecia in 2021, I now have complete hair loss across my entire body and the impact of this on my physical and mental health and the added pressure on my family cannot be over stated. I am not satisfied that the consultation fully considered the impact on quality of life or the associated cost of treating connected symptoms from this disease.	

Cost compared to current treatment - there are no suitable treatments available for alopecia at present and so patients with the condition are not currently a burden to the NHS due to the hair loss alone however, there are and will be costs associated with other symptoms especially around eye care, ear, nose and throat and mental health.
Quality of life - comparisons are drawn with other physical conditions like arthritis, it is easier to assess improvements in such a condition as you can measure a reduction in physical pain and resulting increased movement etc. whereas not having hair is not considered to be physically painful or to limit movement.
I have been wearing a wig for 18 months, I have no eyebrows, no eyelashes, no body hair at all and every single day is a miserable effort in everything that I do.
I have pain in my eyes as I no longer have eyelashes to protect them, they are dry, itchy and red all of the time to the point that I find it challenging to do my job every day.
I have issues with my sinuses and my nose bleeds daily, not having hair to act as a filter and protect me from allergens causes me no end of grief especially as I already suffer from eczema and asthma.
I have lost all confidence in myself, I struggle with work and all social situations, I think about my hair every minute of the day and I have nightmares about it. I am mentally exhausted and worry about my ability to continue for much longer.
While I appreciate alopecia itself may not be considered a threat to life the impact it has on a person certainly does. In moments of clarity I can acknowledge that many other conditions would be worse to deal with but it is relative and as I write this with tears streaming from my eyes I think of the many people who suffer in silence, perhaps don't leave their house, no longer contributing to society, not supporting their families and friends because they can no longer function in the world and I ask that you please consider the seriousness of this condition before making your final decision.
I would like to add that my condition was triggered by the administering of the Pfizer Covid Vaccine (which I have reported) I had two doses and a booster and the hair loss started and worsened after each dose.

Has all of the relevant evidence been taken into account?
Have you fully considered costs resulting from associated symptoms?
Have you fully considered the varied physical and mental challenges arising from the condition and the impact on quality of life not only of the patient but family, friends and impact in the workplace and society in general?

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
To read that patients diagnosed with alopecia are not presently a financial burden to the NHS due to lack of available treatments is in itself depressing but not more that the thinking that providing hope in the form of a JAK inhibitor like baricitinib is not value for money.
Measuring the value by cost alone is not sufficient.
There are additional treatment costs connected to alopecia including other physical symptoms and of course associated mental health treatments.

There is not enough data to properly consider the impact and wider costs that could be offset should an improved treatment option be available.

Are the recommendations sound and a suitable basis for guidance to the NHS?
I don't believe that there is enough evidence contained within the document to adequately make a recommendation. I would like to see more case studies, additional data from the USA and Europe and from trials.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Alopecia does not discriminate and neither should the NHS.
Not recommending this treatment for use in the NHS could in itself be considered discriminatory, the suggestion that this is a cosmetic disease that isn't deserving of the same level of attention as arthritis or crohn's disease for example is prejudiced and unjustified.
This consultation document does not go far enough to consider value for money in the context of improving quality of life across all characteristics or to understand how to proactively manage or deter against any future physical or mental health related issues.

Name	
Comments on the DG:	

Recommendations
I believe that this drug is licensed all over the world and research is showing that it has positive effects and results with patients with AA

If patients who are already on the drug are allowed to continue then surely this is showing positive results with the handful of people
Others should have this chance to change their condition take control and have life changing results
I understand that the cost would be large however so is the effect's physical and emotionally from AA. Let patients get their life back . I understand cost is high when purchased from companies that they gain financially. I know of many patients who have purchased from abroad for example Indian at a fraction of the price

Price
The cost is huge when purchased from profit making companies. Could the drug be outreached from drug companies abroad at a fraction of the price

Effects on quality of life
I totally agree with all this, the effects physically and psychologically are huge effecting all aspects of daily life. Personally it has effected myself in both even contemplating suicide . I have grown up watching my mother and how it effected me as a child growing up and now history is repeating itself with me with AU

losing your hair has a huge impact on not just the individual but the whole family. I am second generation to have alopecia as a child the impact of having a parent was huge, limited activities, teasing and bullying which then had psychological impact on myself, then to become a sufferer history repeats itself.
My life has been limited by alopecia areata. Do I need to be ruled by this all my life. This drug could change my life my families life.

Treatment options
Personally I have tried a few treatments, creams, injections etc
Then sent away with a prescription for a wig..... a wig is not the answer its like putting a badly fitted bandage of a cut, a cut so deep it cant be covered. I have tried wigs, psychologically its not the answer for me, I know its a wig, stealing my identity!!!
I want my own hair, to have my own lashes, eyebrows to regain my identity. Alopecia has stolen it, I want any chance to get it back!

Positioning of baricitinib
I understand that some treatments should be tried first, and also some patients may not want this treatment. But let patients choose.

Treatment response and health-related quality of life
if this treatment was widely available there would be better understanding of the benefits and the impact on quality of life

Adverse events
This maybe true but is this not the case of all drugs?

Composition of best supportive care
I have tried some treatements. You state that patients may not be willing to try other treatments. I strongly disagree I would try anything and I am sure if you spoke to patients in the AA community they would agree with me

Best supportive care use after non-response
some patients may not respond to Baricitinib but why should wigs be the answer? Other Jak inhibitors have been proven to be effective. Patients should have the right to explore other drugs available

Acceptable ICER
why does have to cost this amount when drugs can be sourced out with the uk much cheaper

Has all of the relevant evidence been taken into account?
No I dont believe it has, the evidence on the psychological impact of AA on patients and the effects it has. Talk to the AA community we want a treatment that gives us hope

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?

NO! source from abroad, much cheaper, could be monitored. Patients are ordering themselves some not being monitored. Surely having this drug more cheaply from abroad and being monitored by NHS doctors is a much better option

Name	
Comments on the DG:	
I believe this drug could be a complete life changing thing to not only an individual but to alopecia areata sufferers all over the uk. Compared to other traditional treatments ie wigs which I feel isn't getting to the root of the problem. I have know a close friend who has been on this drug and the change in health and mental health I have seen a incredible improvement. This person has been paying privately for a prescription of this drug and has already seen a good transformation. If you look at other treatments and drug costs for other conditions this needs to be approved and commissioned for treatment. Children and adults who have this condition will have a better quality of life are in need of this to happen.	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? Yes **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** Yes Are the recommendations sound and a suitable basis for guidance to the NHS? I do not consider the recommendations to be fair for people who suffer from alopecia. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** Not as far as I can see	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? No. See below Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence? There are two huge flaws in the cost effectiveness analyses that have been undertaken. The first relates to the evaluation of quality of life. To begin with, the EQ-5D, HADS and Short-Form 36 questionnaire are not appropriate tools for assessing quality of life in patients with alopecia	

areata. Alopecia areata does NOT cause ongoing physical pain or discomfort, affect mobility, impact self-care (e.g. washing/dressing), limit physical activities such as shopping/lifting/climbing stairs, directly affect energy levels, or impact “general health”. These are therefore completely irrelevant assessments of quality of life and it is unsurprising that there were no improvements demonstrated within the trials.

EQ-5D was not a primary end-point of the BRAVE trials. If it had been a primary end-point, there should have been a more representative distribution of baseline scores. Almost half of the patients with severe or very severe alopecia had EQ-5D scores of full health and were therefore unable to show any improvement in their EQ-5D score, adding further evidence to the inappropriateness of this measure within the cost-effectiveness analysis.

The Skindex-16 alopecia areata tool was primarily designed for the assessment of skin conditions not hair loss. A chronic autoimmune condition causing extensive hair loss is NOT comparable to a skin condition such as eczema. Hair loss does not cause persistent itching, burning, pain, or irritation making questions 1 to 4 irrelevant. Furthermore, patients with Alopecia Universalis, by definition, are at the maximum threshold of how bad their hair loss can get making questions about the “recurrence” and “worsening” of hair loss (questions 5 and 6) irrelevant as well. This means that 40% of this questionnaire is inappropriate. As a result, it is again not surprising that no significant improvements were demonstrated within the trials.

In addition, many of these questionnaires ask about “today”, “the past week” or “the past 4 weeks”. Many people with alopecia areata, including myself, have been suffering with hair loss for several decades! We have been forced to adapt to our hair loss because there have been no treatments available. Our baseline quality of life assessments are likely very skewed and over-estimated as a result of these adaptive coping mechanisms. Asking about such short timeframes in the context of several decades of “severe psychological distress” cannot justifiably capture the long-term psychosocial impacts that this condition has had.

It is notable that within the Skindex-16 assessments, there were statistically significant improvements in the emotional and functional domains. This covers areas such as feeling embarrassed, ashamed, and depressed about hair loss, as well as the impacts on interactions with other people and daily activities. These are the parts of this questionnaire which are relevant to patients with alopecia areata and the fact that this showed a significant difference are supportive of this.

Anecdotally, if I completed the EQ5D (having looked at the questions) I would have full health at baseline. This does not reflect the impact that alopecia areata has had and will continue to have on my quality of life. I am 35 years old. Having lived with alopecia for 25 years, I can categorically tell you that taking medication that would make my hair grow back would improve my quality of life beyond comprehension. Living with this condition has significantly impacted my mental health, causing severe depression and anxiety, to the point where I have considered taking my own life on multiple occasions to end the mental pain. As clearly documented in the draft guidance, alopecia areata is inescapable and bleeds into every aspect of

your life by eroding and destroying your self-worth and identity – things that cannot be measured and captured in such crude quality of life tools as those used within the trials and for the basis of this cost-effectiveness analysis.

For prolonged periods I have been unable to look at myself in a mirror. I have struggled with exercise and physical activities, felt ashamed, embarrassed and self-conscious in social settings which has manifested in a severe social phobia, and have remained single (I am not married and have no children) for a prolonged period of time because of the difficulties it has created in forming intimate relationships and believing that someone could love me when I believe myself to be physically repulsive. In a world where social media and focus on external appearance is ever-increasing, I dread to think how young women will cope with hair loss having personally been subject to cruel comments and rejection whilst trying to navigate dating and romantic relationships with this condition. I also watched my sister who has alopecia areata get bullied relentlessly at school because of her hair loss.

To conclude, alopecia areata, as clearly detailed within the draft guidance, causes “severe psychological distress” which is NOT being adequately captured within these quality of life assessments because they are not appropriately designed for hair loss. It is likely that the ICER is so high because the differences in measured quality of life in the trial are so small – this likely dominates the results of the ICER and means the ICER is flawed and inaccurate.

The second flaw is the fact that there is no clear consensus on the standard of care or “best supportive care”. And yet, the reason for there being no consensus is because of the lack of evidence on cost effectiveness for this condition. This means that patients with alopecia are being penalised because there are no available treatments. As a result, a treatment with clear evidence of working is being withheld. It is incomprehensible that the basis of the ICER is that patients with alopecia are currently not costing the NHS money, when this is because there are no treatments available. This argument is entirely circular and ludicrous. We cannot directly cost the NHS money if there are no treatments available and this should not be allowed to be a reason to not provide us with a treatment that has finally been shown to work.

People with alopecia are currently not “directly” costing the NHS money purely because there are no treatment options available. The bigger picture is that significant numbers of patients with alopecia are going to indirectly cost the NHS, and indeed the country, money through the proven high rates of depression (30% higher than average), anxiety (30% higher than average) and unemployment/sickness (80% higher than average).

Anecdotally, I have been generally appalled at the care I’ve received over the past two decades. Not once has a medical professional ever offered me any sort of psychosocial support for my alopecia. I’ve been told continuously to essentially go away and get on with it because there is nothing that can be done. I have had countless dermatology appointments across four different NHS hospitals, wasting money on treatments that have no evidence base (dithranol, steroid creams, intravenous steroids, intralesional steroids, immunosuppressants). Surely this money is better spent on a

treatment that has actual proven benefit? To withhold a treatment with clearly documented results after decades of such care is frustrating beyond comprehension.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No - as detailed above.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
There has been no differentiation of patient groups in the assessment of quality of life. For example, the impacts on quality of life are likely to differ according to age and gender. In addition, the “patient experts” are both of a similar demographic. There is no representation of males, younger patients, or ethnic minority groups. The impact of hair loss on males needs to be considered separately from females given the difficulties in trying to cover the loss of, for example, eyebrows and eyelashes, given that most males would likely not feel comfortable wearing, for example, false eyelashes.
It is commonly accepted that patients from lower socioeconomic status and some ethnic minorities are much less likely to participate in clinical trials. Alopecia areata has been shown to disproportionately affect patients from a lower socioeconomic status and ethnic minority groups, as well as having a peak prevalence in the mid-twenties. It is therefore highly likely that the trial population is not truly representative of real-world practice, especially with regards to the quality of life assessments.
The terminology of “best supportive care” is frankly offensive. This term is usually used to describe patients who are being managed in a palliative setting because they are dying. This terminology should not be used in relation to alopecia areata. In addition, patients from lower socioeconomic backgrounds are being discriminated against in the use of “best supportive care”. I have spent thousands of pounds on private therapy to try to deal with the mental issues my alopecia has caused. I have also spent thousands of pounds on wigs to try to replicate my own hair as much as possible. There is huge variation in who is eligible for support in buying wigs, and often the wigs offered on the NHS are synthetic rather than human hair. I have also now spent thousands of pounds to be seen by a private Dermatologist and to obtain this medicaiton privately. The personal financial implications of trying to manage this condition yourself need to be considered as this is extremely discrimantory to those of a lower socioeconomic standing.
Finally, and most frustratingly, this medication is already available on the NHS, at the exact same price, for rheumatoid arthritis and eczema. This is because these conditions have had appropriate quality of life assessments undertaken, and there are comparable treatments. Patients with alopecia areata are being discriminated against for factors which are out of our control e.g., there are NO recognised treatments for comparison and an appropriate quality of life metric has not been validated and measured.

Patients with alopecia areata are persistently discriminated against because this condition is often deemed to be “cosmetic” despite clearly being shown to be a chornic autoimmune condition with other associated diseases. This is yet another example of how chronically neglected proper care for this condition has been.

Name	
Comments on the DG:	
Treatment response and health-related quality of life There is a clear issue here when using this 'quality of life assessment tool'. The assessment is considering health related impacts as perhaps used when making decisions around the impact of a pain relief drug for example. Mental impact should be considered in the same way as physical impact, both can be debilitating and life limiting. Please consider my lived experience, Having been on baricitinib 4mg for 8 months and having seen the full regrowth of my hair from SALT score of 99.9 to a SALT score of 0 please let me assure you all that the improvement to my quality of life has been significant. I lived with alopecia universalis for five years of my life. I lost my identlty and my confidence. I became isolated socially and suffered depression. Each day followed the same pattern; Getting up in the morning and avoiding looking in the mirror, then having to put on my 'disguise' of false hair, eyebrows and eyelashes to try to make myself look as normal as possible. Not wanting anyone to look at me when I was not in my 'disguise', including my family. Hiding away in my room and feeling ashamed of how I looked, which ruined my relationship with my partner and impacted my children's lives. Constantly self-conscious and afraid that someone was going to comment on my obviously fake features. Trying to avoid situations where people will scrutinise me. Worried that my wig, eyebrows or lashes would fall off or become smudged without me being aware. Avoiding doing activities that I would formerly of undertaken without issue - going to the gym, taking the children swimming, going to theme parks, going to dances or parties, going to music events. For fear of my wig falling off and issues around getting hot and wearing a full disguise that is itchy, hot and uncomfortable. Missing out on work opportunities due to my loss of confidence and shame of how I looked impacting on me going to interviews or doing work place presentations.	

Not going out in the evening as by that point in the day I could not stand the discomfort of my wig and lashes and wearing glasses and needing to go home and get relief from them. During covid wearing a face mask on top of this was unbelievably difficult.

Please consider this and try to imagine me as a 42 year old woman looking into the mirror and not recognising the face looking back. Hair is a massive part of our identity and the shame and helplessness I felt that I could not even have that most basic and universal feature pervaded every day, reminders of this fact were everywhere I looked - people with hair, adverts for hair and beauty products, people talking about going to the hairdressers. ect

Please also consider the fact that my eyes were constantly sore and watery and gritty, eyelashes really are there for a reason. Without nostril hair my nose ran constantly as soon as the colder weather began and was always sore from having to use tissues all day every day.

The difficulty of obtaining a wig on prescription and subsequently having to purchase them along with false lashes on a regular basis - wigs do not last like hair and once they have been washed a couple of times/ rub on clothes they start to look 'wiggy' making the wearer even more self-conscious. Many in society laugh at people wearing wigs, they have traditionally been a source of comedy, all of this is in the mind of those wearing them, the stigma is real.

I could not even access counselling services due to the feelings outlined above, having someone

I sit here now with a full head of dark and curly hair, eyebrows and eyelashes. My heart sings when I type that fact. I have been given the opportunity to live a normal life through this drug and I could never express in words what this difference has made to my life - it is not just hair. I am a sensible and professional woman, I work hard in social care and have built a good career in what I do, please understand I am not an emotional 'weak' person - every word that I have written is a true reflection on how living with no hair on any of my body made me feel every day.

Baricitinib and the other JAKi's that are currently undergoing clinical evaluation will give those with currently no hope of successfully managing this disease hope that they may live normally again. Please consider this, I tried the handful of treatments currently available on the NHS to treat this and lets be honest, they are outdated and do not treat the systemic root of the condition in the same way that a JAKi can - we must embrace this in the same way that it has been used for those living with other debilitating conditions. Please follow the lead of the US and Europe and recommend Baricitinib as a treatment. In my opinion it is a glimmer of hope in a disease that has been up until now largely ignored and unsuccessfully treated, it would be cruel to deny those living in the UK this opportunity.

Finally, I have been forced to source my Baricitinib from abroad, it was stressful and difficult. I was desperate, I forged ahead and it paid off. I am supported by a pragmatic and knowledgeable private consultant who monitors my bloods and advises accordingly. The thought of not being able to get hold of this treatment is unthinkable, and a constant worry. The experience of living how I did for those years has impacted my mental health deeply. My reaction to losing my hair again would be extreme and I will not allow myself to consider the outcome.

Composition of best supportive care
I agree with the final assertion that 'it concluded that there is wide variation in access to treatments, and that it is likely people would have limited pharmacological options and are more likely to use wigs and orthotics.' Dermatologists are not experts on autoimmune disease and it is not fair on them or their patients to expect them to have extensive knowledge on how to treat them. Patients should be referred to specialists in hair loss who are experts in their field.

Preferred assumptions
It is not really fair to compare the cost effectiveness of Baricitinib to the present costs incurred to the NHS.

Currently there is no treatment that consistently works so people suffering from Alopecia stop trying. In my case I was given topical ointment and steroid injections into my head. Neither worked, the topical treatment was difficult to apply and irritated my skin, the injections were extremely painful and intrusive. After this my case was closed and I was only left with the option of trying to get wigs, this was difficult and the approved supplier had a limited range to try. So I stopped costing the NHS anything as they could offer me nothing.

Does this mean we should never receive any help? as based on this assumption any new treatment coming along will be rejected as not cost effective compared to the current state of affairs.

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? No **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** No. Eczema and alopecia areata in clinical trials are related, it would seem right and proper to make Baricitinib available for both. In the measure of well being it would bring equal benefits to those in need of either treatment. It is not good practice to be using treatments on the present varied results prescriptions when the tests for Baricitinib show advantages.	

Cost of repeat unsuccessful visits to a dermatologist and medication need to be considered.

Are the recommendations sound and a suitable basis for guidance to the NHS?
Yes, these comments are forwarded on the basis of experience.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
No

Name	
Comments on the DG:	
I assume from people who Have accumulated this report and made the decision about this particular drug for the treatment of alopecia, have not got family members who have the condition, or go through the trauma of having a condition themselves or watching love one go through the trauma of having alopecia of any form. I have a family member, a daughter, who I have watched from the age of five battle through her journey of alopecia from a small patch on her, get any hair cut to cover the patches, different hairstyles to cover the patches and as she got older, we had to Look at alternatives. Ages 10 she chose to shave her hair because she was waking up to clumps of hair on her pillow, clumps of hair falling out in the shower. No, 10-year-old should ever have to face that things didn't stop there. It's only got progressively worse as she's got older and hit high school, she was different, but she was made to feel different. People knew she was different . My daughter has no friends at school no friends outside of school. She's currently waiting to see a psychiatrist because she wants to take her own life because she hates the way she looks the way she sees herself and the fact she doesn't feel like she belongs in life. I can buy all the wigs in the world, the eyelashes and the eyebrows, but if there's a chance that there is a drug that can be provided on the NHS for the treatment of alopecia, why would you not allow this drug to be given to people with alopecia men and women children, teenagers. Treatment is given to various conditions, some which are more important than others. I fully understand but alopecia is up there with the serious cases because it's a huge confidence blow. If you're reading this and you have children, put yourself in somebody else's shoes with alopecia and how would you feel if you had no hair no eyebrows no eyelashes your family member had it? What would you do? What length would you go to what fight would you take to make sure there is a drug available on the NHS to help potentially combat alopecia if your answer is exactly what we're doing then, maybe the decision shouldn't be a no to this drug now or in the future maybe it should be a yes this drug is a good idea because it will change so many lives. I don't want to wake up one day and not have a daughter because she can't cope with the world. The amount that Jack inhibitor costs compared to how much you pay out on wigs, per	

person per year. I am sure the drug is cheaper in the long run because you will save on Wigs and also mental health side of the NHS. It will relieve some pressures from the mental health capacity on the NHS. Please don't decline this look on the NHS, make it available for them and make it an option. Make them the confident people that they so desperately want to be again. Let's get these people back out in the world where they belong.s

Name	

Comments on the DG:

Has all of the relevant evidence been taken into account?
No I don't believe all the evidence has been taken into account. As a husband of someone who has Alopecia the disease that impacts my wife everyday of her life physically and mentally also impacts family members.

Firstly financially the options that are currently available to treat Alopecia aren't available in all postcodes and would require private consultation or products bought without prescription support. The impact on work is also another consideration, my wife can not always mentally be prepared which also impacts us as a family despite the love and support we continue to provide. In addition to clarify wigs are not made available to all and to obtain a reasonable wig which will need replacing yearly costs around £1000 per year, either make these available or provide some financial support.

Mentally this doesn't only impact the Alopecia suffere it directly impacts family members, i have been on prescribed medication to support, however my wife is still waiting for counciling after 24 months, and this has also affected one of my children which is another drain on the NHS where it may not need to be.

Unfortunately the evidence NICE have looked at isn't the big picture and the costs and support for people that surround that person also need to be considered, and the facts that the current treatments are a postcode lottery. Also consider every time a treatment doesn't work this also has a negative impact and even more so knowing there is a drug available that will help a lot of families get back their life! Please live a day in our shoes it impacts every aspect of every day life for all of us!

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
As above cost effectiveness needs to look at the bigger picture and consider the impacts of the disease relating to costs for additional medication and therapy to support mental health issues linked to this and time of NHS supporting with treatments that are less effective. Also consider depressions has a negative impact on keeping healthy which leads to other issues which directly anre an on-cost to NHS. Also look at samples of impacts to a family rather than an individual.

Are the recommendations sound and a suitable basis for guidance to the NHS?

The recommendation should provide anyone with severe and life changing impacts from Alopecia the option to try this treatment plan. This should not be a postcode lottery!

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
The current treatments available discriminates against postcodes and financial status.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
No I don't believe all the relevant evidence has been taken in to account. I do not believe that a large enough cross section of people living with Alopecia was studied to give a true insight in to the reality of living with this life debilitating condition. A larger cross section and more varied amount of patients should have been considered and monitored. I also believe that more patients living with the reality of Alopecia on a day to day basis should have been present at the committee hearing and heard.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
I passionately believe that they are not reasonable interpretations. My life has completely changed after the sudden complete loss of my hair 4 years ago in a period of just 3 weeks. There has been no consideration to the cost incurred due to the mental health impact and the financial life style changes made as a result of its impact. I have taken numerous GP appointments, seen counsellors, spent a fortune on lotions, potions, herbal, shampoos, vitamins anything that offered a glimmer of hope. Alopecia impacts me on a daily basis. I have changed from someone that would be the most confident, active and outgoing person in a social group to a person that shy's away and stands back. I have avoided numerous social events purely because I can't work out how to cover my head in a way I will feel comfortable both physically and mentally. Having worked full time for over 35 years I no longer work as it is just too stressful. I haven't looked in the mirror for 4 years and liked what I've seen, I don't even recognise the reflection looking back at me. Every time I have to leave the house I have the anxiety and discomfort of covering my head. What will I look like? Will people stare? How will it feel? Every time I am invited somewhere my first thought is how will I deal with covering my head and sometimes there isn't a solution that works for me so I won't go. I have completely changed my life to try and remove any root cause. I resigned from my successful career in Sales as it was at times a very stressful challenging role. It was one I really enjoyed and actually excelled at but I had to put my health and hair first. This has meant my husband and I have had to downsize from a house we loved and had spent 7 years renovating to a smaller property but again we had to reflect, take stock and prioritise what was important in life. I felt cheated and

angry, how could this be happening to me. This condition has impacted my professional life and career, my social life and my personal relationship with my husband all in a deeply negative way. Something which wasn't a result of any poor lifestyle choice.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No I firmly believe that the recommendations are not sound and are in no way a suitable basis for guidance to the NHS. Having the option to try Baricitinib would be the opportunity to try a life changing drug for me. To have my hair back would be life changing - the sentence Alopecia isn't life threatening but it is life changing is so true. I really can not stress enough how much I am impacted daily by this awful condition. Every time I have to answer the door or leave the house I am faced with dilemmas that aren't always solvable. To have hair would enable me to live a carefree life again. I would be able to make impulsive decisions and choices. I haven't been on holiday for 4 years as I simply cannot face having to deal with how I can hide and cover my head in a comfortable way.
When the USA and Europe recognise how important and beneficial this drug could be to the treatment of Alopecia and the improvement of a sufferers life how can the UK get its interpretation and guidance so wrong?

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
It would appear having read much documentation and observations from the committee discussion that male sufferers of the condition were not given the same amount of consideration as females and I consider this unfair. Even though it is socially more acceptable in society for a male to be seen bald the mental health impact at the loss of ones identity is still the same and has the same deep mental health impact as women.

Name	
Comments on the DG:	
It is extremely puzzling that it is acknowledged here that hair loss causes severe psychological distress but not concluded that therefore regrowing this hair would improve quality of life. Hair regrowth would reduce psychological distress and therefore clearly improve quality of life. Speaking from personal experience, I can confirm this to be the case. In terms of the "range of medicines" offered by dermatologists, this implies that there are other treatment options. None of these options have good response rates for severe alopecia areata, nor are many of them available in every geographical area even if they did have good response rates. Therefore, in my experience and opinion as an alopecia sufferer, they are not reasonable alternatives.	

The approximately 50% regrowth rates offered by Baricitinib are a huge step forward in this area, if even half of people could be spared the severe misery and pain of this condition, it would be a massive improvement.

Personally I have been obtaining a JAK inhibitor outside the NHS (which I am struggling to afford, and should not have to source independently as I contribute towards the NHS through taxation and national insurance contributions) for 6 months and have experienced significant regrowth. Prior to this I had exhausted all options offered by the NHS in my area and none had induced any regrowth at all. I acknowledge my privilege in being able to access these medications independently, but worry that there will come a point when I am unable to. This medication has been nothing short of a miracle and should be available to all, regardless of their financial position. Furthermore, my private dermatology consultant has experienced regrowth rates of far higher than 50%.

Regarding the reference to wig prescriptions, this varies between locations, with some localities offering very little provision at all. Offering only synthetic hair is not reasonable as it does not adequately resemble human hair. Nor are the wig options sufficient for men (which some could argue is discriminatory) or often for children. Should patients be offered human hair wigs then the NHS would find that the cost of providing this would be massive, which would therefore influence considerations on the cost effectiveness of Baricitinib.

It is also worth noting that being given a wig prescription still requires a large financial contribution from the patient towards the prescription (I believe in the area of £70) which is not affordable to some (again, this could be seen to be discriminatory).

Accessing a wig prescription also does not address the difficulties posed by having no eyebrows or eyelashes. Again, although false eyelashes and microbladed eyebrows are available, these are expensive and so not affordable to all, and are not included in your cost calculations. Furthermore, many of these options are not appropriate for men or children.

In my experience, the wearing of false eyelashes has also resulted in multiple eye infections and inflammatory reactions, costing the NHS in terms of GP appointments and topical medications.

It is also worth noting the not insignificant cost of medications to address the severe anxiety and depression caused by this condition. Plus the cost of psychological therapies. Again, psychological therapies are something which I have fortunately been able to access independently of the NHS, as the waiting times within the NHS are astronomical. At the time of accessing therapy, following (and necessitated by) my second experience of alopecia universalis, I was measured to be experiencing severe depression and moderate anxiety.

It is egregiously unfair to attempt to calculate the cost effectiveness of this drug whilst excluding the huge financial burden that patients are having to shoulder themselves. Comparing the cost of Baricitinib to the cost of best supportive care does not come close to demonstrating the actual financial cost of this disease. As mentioned, best supportive care does not cater for human hair wigs, prescription contribution costs, microblading of eyebrows or other cosmetics, false eyelashes, psychological therapies or antidepressant (and similar) medication. In addition to this, alternative treatments such as topical immunotherapy require a huge contribution from the patient in terms of regular attendance at hospital and the associated costs of time off work, transport to and from hospital etc. There are also the costs of seeking private consultations due to extensive dermatology waiting list times, and the aforementioned costs of medications for related conditions.

In conclusion, the fact that the NHS does not currently adequately support alopecia patients, and requires them to shoulder almost all of the financial burden themselves, should not be allowed to influence whether or not baricitinib should be approved. Were the NHS covering all these costs, then the cost of baricitinib would not be too large in comparison.

The fact that most patients are not receiving active treatment is because most patients are told that there are no treatments, which will continue to be the case if you refuse to approve new treatments.

It really is infuriating that many health conditions which are avoidable (such as those associated with smoking or drinking) are treated on the NHS, yet an alopecia treatment is being denied on the basis of its cost.

As mentioned at the start of this comment, this decision cannot be based on quality of life considerations, as it is obvious that this drug would make, and is making, massive improvements in this area. If this was not the case, people would not be pursuing access to it. It is maddening that psychological pain is being deemed less important than physical pain, given that other JAK Inhibitors have been approved for conditions such as arthritis.

Lastly I would just like to reiterate the impact that the regrowth I am experiencing through accessing these medications independently is having on my life. I had lost all hope of regrowth. I never want to experience the severe depression I was diagnosed with ever again, and I fear that this is what will happen should my access to this medication be revoked. There have been documented suicides related to alopecia, surely that alone should be enough evidence to satisfy quality of life considerations. I would ask the members of the committee to consider how they would feel facing the world having no hair, eyelashes or eyebrows and then to consider whether they think an opportunity to reverse this would impact their quality of life. Lets not forget that throughout history the shaving of heads has been administered as a punishment. Additionally, hair loss is a major concern for

cancer patients, despite already facing a life threatening illness. I hope this adequately demonstrates the impact JAK Inhibitors may have.

Has all of the relevant evidence been taken into account?
No- please see my comment.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No- please see my comment.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No- please see my comment.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Yes- please see my comment. Plus additional concerns regarding socioeconomic discrimination.

Name	
Comments on the DG:	

I am a 60 year old woman with Alopecia Universalis. I lost my hair 3 years ago. very quickly and suddenly . Before that I was a healthy happy person with a successful career and family life. I was looking forward to retirement and spending more time with close ones. After a private appointment with a dermatologist where it was explained there was no treatment for the condition and coping with the sudden loss would be hard I fell apart.

I did not know Alopecia was an auto immune condition and like the majority of people I thought it was stressed related.

The impact on losing all my hair has been devastating . I no longer work , I don't want to leave home and really don't want to socialise. The condition has effected my family life as its so difficult for them to see me not coping with the condition.

To read there was a drug that already existed could treat my condition was wonderful and brought for the first time some hope.

Recommendations
Whilst I appreciate NICE evaluating the use of baricitinib I would question how can the cost effectiveness be evaluated when as in my case I was not offered any treatment . What is there to compare?

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
The impact of alopecia is not something that can easily be measured and this is evident throughout the guidance so no, I do not believe that the recommendation is based of sound evidence. The committee does not seem to have a good representation of experts in the area of Alopecia.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
There is high level of uncertainty on the cost effectiveness which likely comes from a lack of understanding or empathy on the true impact that alopecia has on someone so I struggle to understand how the recommendation was concluded. The fact that the trials showed great success is enough to make be believe this treatment would be very cost effective. It could potentially change the lives of many people suffering with alopecia, myself included.

Are the recommendations sound and a suitable basis for guidance to the NHS?
The recommendation made is very disappointing. I am a 30year old female who has suffered with Alopecia for the majority of my life. I have tried many other available treatments with no success. I was very excited when I heard Baricitinib had received approval and to now find out I will not be able to receive this potentially life changing treatment through the NHS is extremely disheartening. I feel the cost of wigs and other non successful treatments I have had over the years would far exceed the cost of Baricitinib. I don't believe this guidance truly captures the impact that alopecia has on an individual.

Name	
Role	NHS midwife
Other role	Person with alopecia areata
Comments on the DG:	

I am an NHS midwife with Alopecia Areata. I have followed this review closely because it's something that means a lot to me. Finally there is an opportunity to help patients with alopecia.

I feel like the huge psychological impact that alopecia has on people has not been regarded as important enough in your review.

I understand that this is an expensive drug, but I do not feel that a cost benefit analysis can be put on peoples mental health. Just as an example - I had to take 6 months off of work when I first got diagnosed. This was 6 months full pay by the NHS. I was told by numerous GPs that I should minimise stress. How can you minimise stress when you are watching your identity fade in-front of your own eyes? The worst is that after trying numerous treatments, paying privately for tests, investigations. Paying for nutritionists, acupuncture, reflexology to help with lifestyle and balance.

After all this, there is still no hope that any medical professional can give you. I got told on numerous occasions by a GP that it was 'just hair'. I bought 2 wigs over the last 5 years which have cost in total 10,000. I feel like I'm walking around hiding a big secret and inside I am deeply unhappy.

The support on the NHS is currently terrible. Because there are limited treatments, once all of these have been trialed you are left alone to deal with the fact that there is no hope.

Please consider offering this drug on the NHS.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
No it has not. There is a vast amount of direct evidence across the USA and EU as well as the UK to demonstrate the positive effectiveness of Baricitinib for treating Alopecia, and subsequently the mental health impact of this disease by enabling people to feel like a normal human being.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No they are not, as a sufferer of Alopecia Universalis my life as been devastated by this disease for which there is no existing effective medical treatment. The mental health impact of this "apparently just cosmetic" issue has been completely undervalued. Given the emphasis on mental health in the last few years how can anyone say that Alopecia is just cosmetic when people commit suicide, don't leave the house, don't work, withdraw from friends, family and society as a result of Alopecia? Why is hair loss treatment and support for cancer sufferers even considered if this is truly the case? You cannot put a price on mental health. The clinical interpretations represented are inadequate.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No, please tell me what alternative I have on the NHS? The NHS gave me prozac to help with anxiety but nothing to fix the Alopecia which causes the anxiety.

Fortunately as a UK resident and UK taxpayer I am buying this medicine from India directly for less than the price of 4 wigs a year. I get no help with wigs, eyebrow tattoo treatment or anything. In 4 months I have had FULL regrowth using this medicine, it is not the price that is the issue for me as it is super cheap to buy from abroad but the lack of NHS support is despicable for me and many others, and now something is available the evidence is being watered down and dismissed. Alopecia is an auto-immune disease, an inflammatory condition that can lead to other diseases, you are only considering the physical aspects and given the extensive list of nonsense treatments the NHS do fund it is a huge insult to say people like me do not matter. If I do get adverse effects from Baricitinib from the indian treatment I am sourcing personally, the NHS will have to sort that out and

many people are ignoring all the routine recommended blood tests etc to ensure they do not suffer serious side effects because they are desperate for their hair to grow back.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
No

Name	
Comments on the DG:	
I began losing my hair around a year ago which has led to losing my hair all over my body completely and has since had a detrimental affect on my life where I've been having days off work struggling mentally and also not seeing friends or family since July of last year and never ever going out anywhere as I am too embarrassed of what I have become and have seriously questioned my very existence, and hearing about this drug gave me some hope that something could be done and I wouldn't be like this forever as much as I know it is not guaranteed it was an option and some hope which is something rare when it comes to treating alopecia so the fact it has been rejected is extremely disappointing, especially as I have been referred to a dermatologist since July and have still a long way to go before even getting an appointment so whilst something could be happening to bell treat this it's not possible because of the ridiculously long waiting times to even just see a dermatologist. I noticed you talk about the cost effectiveness and basically doesn't impact a persons living standard well let me tell you until you have experienced it you can't imagine what it does to your mental health. To talk about the cost is ridiculous I feel because the NHS are prepared to pay for treatments for problems that people inflict on there own body through there own doing such as obesity, alcoholics needing transplants, smokers needing treatments for many issues, drug users and all there problems that's all fine to find money but something which has happened to me and others that is completely out of our control you refuse a drug which could potentially help a big deal. I've even just read that you have recently approved a drug for obese people to help them lose weight how much is that going to cost considering how much money obesity is already costing the NHS and without being funny but surely the most cost effective thing to do which would cost absolutely nothing would be to tell them to stop eating and start exercising but again money is found for that. I would just strongly urge you to change your decision and at least give people who are suffering from this at least some hope and a chance of regaining our life because none of us have asked for this it is beyond our control and it really is detrimental to both of our physical and mental health.	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? I can only comment on my personal experience. Over the past year, I have been treated on the NHS in the East Midlands with Baricitinib for atopic dermatitis. I also suffer from severe alopecia areata. Within three months, my hair had begun to regrow. I am now a year into treatment, properly monitored by a consultant and with routine blood tests. I am currently symptom free. Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence? In terms of cost effectiveness, being treated with Baricitinib on the NHS has meant coming off anti-anxiety and insomnia medication, topical medications and steroid injections. I also do not need my wig prescription and have not needed to access NHS counselling sessions. In the past, I have experienced a nervous breakdown and hospitalisation associated with alopecia areata, all of which have costs to the NHS. The truth is that with the lack of treatment on the NHS I am one among many sufferers who have spent a personal fortune on alternative treatments including from private consultants, trichologists, nutritional therapists, herbalists and nutritional supplements. None of these worked. The lack of treatment leaves us vulnerable to those in the medical profession and beyond who are happy to exploit us. It includes the extra anxiety experienced by those who are currently sourcing baricitinib off-label from overseas and take the medication without proper medical supervision. The lack of treatment adds to the cruelty of our experience of the disease and the anxiety it causes. This associated burden could be avoided by the NHS providing this effective treatment for all sufferers.	

Name	
Comments on the DG:	
I am disappointment in the decision from NICE to reject the use of Baricitinib for alopecia. There is clear evidence for the effectiveness in patients with alopecia. NICE have overlooked the severe psychological distress caused by alopecia. Clearly, improvement of hair growth in this distressing condition would improve quality of life. I ask that NICE urgently reconsider it’s decision.	

Name	
Comments on the DG:	
The report does not take into account the impact on mental health of sufferers. This is an omission which should be corrected. **Has all of the relevant evidence been taken into account?** Fails to take account of the mental impact on sufferers. Evidence shows a strong causal link between sufferers and negative mental health outcomes. This should be corrected. Patient impact statements and reports should shine a light on the physiological impact. **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** The drug has a high success rate (and NICE have approved drugs with lower success rates in the past). Given this is an under resourced and under appreciated area it seems wise to approved such effective drugs for use. **Are the recommendations sound and a suitable basis for guidance to the NHS?** It goes against the key pillars of the NHS to prevent the use of this drug. It must be stressed that the impact on individuals is acute. It would be wise to reconsider the initial recommendation for rejection. Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity? The EA 2010 must be considered here for its impact on those with a disability (as sufferers could arguably be caught under the act). Regard should also be had to the potential grounds for discrimination on the basis of sex given the higher negative impact of hair loss on women than men.	

Name	
Comments on the DG:	
I wanted to comment on the effect of alopecia on quality of life. I've had alopecia for almost two years, and the impact of this condition on my mental health has been profound. My anxiety around people has meant I've avoided seeing family and friends, neglected meeting new people since moving to a new town, and had issues with social anxiety when mixing in public. I had been looking after my daughter until September when she started school, at which point for my family finances I needed to find work. Due to my social anxiety I've found it incredibly hard to put myself out there and as a result I haven't found employment in 6 months. As a young male,	

aspiring to help his family but unable to, I have had periods of depression that have taken away enjoyment from activities I used to enjoy and only able to do the most necessary tasks. Any treatment that may encourage hair growth being available would have stopped this spiral towards depression and social anxiety, but instead I'm using the NHS for ineffective treatments and to put plasters over the problems caused as a result of it.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
I believe that all of the relevant evidence has not been taken into account.

Some of the evidence that you have used and refer to is too minimal. The Adelphi study recruiting only 117 people through dermatologists in the UK is not an accurate study and should be disregarded in the decision making process. The fact that only 117 people were actually recruited is a true reflection of the minimal amount of people in the UK with alopecia that are actually under a dermatologist...most have either exhausted the minimal options that a UK dermatologist is willing to provide or are still waiting to see a dermatologist. NICE estimate that there are approx 100,000 people in the UK with alopecia. Placing significant importance on only 117 of these people is unrealistic and non reflective for appropriate use as evidence. On this score you are using evidence from a source with only 0.117% of estimated people in the UK at any one time with alopecia. Also I would like to assume that the full breakdown of the patients sex, ages, length of time with alopecia, severity at the time of taking part in the Adelphi study was presented to the technology appraisal committee for it to have been used as valid evidence and also full details from the other Adelphi studies in all countries that took part in this study ....not only the UK with it's 0.117% representation of people with alopecia.

USA initially and then Europe have given approval for Baricitinib in the treatment of alopecia. There must be a larger volume of evidence for this to have been granted. Why has this not been been presented as relevant evidence.

The 2 clinical expert dermatologists at the technology appraisal meeting are exactly that....experts ...most NHS dermatologists in the UK are NOT experts in the treatment of alopecia. Dr Matthew Harries is a Consultant Dermatologist at Salford Royal Hospital and has focused on hair loss conditions during his medical career. Dr Harries is a member of Alopecia UK's Research Committee.

Dr Abby Macbeth is a Consultant Dermatologist at the Norfolk and Norwich University Hospitals Trust. Abby has a clinical and research interest in hair disorders, in particular Alopecia areata (AA). She was Co-Champion and Data lead for the Hair Loss Priority Setting Partnership funded by Alopecia UK.

Evidence provided by both Dr Harries and Dr Macbeth, again did not represent the majority of dermatology experience for patients nor outcomes for alopecia. My son was only ever offered scalp solution and steroid injections and no further treatment or follow up after this.

Evidence to represent patient perspective from [redacted] (Alopecia UK Trustee) and [redacted] (Alopecia UK CEO) was not enough evidence to provide a full picture of patient perspective from different demographics (age, sex for example). I was a public observer at this meeting. Lynn and Sue did detail quality of life and mentioned suicide once as an end result of alopecia. For example they did not/could not give an accurate representation regarding quality of life of a male living with alopecia, nor a teenager going through puberty. There should have been a male representative. There should have also been at least 2 (one male/one female representatives that were not representatives from Alopecia UK). Alopecia UK aim to promote a positive approach to living and dealing with alopecia, which unfortunately is NOT the experience that thousands and thousands of people are having with their own alopecia.

Key evidence that would influence a final decision at the meeting came from the 2 clinical expert dermatologists and the 2 representatives for the patients perspective. I have detailed above why this was a poor source of complete evidence to be presented at the technology appraisal committee. I am not surprised from the evidence provided by these select 4 that the potential outcome is going to be denial of Baricitinib by NICE. I am outraged at the limited scope of evidence.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
To a partial degree BUT the cost effectiveness was compared to treatments that included wigs - price over a lifetime etc.

There was no comparison to the cost of dealing with the mental health impact of having to live a life with alopecia - or the socio-economic cost ...

For example my son is 18 now. During the past 4 years of losing all of his hair - scalp, facial, eyelashes, eyebrows and all body hair (every bit of hair on his body) he now lives in his bedroom at home and does not go out - from ages 14 - 18 his life has become smaller and smaller due to the lack of self esteem he has from his visible difference. He had to leave school and college because of the stress and negativity he felt about his appearance at such a crucial time in a young persons life. He has recently attempted to commit suicide as he can't see future for himself.
- he has been to see his GP over the 4 years at least 30 times
- he has contacted CAMHS service 8 times
- he has had NHS health psychology 5 times
- he has had private counselling at £60 per session because CAMHS said they could not help
- he had to leave school as he became too ill to do his GCSE's because of his self loathing

- he has not been able to stay at college and now has no A levels, despite being an A* predicted student at age 14 before he developed alopecia
- he does not go out, lives in his bedroom
- he has recently attempted to kill himself
- The NHS mental health crisis team have made 14 visits to our home
- he has just been referred on to the NHS community mental health team

My son's life has been destroyed by alopecia, this is a case where Baricitnib treatment would have been a suitable option. He has severe alopecia. Baricitinib could save his life and help him to move forward in life. My son's story is not an unusual story of a teenager living with alopecia. There is a vast array of evidence of similar cases on multiple Alopecia Facebook groups. Thousands of parents with children wanting to take their own life as they can't see another solution. Thousands of adults of all ages, male and female who are living the life of a recluse.

It is imperative that Baricitinib be granted by NICE for severe alopecia areata based on present quality of life for an individual patient with their personal/individual history of alopecia both psychologically and medically being a deciding factor.

Are the recommendations sound and a suitable basis for guidance to the NHS?
The recommendations are not based on an accurate cross section of evidence. Any recommendations for a sound and suitable basis for guidance to the NHS can only come from an accurate cross section of provided evidence. This, unfortunately has not been the case.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Yes. There has been unlawful discrimination against men. I was shocked that a member of the external assessment group (EAG) asked the representatives from the patients perspective ([redacted] and [redacted] from Alopecia UK) if she was right in thinking that it's not as bad for a man to have alopecia, that there wasn't such an impact due to you often seeing men without hair implying that a man's response to alopecia or their deterioration of quality of life would not be as severe as a females. Again this was evidence and discussion that contributed to the NICE recommendations ...evidence that came from a biased sexual discriminative stance from a member of the external assessment group.

This instigated a conversation about wigs, where either [redacted] or [redacted] (I can't recall which one) explained that she does not leave the house without a wig. There was no discussion on the fact that it is practically impossible for a male to get a wig that would look like real hair. Men are very restricted due to having short hair in the remit of wigs available. A teenage boy would

not be able to get a suitable wig and most men would also not be able to. Therefore the Modelling of Best Supportive Care in 3.10 stating that it is likely people would have limited pharmaceutical options and more likely to use wigs is in fact inaccurate, particularly in the case of men. It appears evidence from males on this score has not been sourced. There was a female bias regarding wigs as wigs were only discussed in the technology appraisal meeting in relation to women...I feel that assumptions regarding wigs as a whole to anyone with alopecia (male or female) were incorrectly concluded by the committee as a result of this.

In 3.11 the EAG's assumption that people who's condition had not responded to treatment in both arms would only have wigs and orthotics is inaccurate..females are more likely to access wigs than males.

In 3.14 include only wigs and orthotics in best supportive care ...again biased towards female

The EAG considered it unlikely that people would be willing to try more pharmaceutical treatments that have limited effect over a lifetime horizon after all other options have been exhausted. This is a massive assumption based on the evidence and discussions had during the technology appraisal meeting and the way the conversations repeatedly were steered back to wigs by the EAG members.

The evidence was biased and discriminative to men. No male representation of patient experts were present at all.

Name	
Comments on the DG:	
It’s is important Baricitinib is available to those suffering from one of lives truly cruel diseases, Alopecia. I’ve suffered from it since I was 18 and now 36. It has affected every part of my life, relationships, careers, self-esteem, dating, trying to fit into society, feeling and looking different. Quality of life has suffered massively yet time and time again I’m reminded it won’t kill me and it’s ‘only cosmetic’ and to put a wig on. I can’t imagine suffering from this all my life with no hope and have felt extremely suicidal. Thankfully I have sourced baricitinib overseas for 8 months now and am responding well. This drug works! My bloods have been fine. Help stop the pain and suffering of the unheard alopecia community.	

Name	
Comments on the DG:	
To whom this may concern, I am a 26 year old single woman, with Alopecia Totalis. I developed this when I was 24, buying my first wig (at my own expense) for £1,100 in August 2021. I am still yet to receive any NHS support for a wig, and have spent £5,000 so far in the last two years on wigs. My father has Rheumatoid Arthritis, and has been prescribed a JAK inhibitor for 4 years now. Having seen the vast improvement in his condition as well as his overall well being and outlook on life, it is very hard to watch while struggling myself. I strongly believe that JAK inhibitors will give me a better quality of life, and a much more positive outlook. Having suffered with periods of depression and suicidal thoughts due to my condition, to be denied a treatment or promised treatments that have incredibly low success rates such as Methotrexate and Ciclosporin will be costing the NHS more money on providing me mental health support. I look forward to seeing the outcome of this. Yours faithfully,	

Name	
Comments on the DG:	
I am so utterly disappointed that the recommendation is for this not to be approved to treat alopecia. I lost all of my hair 6 years ago. The NHS dermatologist I saw had no treatment available and I was prescribed a wig which was useless as I could only use it with a certain provider who were unhelpful. They offered limited choice and the prescription barely met the cost anyway. I ended up purchasing online and never used the prescription. The NHS dermatologist lacked empathy and signed me off their caseload as soon as they could. I've had to navigate almost 2 years of depression brought on by a sudden change in my appearance. Do you understand the psychological impact from an unwanted loss of self identity? It has affected me socially. I retreated into myself. The psychological impact on my life has been huge. I didn't want to leave the house. I've lost friends. I almost lost my marriage because I was depressed and felt sexually unattractive. It has stopped me having a fulfilling family life as I avoided activities with my children e.g swimming, going on holiday. It has halted any career progression as I feel self-conscious. It's not just a case of sticking on a wig and some false eyelashes and all is ok - it's a complete loss of self-identity. I felt bereft, isolated and worthless. Do you know how difficult it is to get into a swimsuit with a bald head, no eyebrows, no eyelashes - you feel like a freak. I have now resorted to purchasing the medication from abroad and I am	

seeing regrowth within a relatively short space of time. It’s unbelievable you can obtain treatment to treat other cosmetic issues eg acne or get breast enhancement on the NHS but nothing for alopecia. Or not through my trust provider anyway - it depends on where you live I guess. I’m sick of hearing it’s just a cosmetic issue. My body has a disorder whereby it is rejecting my hair. It is not a cosmetic problem!!! I am been lucky to have joined alopecia support groups and gained knowledge and information from them as the support on the NHS was zero. At the same time I have had to read many encounters of individuals feeling suicidal from the loss of their hair and I am angry it’s still not being taken seriously and brushed under the carpet. This report has just reinforced the total lack of empathy and understanding there is towards alopecia sufferers.

Name	
Comments on the DG:	
I do not agree with the decision made by NICE as part of this document. The decision about the cost compared to treatments now is not inclusive of all the relevant factors. The current treatments hardly work, so the cost effectiveness is probably quite low in comparison to this. Furthermore, lots of people with alopecia stop bothering to get treatment because it doesn't work and there aren't any new treatments, so if your economic case considered these individuals in the right way (rather than just accepting they are cost neutral to the NHS), this would be more cost effective. Referring to the wig allowance is also not really beneficial; the wig provision varies between trusts, and the financial support given is very minimal, meaning that most individuals have to get wigs privately, which also isn't in your figures. For me, in Sutton, I was told that I'd have to agree to pay £40 in advance just to visit the wig shop (Joseph's) that are the wig provider for my local trust (epsom and st helier), and from what I could see on the website there was little choice, and most of the wigs were aimed at elderly women. Similarly, your quality of life assessment is also lacking. The quality of life from my current treatment, DCP, means that I have to have my head in a hat for 24 hours and not wash my head for 48 hours. This means I can't exercise, I have to go to work with a hat on (regardless of the weather) and I feel like I have to explain to people why I'm wearing a hat. The clinic is also quite infrequent, because it's only one day a week, so I have to take time out of work. I have also had the steroid injections - these are painful, they cause scar tissue around your skull and sometimes the marks remain for a long time, as well as bleeding. It is quite painful for many hours afterwards. Regardless of all this, having alopecia in general affects my confidence, self esteem and social anxiety, and the fact that there are hardly any treatments and a lack of research makes it worse. If NICe doesn't approve these sorts of treatments, you're strengthening the signal given to the pharmaceutical and life sciences industries that alopecia isn't a condition that's worth treating as it's purely cosmetic.	

Name	
Comments on the DG:	

Recommendations
Wait times to see a dermatologist are long and not all dermatologists understand the physiological effect .Wigs are not widely available on the NHS and are certainly not prescribed by every health trust.

Treatment options
“They also offer immunosuppressant medicines and wigs on prescription.“

This is incorrect wig prescriptions are a postcode lottery

Health-related quality of life measures
I feel this is an unfair assumption as many people with alopecia receive no care or offers of trials. Specialist dermatology appointments can take years to happen (8 in my case). Using people already receiving help is not a true reflection of the full impact of those affected.

Quality of Life Assessment tool – EQ-5D – that has measures the impact of a health condition with dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression, this is not the most appropriate tool for measuring the impact of alopecia areata on quality of life.

Acceptable ICER
Alopecia currently costs the NHS little in terms of treatment as there is no set process in place . Not all treatments are widely a available on the NHS, some drugs mentioned are blocked by some healthcare trusts so despite being prescribed are only available privately

Has all of the relevant evidence been taken into account?
No. I do not feel that the full effect of alopecia in Every day life has been considered. The full impact on mental health has not been considered

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
Alopecia has hugely affected my quality of life in every single aspect. It has affected my ability to enjoy lots of everyday activities. My relationships have suffered , my working life has suffered and my ability to just live a normal functioning adult life has diminished.

Current financial burdens placed on patients are not considered

My confidence has been hugely effected .

I receive no wig prescriptions and therefore I have also suffered financially as wigs and their care are not cheap

Are the recommendations sound and a suitable basis for guidance to the NHS?

I do not believe they are, baricitinib Is a proven drug that works in lots of other dermatological conditions and has shown it does work in alopecia.

A treatment that is show to work and be available in n the nhs would be a huge improvement to current options offered.

The quality of life assessment tool used does not seem to be completely appropriate for a person with alopecia areata

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
Yes. From the evidence you can see the high success that JAKs has on a patient with severe alopecia. Eyelashes , eyebrows and scalp growth vastly improves from the SALT score. It is the most successful treatment for alopecia areata at the moment, in comparison to other immunosuppresants offered.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
Alopecia has effected my quality of life for the last 2 years from when I was first diagnosed. It effected me attending any social events, causing me to stay indoors all the time, worrying to step outside and feeling extreme anxiety when I do have to (for example food shopping). This took a huge toll on my mental health resulting in me needing therapy via the NHS and this to still be on going due to such a traumatic experience to happen in my early 20's. My 2 year old toddler suffered also as I dont want to attend any baby groups with him, my marriage has taken a huge strain due to my lack of confidence and depression. Things that I used to love like going to the gym I can no longer do, as being in such a environment is scary and worrying meaning that my normal healthy lifestyle doesn't exist. I avoid meeting with friends, crying at any old photos I come across of my "old self" wishing I would do anything to be able to get my hair back.

Are the recommendations sound and a suitable basis for guidance to the NHS?
I think Baracitinib SHOULD be available under the NHS. The clinical trials show it is the most affective treatment for severe alopecia. Experts have first handedly stated it is much better than any other immunesuppresants being offered currently and steriods/injections cannot be sustained long term meaning the relapse rate for people with alopecia is certain. I myself have tried every treatment offered through the NHS including Steriod tablets, injections, methotrexate and ciclosporin. All of these failing to work or causing severe side effects to myself. Baricitinib is a great medication for treating severe Alopecia and people ARE accessing it without being monitored by a health care professional and from overseas due to it being so expensive privately, meaning they are taking a huge risk in a desperate bid to get their hair back. Who would have £1000 a monthly basis to spare

on this treatment, not to mention the cost of living crisis we are all experiencing in todays current climate. JAKS are already funded on the NHS for arthritis, though patients who have arthritis don't go through the same amount of emotional and physical trauma to those with alopecia. I myself have considered taking my own life due to the disease and there is an opportunity to have the drug funded and be life changing for some of us. We spend thousands of pounds on wigs, private health care in order to get back some of our identity and theres finally a drug that can help with this and its not being considered as "cost effective" are these decisions being made with someone who still has their hair,eyelashes and eyebrows? Unless you have severe alopecia you have no idea how much this effects our quality of life. I am costing the NHS loads of money due to treatment needed for my mental health and physical health due to eye infections, nail infections, depression medication - this could all be saved if offered the opportunity to try Baracitinib under the NHS.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
I dont feel there is any unlawful discrimination.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
Has mental health issues been taken into account . It is not our fault we are hairless .it affects our identity and self esteem .ok a wig can disguise but they are hot and false . I have worked as an nhs Midwife until I was 69 .I paid taxes and N.I for 50 years .developed Covid then Alopecia universalis . I feel strongly we need to be offered treatment on the N.H.S .so many people with this condition do not live a normal life suffering agoraphobia anxiety and other health issues .please listen it’s not just about hair .

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No they don’t consider our illness .It may not be life threatening except suicide risk but certainly is life limiting . It isn’t just hair ,it’s our whole identity and changes our life and relationships . .the cost effectiveness does not consider mental health issues ,anxiety and agoraphobia and even suicide

Are the recommendations sound and a suitable basis for guidance to the NHS?
Recommendations need further exploration about mental health issues and impact of severe Alopecia Areata on men and women .It is not a condition that’s covered by health insurance and it’s wrong we have to look for drugs abroad for treatment and certainly unaffordable for many

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any

group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
This condition effects all races and genders and can occur any age. As a female with no hair I look like a man .I'm sure the committee have not discriminated but they need to look at our feelings .Again it is not lifestyle or abuse that have caused this condition .we are innocent people with a horrible condition .Please please listen and support this drug . Other countries have approved Baricitinib .it is expensive I understand but would help so many people .PLEASE a listen and support

Name	

Comments on the DG:

I feel Baricitinib should be recommended within its marketing authorisation, for treating severe alopecia areata in adults as clinical evidence shows it grows back hair in a proportion of patients with this condition and there is also an unmet clinical need for a safe, effective and licensed medication to treat severe AA. If we look at personal experiences and further clinical data from trials I am sure it is very easy to conclude Alopecia has a profound impact upon an individual experiencing hair loss of any extent but even more so with severe Alopecia Areata. The Alopecian community deserve a licensed treatment to treat this disease in which currently there isn't. I hope my own personal experiences living with Alopecia has made an impact on the overall outcome and will see Baricitinib available to try in clinic later this year.

Just wanted to acknowledge I am a 44 year old adult currently with Alopecia Universalis(very severe Alopecia Areata) with 95-100% hair loss in all hair bearing areas such as scalp, lashes. eyebrows, facial and body hair. No treatment to date has been successful in growing my hair back so I hope Baricitinib is approved as it would likely regrow my hair and as of result improve the quality of my life greatly.

Has all of the relevant evidence been taken into account?
No, I don't think all the relevant evidence has been taken into account. More data from clinical trials and comments from personal experiences of living with Alopecia needs to be taken into account in order to reach a final decision on whether to recommend Baricitinib for clinical NHS practice.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
No, the summaries of clinical and cost effectiveness are not reasonable interpretations of the evidence. More clinical data and personal experiences need to be taken into account before a final decision can be made.

Alopecia has had a profound impact on my physical and mental wellbeing which as a result has reduced my quality of life greatly in the following 2 ways:

1- On a physical level having no hair has meant I feel strange and unsightly. I don't feel attractive and feel different looking to other people. I did not recognise the person(loss of identity) looking back at me in the mirror when I started losing hair such as eyelashes and brows in particular which frightened me so much. I feel uncomfortable everywhere I go such as work and sometimes I avoid this through feeling embarrassed. I get no protection from the sun nor a sense of warmth from cold weather unless I put a hat on. My eyes get sore and I get cold more easily due to having no hair to warm me up so temperature regulation is difficult without body hair. My eyes get watery and irritated due to dust particles getting into them due to having no eyelashes. No nasal hair causes me to have often a runny nose as there are no hairs to trap the mucus. I also have got to the point now where I've reduced contact with relatives and just keep to close family due to feeling uncomfortable with my appearance.
B-On a psychological/mental level the loss of hair has resulted in a decreased self-confidence. It has been a very traumatic and stressful experience losing hair in which I've cried daily. I have had profound anxiety when I've worried about when I was losing the hair and whether it would come back or not. I got very depressed and had a real psychosocial impact since I experienced difficulty socialising with others and withdrew from activities I once enjoyed such as dancing, swimming and cycling. I avoided mixing socially with other people as I felt afraid and had very low self esteem. I have felt frustrated/despair at not knowing the cause and a sheer lack of hope with treatments. The feeling of loss of masculinity(beard/body hair makes you feel an adult man) had impact on my social and physical well being and made it impossible to form relationships with woman.

Are the recommendations sound and a suitable basis for guidance to the NHS?
The recommendations are not sound and a suitable basis for guidance to the NHS because I think Baricitinib should be approved and made available on the NHS immediately to treat adults with severe Alopecia Areata.

I feel Baricitinib would improve my quality of life greatly as it would likely regrow my hair back. I would no longer feel anxious, different and strange to other people. I would be much happier as a person(no longer depressed and I would interact with others better. With more self-confidence and a higher self-esteem I would be able to achieve more in terms of work, leisure and socially. I would feel like a man again and my mental health would be greatly improved. With no longer any anxiety about the way I looked it would mean I would see improvements in all areas of my life. I could return to activities like cycling, swimming and dancing I used to enjoy. I would feel comfortable and warm with having hair instead of giving me anxiety and the need to cover my head with a hat when faced with hot or cold weather. It would bring me finally a sense of hope/closure that a treatment has been licensed to treat this condition and has a good success rate. I would no longer feel guilty with having this different appearance as I would blend in more with how other people look and not feel so isolated/alienated to anyone. It wouldn't also reinforce/highlight the difference my Phenylketonuria metabolic condition impact has upon me with others(food

restrictions) as I look normal with hair. I would no longer cry nor feel emotional/upset as with hair it will bring me back the joy, satisfaction and comfort it used to bring me. I can also have a haircut again which I've missed so much and that feeling of being revitalised and looking smart/attractive afterwards which you get from having your haircut.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

Yes but on the grounds of disease duration of 8 years. I don't feel anyone should be excluded from being treated with Baricitinib in terms of their disease duration set at no greater than 8 years. I feel it should be widely available to those with severe Alopecia Areata regardless of how long they have had it for. From anecdotal evidence I have heard many people of disease duration greater than 8 years growing their hair back successfully to include eyebrows, eyelashes, facial, scalp and body hair. I also don't feel that in order to be treated with this medication you should have tried other powerful oral immunosuppressive drugs as the majority of patients in clinic would never have been given them already for their severe AA(I certainly haven't). In terms of age I would like it to be available from the age of 18 upwards. The only conditions set in order to be prescribed this medication is for only severe cases of Alopecia Areata and adults above the age of 18.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?

No! Absolutely not. You have minimal evidence to support the denial of this drug. This is a severe autoimmune disease which is hugely under resourced and underfunded. You have used an extremely small proportion of the alopecia population resulting in inadequate and irrelevant evidence. It is plain to see that the JAK inhibitors work and are a simple yet effective way of improving peoples lives.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?

No! I personally have suffered from various types of alopecia for around 10 years. Over this time I have attended various GP appointments, NHS dermatology appointments, private dermatology appointments, trichologist appointments plus many more. Whilst doing so I have received a multitude of treatments which have been fully funded by the NHS such as topical steroids, steroid injections, phototherapy treatments in addition receiving four fully funded NHS wigs on a yearly basis. How can NICE guidelines state the use of JAK inhibitors wouldn't be cost effective?! Please rethink this ridiculous statement!

Are the recommendations sound and a suitable basis for guidance to the NHS?

No, absolutely not. The NHS must be led by suitable and sound guidance to help support people suffering this horrible disease. By denying the use of JAK inhibitors you are preventing health care professionals in their duty of care to their patients.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

Yes! As a victim of this horrible autoimmune disease I was absolutely devastated and somewhat offended at the information in the guidance. Stating that people suffering with eg arthritis may benefit more greatly from the JAK inhibitors due to pain etc. However, as a sufferer of alopecia the emotional pain is indescribable. Can you imagine waking up each morning and not even recognising yourself in the mirror? Horrified to see yourself in any reflection. Unable to open your blinds until later in the day when you can face putting on an itchy wig to cover up your differences. I was an extremely active person prior to my disease but alopecia has prevented me from remaining active. The pain faced by having no eyebrows or eyelashes whilst trying to exercise is so difficult it barely makes it worth it. I, along with the whole alopecia community feel extremely discriminated and under valued as human beings. I am an intensive care staff nurse and have worked within the NHS for 11 years, I work hard every day and value the NHS and think of it as a great service. You are not providing support or reliable guidance in the use of JAK inhibitors to allow me plus many others to continue with their lives. Please, please rethink this unjustified decision and allow/recommend the JAK inhibitors!

Name	
Comments on the DG:	
There is no appropriate evidence on the Impact on Quality of life. It is ludicrous and simplistic to use the quality-of-life assessment tool for alopecia as it only focuses on the physical aspect of illnesses. There are physical ramifications from having alopecia and these include difficulties with wearing wigs, and eye/nasal problems due to lack of protection from hair. Sports participation in and out of doors is very challenging and requires sheer determination. However, the tool does not acknowledge the devastating psychological effects. Alopecia affects patients every moment of every single day as it is impossible to forget about it. This is comparable to other illnesses; it is just more difficult to measure.	

Name	
Comments on the DG:	
I am very upset that Baracitinib may not be approved by NICE Let me give you abit of my history..after years of AA I became AU in2019,,to say I was devastated is an understatement...I considered taking my life Our local dermatology dept were not interested So I set about finding help myself So	

3yrs later and at a huge financial cost to myself I found a consultant In Cheadle who would help But at £1,200per month for Baracitinib I could not afford this So I am now buying them from India and being monitored by the Consultant The medication has saved my life, as I now how full regrowth,eyelashes and eyebrows and believe me,it is not cosmetic,as without eyelashes I was suffering from eye infections.Also with out nasal hair I was suseptible to infection Alopecia is brutal,it zaps your confidence and steals your identity I am a retired nurse...the last 25yrs working in general practice...I had patients coming in with panic attacks I sometimes thought...pull yourself together,but a few years later after the death of my mum,I had panic attacks and realised you can't pull yourself together So I feel the decision makers on whether JAKS should be available for severe alopecia Areata should try living with AU I do not agree that it's 'cosmetic' we shouldn't be denied this treatment If we lost a leg due to smoking,we wouldn't be denied a prothesis because it's deemed 'cosmetic' I feel very strongly about this lack of care/understanding in our plight I have spent thousands of pounds over the last few years in my effort to get help i.e Consultations.wigs,microbladding,supplements and Jaks which I purchase myself.....I never thought I'd be spending my pension fund this way....so I ask.please,please consider all aspects of this horrid condition

Has all of the relevant evidence been taken into account?
No....you are not looking at the bigger picture,,,you are just seeing it as 'cosmetic' not the impact it has on your mental health and day to day living For example my son and his family (2 small grandsons) live in Ecuador and I haven't visited for a number of years as I couldn't contemplate doing a long haul flight wearing a wig...so that has not only impacted on my life but also my family

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No...I don't think you are looking at the cost of our mental health...I have been on antidepresants since 2019

Are the recommendations sound and a suitable basis for guidance to the NHS?
I realise these drugs are expensive but I'm sure many Alopecians wouldn't mind making a small contribution to the cost to get our lives back...believe me I wouldn't wish this condition on anyone

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
I feel we are being disciminated against IT IS NOT COSMETIC

Name	
Comments on the DG:	

Recommendations

Limited focus was applied during trials on measuring improvement in baseline mental health and wellbeing. Baseline measures need to be improves and generally effort to obtain large samples of results need to be increased. Therefore, this data is not statistically significant or imply causation that their is no MH&W benefit.

I operate and represent a MH&W group for Alopecia sufferers in a global organisation - Those in the US advocated the vast improvements in their baseline MH&W i.e. confidence, reduction in depression and reduction in thoughts of suicide. These are the measures that need to be more accurately assessed in trials.

As a personal alopecia sufferer, I can advocate this sentiment is incorrect . JAK inhibitors offers hope to UK sufferers but if not effective also provides closure that medically everything has been attempted to resolve the condition. Allowing those to try and learn to live with the disease rather than contemplating "what if".

Also, personally this condition has made feel suicidal at times and i have increased levels of anxiety/depression. This has effected my career and family life, their is limited measures to analyse the detrimental effects this disease has on a patients family and career.

Effects on quality of life

Agreed - Patients pay their Taxes & National Insurance and should have a human right to access treatment for a condition they have. Not be denied it, it should be the patients decision also

Agreed, those with alopecia are statistically significantly more likely to get other autoimmune conditions if not treated. Also, high levels of inflammation and dysfunctional immune system can significantly effect the quality of life a person has

Has all of the relevant evidence been taken into account?

No:

1. Effect on Patients Family MH&W and Career prospects
2. Effect on Patients social circle i.e. bullying and discrimination

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?

If you considered all the expenditure incurred by patients on trialing so many different products and solutions externally due to limited effective treatment options on the NHS, it wouldn't seem so expensive.

Additionally, alopecia patients will continue to be on no active treatment if they won't actually approve treatments that are proven to be effective. Their is limited treatment options

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? We have an adopted child who has recently been diagnosed with Alopecia Areata. Having joined a number of support groups looking for information that will help reassure our child that they are not only are they not alone. But that there are treatments that are being developed, that may potentially be of benefit when they are older. kind regards. **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** AS our child is or school-age, we are worried not only about the impact her hair loss is having on her currently, as she is learning to process what this will mean for her now. But as she gets older, the impact that her hair loss will have as she moves into her teenage years, may be traumatic. Where appearance and fitting in become more important for her, and the negative impact her hair loss may have on her mental and physical well-being, at one of the most formative times of her life. **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** I think the negative impact of hair loss, and it's impact, cannot be overstated. It would also be disappointing to see potential successful treatments denied. I have concerns that a person's socio-economic status, which can be tied directly to a person's ethnicity, will often negatively affect that persons' ability to afford and access treatments, that can be accessed outside the National Health service. A two-tier system for treatments that can be accessed by those with the means is discriminatory. I cannot see any consideration made for this aspect of quality of life in the NICE decision	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? Difficult to say, but from what I understand the drug has been sucessful for many patients and on balance is postive for their QoL. Are the recommendations sound and a suitable basis for guidance to the NHS?	

No. Clearly it's very expensive but surely the benefit to so many people should outweigh the cost, and perhaps cheaper sourcing of a generic can be explored.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Pass

Name	
Comments on the DG:	
Have the best interests and mental health of people suffering with the long term effects of alopecia been fully considered, following the decisions to not allow baricitinib to be a recommended for them on the nhs? Alopecia can be a debilitating condition by affecting the patient with severe hair loss. This can go on to cause a number of problems with their mental health and self confidence, which can lead to secondary complications such as anxiety and depression. Awareness of the cost effectiveness as been taken into account regarding baricitinib, however surely further care should be taken in considering the potential benefits for people suffering with alopecia.	

Name	
Comments on the DG:	
Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence? No. Treatments such as topical corticosteroids are not offered to people with Alopecia Universalis (total head and body hair loss) and wigs are not a medical treatment, they are a sticking plaster. They do not cure or treat the problem, they merely cover the symptom. So as it stands, there are no treatments available to people with total hair loss. Are the recommendations sound and a suitable basis for guidance to the NHS? No. The health-related quality of life assessment is not appropriate for this health condition. Having alopecia causes complex and sometimes severe anxiety and depression, but this is unique to people with hair loss. Alopecia should be considered a disfiguring autoimmune condition and I don't think the quality of life assessment properly reflects that. Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and	

maternity?
Yes, although men do suffer with alopecia, it is predominantly women that suffer the most with mental health issues linked to their alopecia. Rejecting this medication could potentially be discriminating against any women. Especially when some women are told that alopecia is "just a cosmetic issue".

Name	
Comments on the DG:	
My daughter has suffered from Alopecia since the age of 9- she is now almost 21. She is training to be a professional dancer and this disease has been devastating for her. She wears a wig which we have had to source at our own expense - NHS wigs (which she hasn't been offered in almost 3 years) can't be put into a tight ballet bun. The current wigs she wears cost almost £1000 and this has to be replaced every 9-12 months. Over the years we have tried steroid treatment, minoxidil (purchased by ourselves), vitamins, essential oils, faith healers, creams, shampoos at great personal expense. This is only the the financial side of it. She has been devastated by her hair loss from Alopecia Areata to Alopecia Totalis. She is depressed, suffers from anxiety and her mental health is at an all time low. If she was a smoker and got lung cancer - the NHS would treat her with the appropriate drugs. If she was an alcoholic and had liver cirrhosis- the NHS would treat her with the appropriate drugs. If she was obese and developed Type 2 diabetes - the NHS would treat her with the appropriate drugs. If she had inflicted a disease like these on herself she would be given the appropriate treatment. But no - she has Alopecia - that she has not brought on herself through poor lifestyle choices and yet she is being denied the only treatment that may indeed help her - 'it's only hair' -she is told. I just wonder if anyone on the NICE committee making decisions based on cost of drugs has had to deal with hair loss? Would they feel that oh it's ok - it's only my hair? How would they feel if the first chance they had of hope of treatment in years was snatched away from them because it is too expensive? They'd be devastated like every single person suffering from this dreadful disease. I urge you to reconsider this decision. The chance to make everyone with this disease feel better about themselves will in the long run mean that less money will be needed for mental health treatment. Everyone deserves the right to treatment in a way that will improve their quality of life. Please give all Alopecians that chance. Thank you for taking the time to consider my views.	

Name	
Comments on the DG:	

Firstly, thank you for allowing me to comment on the draft guidance.

I am a 52 year old, professional, white male, I experienced reoccurring Alopecia Areata over a period of 3 years which progressively became worse until I experienced permanent full hair loss, Alopecia Universalis, in 2021.

I am fortunate to have private medical insurance through my employer, so I was able to see a consultant dermatologist promptly throughout my hair loss episodes. I was prescribed topical & oral steroids, all with limited, temporary success.

I would describe myself as extremely pro-active with my own personal healthcare, by virtue of being a commercial airline pilot whose health is monitored by the Civil Aviation Authority, however I very quickly exhausted all treatments available from the NHS.

I extensively researched treatments for Alopecia Universalis and came across Baricitinib, having read about the trials completed in the UK. At this point, I was becoming very despondent at the lack of treatment available for my condition and my mental health was suffering as a direct result, which included extended absences from my job.

In January 2022 I started a course of 4mg Baricitinib daily, whilst the hair regrowth was initially very slow, it has steadily increased to now be classified as Alopecia Areata. I now have significant scalp hair (approximately 75%), body hair, beard hair, eyebrows and eyelashes, but most importantly of all I have regained my identity and self-confidence, which in itself is priceless.

In order to fund Baricitinib private prescriptions, my family and I have made significant financial sacrifices, however the results have made these sacrifices worthwhile. This is not simply a case of male pattern baldness.

Baricitinib has worked for me personally, yes it does take time for results to appear, however the wait has been worth it.

The committee recognises the stress that severe Alopecia can cause, it also recognises the benefits that Baricitinib can bring to some patients, however unless you have personally experienced the physiological stress of losing your identity, having to explain your condition constantly to friends, work colleagues, family and losing your self-confidence, then I think that it is very hard to put a price on Baricitinib for the treatment of Alopecia.

I would be happy to speak in person to the committee about my experiences as a non drug trial patient.

Until another credible alternative treatment becomes available, I would hope that Baricitinib is approved for the treatment of Alopecia on the NHS, all

other treatments for Alopecia do not work, yet still cost the NHS considerable amounts of money. The associated physiological costs alone should make this drug available for the treatment of Alopecia.

Thank you for taking the time to read my comments. Kind regards,
[redacted]

Name	
Comments on the DG:	
I was very sad to hear that this was not approved. I have been on this medication for 12 months and from having hardly no hair left due to alopecia I have now almost full regrowth. I paid £700/month for the medication at first but could not afford this for long so now I have to buy it from Bangladesh. The impact alopecia has had on mental health and my life in general is immense and I really hope you will reconsider your decision. Many thanks,	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? As a sufferer of recent complete hair loss, it does not appear that the impact that alopecia areata has on quality of life has been taken into account so far by this consultation. On diagnosis of this condition, many alopecians battle with a significant decline in mental health, depression and the inability to perform at their best in a work/ university capacity. These impacts are likely to be putting an even greater strain on other NHS resources (therapy etc). **Are the recommendations sound and a suitable basis for guidance to the NHS?** The initial recommendations are deeply disappointing and need to be reviewed in particular with regards to quality of life. If individuals were able to access this drug and it proves successful, the mental health impact are likely to be very significant.	

Name	
Comments on the DG:	
I would sincerely ask NICE to reconsider their initial outcome re bariticinib for severe alopecia areata. My degree is BSc Hons Pharmacy, I can read and understand scientific papers and the subsequent analysis. I truly believe NICE is wrong in its initial judgement. Any hair regrowth even if only partial, not complete, will be hugely valuable. It does not have to reach a SALT score of under 20 to make a significantly positive impact on the life of someone suffering from Alopecia areata. My daughter is 20, consider the devastating loss of hair is to a young adult, especially a female.	

It has become so bad that she is now on an immune suppressant medication that is unlicensed for alopecia. Bartiticinib is licensed and effective. If it's not allowed on the NHS she will need to continue to be given off licence drugs, is that what NICE are endorsing?

Consider the cost of the psychological support, loss of paid income, loss of social life, loss of self esteem, loss of confidence, loss of actually living a life.

She is at university studying Physiotherapy, she wants to work for the NHS on graduating. Alopecia is having such a profound impact on her that she is considering withdrawing from university, stopping her part time job coaching gymnastics to children, ceasing having a social life (which is already very limited due to how bad alopecia makes her feel) and has already resulted in her stopping sports participation. The cost of the drug could very well give her back her life and allow her to make a positive difference to the lives of others.

For some, tragically, alopecia results in considering taking their own life. As a Mum that is a very big fear I have.

Alopecia is not as a result of poor lifestyle choices, no-one can prevent themselves getting it. Please see the people and how horrendously it impacts them and grant approval for a safe and licensed medication to be used.

Has all of the relevant evidence been taken into account?
The evidence relating to partial hair regrowth has not been fully appreciated.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
No, the impact of hair loss has not been accurately captured. And there has not been sufficient consideration of the benefit to quality of life that some, even if not complete, hair brings.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No, bariticinib is safe, effective and used for other conditions. What makes its use for eczema allowable and not for alopecia?

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Yes, under disability discrimination.
Disability is defined in the UK as
'under the Equality Act 2010 if you have a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on your ability to do normal daily activities.'

Alopecia is a physical condition that has the detrimental impact on mental condition and stops sufferers being able to do daily activities. In not allowing access to a drug that could relieve this, then people are being kept as disabled rather than freed.

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
It is of my opinion from reading the consultation report that there is insufficient quantitative and qualitative evidence / data of the psychological impact from severe alopecia areata.

There is currently limited effective treatments for this condition provided by the NHS. Recent studies of longer-term use of Baricitinib have not been included in this report for which in two recent phase 3 trials of this treatment, the efficacy of baricitinib for severe alopecia areata continued to improve over 52 weeks and from this it was observed as potential for long-term treatment of severe alopecia areata.

As a patient with this condition and speaking on behalf of other patients, we live in hope that this observed effective treatment is made available through the NHS. As an employed psychological therapist working within the NHS and as a patient with severe alopecia I am able to speak personally of the psychological, socio-economic impact this condition has had for myself and and for those who I may support in clinical practice.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
It is of my opinion that cost effectiveness of this treatment vs longer-term socio-economic/financial impact of this condition has not been fully captured within this report.

Are the recommendations sound and a suitable basis for guidance to the NHS?
No, I refer to my answers related to 'all evidence being taken into account'.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
No

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
From the evidence provided, it is true that the measurement of the quality of life lacks indicators for the psychosocial impact and effects on patients with alopecia areata. It is essential to use other tools to measure the sense of well-being and psychological conditions of patients.

From my experience as a patient with severe alopecia areata (more than 30 years), the current treatment options are also very limited and have many side effects. For example, intralesional steroid injection could be effective on a specific area, but it still has side effects, such as soreness at the injection spots. Additionally, the current treatment options available are not very effective for patients with severe alopecia areata, and recurrence of hair loss is common. This is also the reason why many patients do not seek treatment.

In section 3.10 of the draft guidance consultation, the use of wigs is suggested as an alternative to pharmacological treatments. However, as a patient, I do not agree with this suggestion because wigs cannot compare to real hair. The psychological impact of wearing a wig can be significant, and it can negatively affect the patient's sense of well-being and quality of life. Therefore, I strongly recommend that pharmacological treatments that have been proven to be effective should be considered the primary option for treating severe alopecia areata.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
As a patient with severe alopecia areata, I appreciate the effort that NICE has put into developing guidance for the treatment of this condition. However, I would like to offer my feedback on the cost-effectiveness of Baricitinib and the importance of patient access to this treatment option.

Regarding the cost-effectiveness of Baricitinib, I believe that NICE may consider commissioning it in the NHS for treating severe alopecia areata to monitor its efficacy in proving its effectiveness. It is crucial to evaluate the effectiveness of this treatment option thoroughly to provide patients with the best possible care.

In the meantime, I would like to encourage Eli Lilly to continue the discussion with NICE and offer a discounted price to NHS to increase the cost-effectiveness at the initial roll-out stage. This would enable more patients to have access to this treatment option and improve their quality of life.

Finally, I would like to stress that living with severe alopecia areata is much more than the cost-effectiveness of treatments. This condition can have a severe psychosocial impact on patients and affect their sense of well-being. Therefore, it is essential to provide patients with effective treatment options

to help them manage the condition and improve their quality of life. Thank you for considering my feedback.

Are the recommendations sound and a suitable basis for guidance to the NHS?
Based on the information provided, I believe that the recommendations for Baricitinib as a treatment option for severe alopecia areata are sound and a suitable basis for guidance to the NHS.

The trials of Baricitinib have demonstrated its efficacy in treating alopecia areata, and it has already received registration with MHRA in the UK, EMA across Europe, and FDA in the USA. This shows that Baricitinib is a well-established treatment option for alopecia areata.

Moreover, severe alopecia areata patients currently do not have any effective treatment options, which may lead to other psychological conditions that require resources from NHS and may cause personality problems such as absenteeism from work due to devastating psychosocial impacts. This could result in far higher costs than providing access to Baricitinib.

Therefore, I strongly believe that the access to Baricitinib is not just giving one more treatment option to patients, but it can also be a cost-effective solution in the long term. Therefore, I support the recommendations for Baricitinib as a suitable basis for guidance to the NHS for treating severe alopecia areata.

Name	
Comments on the DG:	

I'm commenting because I wanted to share my experience with Alopecia and the importance of Baricitinib within my community.

In 2021 I lost all my body hair in a span of 6 months.

No doctor could help me via the NHS, let alone understand what was happening to my body.

After months of research I discovered that I needed support from a dermatologist, who taught me about JAK Inhibitors.

Since July I have been on JAKS and not only is my hair starting to regrow, but I am slowly getting my life back.

To have this medication available via the NHS would mean stability, security, hope and faith restored within the system, and an opportunity for many who suffer from Alopecia a chance to regain their identity and life.

My mental health has suffered greatly due to Alopecia. I have dealt with weight gain, and depression but I was fortunate to keep living my day-to-day.

I know many who can't leave their homes and suffer from poor mental health because of Alopecia.

This isn't just about having this approved, it's about recognising and registering the fact this disease needs further support and needs to be taken seriously.

Thank you,

Name	
Comments on the DG:	
As a layperson reading this document, it appears that the main reason for not recommending this medication is cost and, the measure used to assess this is based on an assessment which the document admits is probably not reflective of the reality of a person suffering from Alopecia. As the parent of a child diagnosed with Alopecia at age 11, I witness the terrible impact of this disease on her and on our family every day. Every day, I read heartbreaking stories from people struggling to live with this disease. However, this impact is not recorded officially because the sufferers of Alopecia are a long forgotten and neglected group which eventually gives up on the NHS as a source of help. Personally, I have also incurred considerable personal expense to try and treat my child and give them cosmetic options to cope at a critical time in their development. It is frustrating that the document recognises all of the negative impacts of the disease but still can't recommend a medication to alleviate that suffering. Every day I read about JAK Inhibitor treatments being used in other countries to amazing effect and it is so frustrating to be offered the various treatments mentioned in this document, knowing that there are much better proven options available. My child is in the vicious circle of constant loss and re-growth which is as debilitating at full hair loss in my opinion. I have been offered Immunotherapy and Immunosuppressants but I can't put my daughter through these treatments when I know and, my dermatologist admits, that JAK Inhibitors are a far superior option. Baricitinib is only one of these medications, but it's rejection as the first one does not bode well for future applications.	

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? No, I don't believe enough work has been done to speak to people with the condition to assess how it affects them in their daily lives. If it had then I think the outcome would have been very different. Can you show some statistics showing how many people with Alopecia you spoke to please? Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?	

No. What will happen behind the scenes, which is what is happening already, is that people are buying these drugs from the likes of Bangladesh and have no idea if they are regulated or anything. People also don't realise that they have to be monitored by a doctor when taking these drugs to monitor their kidney and liver function. Does the NHS want lives put at risk because they don't want to incur these costs?

Are the recommendations sound and a suitable basis for guidance to the NHS?
No

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
The NHS must listen to thoughts and feelings of people actually affected by this condition and not just to the people who manager the purse strings!

Name	
Comments on the DG:	

Has all of the relevant evidence been taken into account?
In my opinion, there is insufficient information here and particularly fails to address the full impact on mental health and wellbeing. Surely, this is something we have been placing far more emphasis on post-COVID.

Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?
Flawed and unreasonable in tone. Surely a 50% success rate is a considerable outcome, which is far higher than in most other cases, some of which are also more expensive. This makes it more cost-effective.

Are the recommendations sound and a suitable basis for guidance to the NHS?
Whilst appreciating the enormous and increasing strain on the NHS, especially in the current climate, with numerous demands being placed upon a limited service, I disagree that this initial recommendation is "sound and suitable". It is very easy to overlook individual stories, such as my niece, who works as an intensive care nurse in the NHS. She has dedicated herself fully to apply all the principles and demonstrate the values on which the NHS is based in her daily contacts with the patients she has responsibility for. To deny her, and others like her, the life-changing opportunity to benefit from this innovative treatment contradicts the whole vision of the NHS.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

The initial decision can most certainly be viewed as being in opposition to the disability section of the Equality Act and would be considered to be discriminatory, likely to result in a successful prosecution.

Name	
Comments on the DG:	
Has all of the relevant evidence been taken into account? No **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** No **Are the recommendations sound and a suitable basis for guidance to the NHS?** No **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?** No	

Name	
Comments on the DG:	
I have suffered with Alopecia since I was seven years of age. It has been the odd patch here and there but a few years ago after the death of a friend, which I believe triggered a stress response. Over half of my hair fell out over 3 years, small patches joined to be one large patches. At time I became very despondent, I was constantly anxious and it took its toll. I stopped going out and have relationships of any kind. I did not go on holiday or any social place. The anxiety of Summer coming where I could not get away with wearing a hat and hiding indoors, really hit me hard. Throughout the last 35 years I have tried every and all remedy that the Dermatologists have suggested. So during this, what I would call alopecia attack, I went through the process of seeing a specialist with zero hope of help as usual. However I happened to meet Dr [redacted], who works privately as well as for the nhs, and has been an advocate for the Barcitinib Jak inhibitor. He explained I was the right candidate but to be level headed and be tentative with my hopes. I decided to go ahead but the costs were so so much. I had to borrow money and sell my car to try this drug out as I was so desperate and my quality of life had become so poor. I took this drug for 10 months and all my hair which had been disappearing over 3/4 years by now, started to grow back.	

I had tufts of hair everywhere which I had to endure to grow out....but I had hair again. I was so grateful and so so hopeful that it would be approved this April. I am absolutely devastated to learn that you have rejected the drug. A drug that has been approved in Europe and America. Why on earth not here?

We all suffer no matter what country we are in. These countries deem our suffering valid and worth treating. You do not know as you are not in my position. And if it was you or a loved one you would realise fist hand how psychologically, socially, emotionally and mentally damaging it can be to have most of your hair fall out in ugly patches. It's affected my health, I put on weight from being too anxious to leave the house, I became depressed, I really struggled to go to work. I avoided any social situation where there could be a risk of my 'exposing' myself. 4 years plus the 9 months it took to grow back have been the worst years of my life. I was unwell not just physically, but mentally.

I am currently suffering with some bald patches right now. I'm dealing with it as best I can but it's starting to get worse, and it's starting to affect my well being and mental health.

I have been praying and hoping that this April 2023 there could finally be a remedy, encase my hair does have an attack again, and that other severe alopecia sufferers would finally get help I was hopeful that the NHS will look after me.
So like I said I am devastated to hear about your decision. I am not in a position to buy these pills again and I'm starting to worry and have sleepless nights again thinking that there is no end and no available remedy this time. Its not available not this time, because no remedy has been discovered, but this time due to your decision. Finally there is a re.edy but we can't have it.

Barcitinib truly changed my life for the better. I am not articulate enough to truly explain how the quality of my life has improved in so many ways, and it has given me hope and a new lease of life, which is hard to write about as this gratitude goes beyond words.

Please please please review your decision to permit this miracle drug to be accessible through the NHS. Please help alopecia sufferers, help them like this drug helped me and maje a huge difference to their quality of life..

There's been no solution up until now. Even the research has been lacking until now as it was not deemed worthy. But I promise you you will be changing lives and you truly have the power to do this. Please please reconsider.

Kind regards,

[redacted]

Name	
Comments on the DG:	
This is extremely disappointing and frankly a disgrace that this drug has not been recommended for use in the NHS. My 32 year old daughter has severe alopecia and has has for many years, she has fought physically and mentally with this disease . I have had to pull her back from the brink of suicide a number of times , she feels like her life is never going to improve and this was a chink of light at the end of a tunnel. I feel that alopecia sufferers have been disrespected as their suffering has been ignored and sneered at by medical professionals and the public in general that do not understand how it feels to have no hope, or help available to them . This drug needs to be passed by the NHS for use on a huge number of forgotten and ignored alopecia suffers in the UK !	

Name	
Comments on the DG:	
It takes an extraordinary amount of time eg years,to get alopecia taken seriously enough to even consider treatment. Then treatment available varies accross the UK. In our local area, there is next to no treatment so the statement of high costs is skewed. When you come from an area that offers nothing, of course any treatment is going to be at a significant cost compared to zero. There is a big emphasis on psychological impact of alopecia. The studies do not go far enough to fairly represent UK patients. There is undoubtedly a huge, long term effect on mental health for alopecia sufferers but not specifically attibuted to cosmetic appearance. The constant assumption that loss of hair due to treatment, say for cancer, the implication that it is 'just' alopecia, that 'it be worse'. The fitting of a wig can be seen as a path to recovery in cancer patients. There is no recovery without treatment for those who suffer with alopecia. There is not enough emphasis about the impact of loss of facial hair, nasal hair, eyebrows, eye lashes causes actual physical side effects, sore eyes, watering eyes, sore nostrils, where the natural 'filters' no longer exist. The person suffers great, daily chronic discomfort with this in addition to sensitive scalp. The possibility of alopecia treatments needs urgentvreview to address this long term chronic illness do that those who suffer may have access to treatment and a good chance of lessening their symptoms and distress. Has all of the relevant evidence been taken into account? No. The research is not representative of uk patients. **Are the summaries of clinical and and cost effectiveness reasonable interpretations of the evidence?** No, the study is not representative of the UK, the physical and psychological effects of this disease, the lack of long term support and where an area provides zero/little treatment is not reasonable to interpret the cost as high when the existing cost is next to nothing.	

Are the recommendations sound and a suitable basis for guidance to the NHS?
No. The studies are not wide enough to make a reasonable interpretation of the evidence.

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, sex, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?
Unsure

Name	Anonymous
Comments on the DG:	

Dear NICE Committee Chairman and members

I understand consultation closed at 5 pm today.

I am therefore sending an informal email to tell you what it is like for me to scratch my head constantly, be woken up or not sleep at night for the itching, have people stare when I go out unless I always wear a hat- and that is of itself bizarre in a cafe or restaurant so I just don't go . Avoid meeting people whether I know them or not,
so don't have the social life that kept me afloat from depression. No longer swim in a public swimming pool , we have communal mixed sex open showers in our local pool and a swim hat gets so hot and dreadfully itchy.

I've worked in the NHS most of my life, and social services emergency work before that, and I do feel that now I need help to avoid the social isolation, depression and sheer avoidable misery of constant scratching, it should be there for me.

Please contact me if any further information would be of use,'

Baricitinib for treating severe alopecia areata [ID3979]

EAG response to company draft guidance comments

March 2023

*This document contains corrections that were made following circulation to committee. These corrections were:

- Accurately citing best supportive care use for baricitinib in the company's revised base case, that is, a relative reduction of 25% of baricitinib compared with the 'no active treatment' arm.
- Amending the descriptions of the scenarios in Tables 1 and 4.

Source of funding
This report was commissioned by the NIHR Evidence Synthesis Programme as project number 135648.

1 Introduction

This document provides the Evidence Assessment Group's (EAG's) critique of the company's response to the draft guidance (DG) document produced by the National Institute for Health and Care Excellence (NICE) for the appraisal of baricitinib for treating severe alopecia areata (ID3979).

The company has revised their base case to truncate best supportive care (BSC) costs to a 10-year time horizon, after which only the costs of wigs, orthotics and pharmacological costs associated with psychological support (antidepressants) are incurred. The company also included the assumption of a 25% reduction in the use of BSC for baricitinib patients who do not achieve a treatment response, defined as Severity of Alopecia Tool (SALT) score of less than or equal to 20 (SALT ≤20), with no reduction in BSC use for the no active treatment arm.

Additionally, the company presents two scenarios around their revised base case exploring a 50% reduction in BSC use for baricitinib patients (as per the company's post-technical engagement base case) and a no BSC use for baricitinib patients in combination with an assumption of 30% BSC use in the no active treatment arm (equated to a [redacted] reduction in BSC use). As a reminder, in the original company base case, it was assumed that [redacted] of patients who fail to achieve a treatment response will continue with BSC treatments, with [redacted] of patients discontinuing treatment. Table 3 of the company's draft guidance comments outlines the percentages of BSC use for the revised base case and the scenarios.

The company's revised base case is presented in Table 1. Results reported include the company's proposed patient access scheme (PAS); a fixed pack price of [redacted]. Confidential medicines unit (CMU) and Drugs and pharmaceutical electronic market information tool (eMIT) prices are available for medicines included in BSC using the NICE preferred secondary care setting for prescribing and these have been included in the results presented in this document (permission granted by NICE).

Table 1. Company's revised base case results post ACM 1

Interventions	Total Costs (£)	Total LYG	Total QALYs	Incremental costs (£)	Incremental LYG	Incremental QALYs	ICER (£/QALY)
Revised base case post ACM 1 - 25% reduction in BSC use for baricitinib patients, 0% reduction in BSC use for no active treatment patients, 10-year truncation to BSC drug costs							
'No active treatment'	[redacted]	22.60	[redacted]				
Baricitinib	[redacted]	22.60	[redacted]	[redacted]	0.00	[redacted]	12,403

Scenario 1 – 50% reduction in BSC use for baricitinib patients, 0% reduction in BSC use for no active treatment patients, 10-year truncation to BSC drug costs							
'No active treatment'	[redacted]	22.60	[redacted]	-	-	-	-
Baricitinib	[redacted]	22.60	[redacted]	[redacted]	0.00	[redacted]	Dominant
Scenario 2 – no BSC use for baricitinib patients, 30% BSC use for no active treatment patients, 10-year truncation to BSC drug costs							
'No active treatment'	[redacted]	22.60	[redacted]				
Baricitinib	[redacted]	22.60	[redacted]	[redacted]	0.00	[redacted]	20,088

Abbreviations: ACM, appraisal committee meeting; BSC, best supportive care; LYG, life year gained; QALY, quality adjusted life year; ICER, incremental cost effectiveness ratio.

In their response to the draft guidance (DG), the company reiterated their views on the key issues of source of utilities and composition of BSC. Additionally, the company commented on the committee's discussion on the willingness to pay (WTP) threshold and the validity of the committee-preferred assumptions (which also reflect the EAG's base case assumptions).

The assumptions preferred by the committee are as follows:

- use no active treatment as the comparator (Section 3.2 of the DG);
- use a SALT score of 20 or less as a clinically meaningful outcome (Section 3.3 of the DG);
- include adverse events (Section 3.8 of the DG);
- include only wigs and orthotics in best supportive care (Section 3.10 of the DG);
- apply the same proportion of people having best supportive care after all other options have been exhausted for both the baricitinib and no active treatment arms, but consider a range of proportions in best supportive care use (Section 3.11 of the DG);
- use utility values derived from EQ-5D data from the BRAVE trials (Section 3.12 of the DG).

Overall, the EAG considers that no new evidence has been presented to change the preferences listed on the DG. Table 2 presents a summary of these issues and the EAG's comments. As new analyses have been presented by the company, the EAG provides a critique of them in Section 2.

Table 2. Summary of issues covered in company's response to DG

Issues in company DG response	Relevant sections of DG	Company response	EAG comment
Source of utilities to inform the economic model	3.12	The company maintains that EQ-5D utility values from the Adelphi DSP study are more reflective of patients with severe AA that EQ-5D utility values obtained from the patient population from the BRAVE-AA trials. Furthermore, the company emphasised that patients who do not experience impairment in their HRQoL would not engage with the healthcare system and therefore would not receive baricitinib.	No new evidence presented. The committee previously heard evidence from the clinical experts, patient representatives, the company and the EAG regarding the health-related quality of life for patients with severe AA, the suitability of the Adelphi DSP study and data from the BRAVE-AA trials. Having considered the evidence, the committee concluded that EQ-5D from the BRAVE-AA trials was appropriate for the cost-effectiveness analysis. As such, the EAG maintains its position that EQ-5D data from the BRAVE-AA trials are appropriate as they reflect the HRQoL of patients who inform the treatment effectiveness in the economic model. The EAG disagrees with the company's comment that patients with limited HRQoL impairment would not engage with the healthcare system, as quality of life is not a driving factor for seeking treatment but that symptoms (in this case, severe hair loss) is the reason people seek treatment. The EAG reiterates that it agrees there is a small, but heterogenous, patient population that is more adversely affected in terms of HRQoL but that the demographics of this population are difficult to identify clinically and consistently. Thus, for ACM1 the EAG provided the committee with the QALY gain needed for the ICER to reach the £20,000 and £30,000 thresholds and this was included in the committee papers and considered by committee when forming their conclusions.
Composition of BSC		The company has revised their base case to restrict BSC costs to 10 years. However, the company maintain the assumption of	No new evidence presented. The committee considered that the same proportion of having best supportive care after all other options

		differential BSC use between treatment arms and provided two scenarios exploring different BSC use for both treatment arms. The company reiterated that in the Adelphi DSP study, participants were actively seeking treatment and that [redacted] were on BSC treatments, even though participants were treatment experienced. Furthermore, the company reiterated that it is expected that for those patients who receive baricitinib and do not achieve a treatment response, they would be less likely than patients in the no active treatment arm to engage further with BSC treatments.	have been exhausted for both the baricitinib and no active treatment arms should be assumed. The EAG considers that company's assumption to restrict BSC cost to 10 years may overestimate BSC costs as the EAG reiterates that patients who have not achieved a treatment response to treatments received previously may be unlikely to engage further with ineffective treatment.
Willingness to pay threshold	3.13	Company disagrees with the committee's consideration that due to the high level of uncertainty, an acceptable ICER would be towards the lower end of the range normally considered a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained).	It is within the committee's remit to decide what the willingness to pay threshold should be based on the level of uncertainty in the cost-effectiveness analysis. The EAG agrees with the committee's consideration that there is a high level of uncertainty in the cost-effectiveness analysis. However, the EAG's preferred assumptions minimise the decision risk.
Face-validity of committee-preferred assumptions	3.14	The company considers the committee preferences contradict the description of the patient experience in the DG.	No additional evidence presented to substantiate a change in the committee's preferred approach. Additionally, the EAG maintains its preferred assumptions.

Abbreviations: ACM1, Appraisal Committee Meeting 1; DG, draft guidance; DSP, disease-specific programme; EAG, Evidence Assessment Group; HRQoL, health-related quality of life; ICER, incremental cost-effectiveness ratio; NHS, National Health Service; QALY, quality adjusted life year.

2 EAG critique of company's revised analyses

The company has revised their base case to include an assumption that for the proportion of patients assumed to incur best supportive care (BSC) costs, these costs are restricted to 10 years. The company maintain their assumption that there will be differential use of BSC for patients who fail on baricitinib versus patients in the no active treatment arm. In their revised base case, the company include the assumption that there will be a 25% reduction in BSC use for baricitinib patients and no reduction in BSC use for patients in the no active treatment arm.

During the first Appraisal Committee Meeting (ACM1), the committee heard from clinical experts, the company and the EAG about the plausibility of patients who failed to achieve a treatment response continuing with ineffective treatments in BSC. The committee concluded the following:

- no clear consensus on composition of best supportive care (Section 3.10 of the draft guidance [DG]).
- no clear consensus on the proportion of people likely to have BSC after all other options have been exhausted, over a lifetime time horizon (Section 3.11 of the DG).
- no evidence on the differential use of BSC between the baricitinib and no active treatment arms after all other options have been exhausted over a lifetime time horizon (see section 3.11).

As a reminder, patients who transition to the BSC health state have not achieved a response to treatment, defined as Severity of Alopecia Tool (SALT) score of less than or equal to 20 (SALT ≤20).

With regards to the assumption of differential use of BSC between the baricitinib and no active treatment arms, the EAG considers that the company has presented no new evidence for the committee to consider. Thus, the maintenance of this assumption in the company base case disregards the committee's preference that the company should apply the same proportion of people having BSC after all other options have been exhausted for both the baricitinib and no active treatment arms.

The committee also considered there was uncertainty in the use of BSC for patients who have exhausted all other options over a lifetime horizon. As stated in the Evidence Assessment Group (EAG) report, the EAG's clinical experts considered that there is no standard treatment pathway. Patients with severe disease are most likely to have had systemic corticosteroids or systemic

immunosuppressants but response to treatment is limited. In particular, the EAG's clinical experts advised that for the prevalent population, patients are likely to have explored all available treatment options. This was reiterated in the stakeholder responses to the DG. A summary of the relevant stakeholder responses is provided in Table 3.

Table 3. Stakeholder comments on the draft guidance related to treatment pathway

Stakeholder	Response
Abby Macbeth (clinical expert)	Patients with severe or very severe alopecia areata (AA) of at least 6 months duration would be offered methotrexate and includes a 6-week tapered course of prednisolone. Also, patients given systemic immunosuppressant or DPCP. The use of wigs alone, or discharge back to primary care, tends to be a "last resort".
Dr Matthew Harries, Consultant Dermatologist & Honorary Senior Lecturer (clinical expert)	It is not uncommon for patients to try multiple therapies over time. Treatments may include courses of oral steroids, ciclosporin, mycophenolate and methotrexate, as well as topical immunotherapy.

The company stated in their comments on the DG, that the comparator of no active treatment in the model reflects that patients may initially receive no active treatment for their disease for 36 weeks in the hopes of spontaneous regrowth as well as waiting times for secondary care. However, as stated in the EAG report, the BRAVE-AA trial population (which informs the model) is most similar to the prevalent population in clinical practice who would be eligible to receive baricitinib at the point of approval, i.e. a later-line treatment experienced population. For the incident population (or newly diagnosed patients with severe alopecia), the EAG considered (based on advice from its clinical experts) that patients are likely to be less treatment-experienced than the prevalent population but are unlikely to be completely treatment naïve.

As such, for patients on no active treatment, who would have likely exhausted all treatment options and have not achieved a treatment response, the assumption of taking further ineffective treatment may not be plausible and as mentioned by one of the stakeholders, use of wigs is the last option (which was included in the EAG base case). However, the EAG considers that if the committee accept there is a proportion of patients who do incur BSC costs, the company's approach to limit the number of years costs are accrued (instead of assuming lifetime costs), is appropriate. Although, the EAG notes that the company's 10-year cut-off for the proportion of patients incurring BSC costs is arbitrary and no compelling evidence to substantiate the assumption that patients would remain on ineffective treatments for such a substantial amount of time was presented by the company.

While the EAG maintains that a 100% reduction in BSC costs for both treatment arms of the model is still preferred, the committee may wish to consider scenarios exploring a range of reductions in BSC (such as 50% and 75% reduction in BSC use previously presented) alongside a BSC treatment cut-off period.

In the stakeholder response from Abby Macbeth, it was stated that for patients who are offered methotrexate, treatment would continue for 12-18 months before deciding if there is no treatment effect. Using information provided by the stakeholder in lieu of any other evidence, the EAG explored scenarios around the committee-preferred base case using cut-offs of one and two years and BSC reductions for both arms of 50% and 25%. However, the EAG acknowledges the scenarios should be considered illustrative as there is accepted uncertainty around whether patients would engage with BSC after failing to achieve a treatment response and if they do engage, the duration patients will remain on BSC. Results of the EAG's scenarios are presented in Table 4.

Table 4. Deterministic scenarios around the EAG base case post-technical engagement

	Results per patient	Baricitinib 4 mg	'No active treatment'	Incremental value
0	**EAG base case post-technical engagement - proportion of patients receiving BSC treatments: 0%**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			425,560
1	**Reduction in patients receiving BSC treatments: 75% (lifetime BSC costs)**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			363,135
2	**Reduction in patients receiving BSC treatments: 50% (lifetime BSC costs)**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			300,710
3	**Reduction in patients receiving BSC treatments: 25% + 1-year truncation of BSC costs**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			422,829
4	**Reduction in patients receiving BSC treatments: 25% + 2-year truncation of BSC costs**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]

	ICER (£/QALY)			415,898
5	**Reduction in patients receiving BSC treatments: 50% + 1-year truncation of BSC costs**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			420,097
6	**Reduction in patients receiving BSC treatments: 50% + 2-year truncation of BSC costs**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			406,237

Abbreviations: BSC, best supportive care; ICER, incremental cost-effectiveness ratio; QALY, quality adjusted life year; SALT, Severity of Alopecia Tool.

Baricitinib for treating severe alopecia areata [ID3979]

EAG response to company draft guidance comments - Addendum

March 2023

Source of funding

This report was commissioned by the NIHR Evidence Synthesis Programme as project number 135648.

1 Additional scenarios

This document provides additional scenarios run by the External Assessment Group (EAG) around the potential best supportive care (BSC) use that might be incurred by treatment naïve patients. For the scenarios, the EAG has assumed no reduction in BSC use for both baricitinib and no active treatment patients upon entering the BSC health state, which is reflective of the company's original base case assumption in which assumed that [redacted] of patients who fail to achieve a treatment response will continue with BSC treatments, with [redacted] of patients discontinuing treatment.

In addition, the EAG has explored the company's truncation of BSC drug costs of 10 years in addition the EAG's scenarios of one and two years. Upon request from NICE, two sets of scenarios are provided, one using the EAG's preferred source of utility values from the BRAVE-AA trials and the other using utility values from the Adelphi Disease Specific Programme (DSP) study (which is the company's preferred data source).

Table 1 presents the EAG's additional scenarios. Results reported include the company's proposed patient access scheme (PAS); a fixed pack price of [redacted]. Confidential medicines unit (CMU) and Drugs and pharmaceutical electronic market information tool (eMIT) prices are available for medicines included in BSC using the NICE preferred secondary care setting for prescribing and these have been included in the results presented in this document (permission granted by NICE).

Table 1. EAG additional scenarios

	Results per patient	Baricitinib 4 mg	'No active treatment'	Incremental value
1	**0% reduction in BSC use for both treatment arms, lifetime of BSC drug costs, Adelphi utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			25,336
2	**0% reduction in BSC use for both treatment arms, 10-year truncation of BSC drug costs, Adelphi utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			36,407
3	**0% reduction in BSC use for both treatment arms, 2-year truncation of BSC drug costs, Adelphi utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]

	ICER (£/QALY)			55,742
4	**0% reduction in BSC use for both treatment arms, 1-year truncation of BSC drug costs, Adelphi utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			59,735
5	**0% reduction in BSC use for both treatment arms, lifetime of BSC drug costs, BRAVE-AA utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			175,860
6	**0% reduction in BSC use for both treatment arms, 10-year truncation of BSC drug costs, BRAVE-AA utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			252,710
7	**0% reduction in BSC use for both treatment arms, 2-year truncation of BSC drug costs, BRAVE-AA utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			386,914
8	**0% reduction in BSC use for both treatment arms, 1-year truncation of BSC drug costs, BRAVE-AA utility values**			
	Total costs (£)	[redacted]	[redacted]	[redacted]
	QALYs	[redacted]	[redacted]	[redacted]
	ICER (£/QALY)			414,635

Abbreviations: BSC, best supportive care; ICER, incremental cost-effectiveness ratio; QALY, quality adjusted life year; SALT, Severity of Alopecia Tool.