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ORIGINAL RESEARCH OPEN ACCESS

Criteria for Commencing and Continuing Subsidised Janus Kinase Inhibitor Therapy in Australian Alopecia Areata Patients—Results From an Australian Expert Consensus Exercise

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ABSTRACT

Background/Objectives: Janus kinase inhibitors (JAKis) have been approved by the Therapeutic Goods Administration for severe alopecia areata (AA) in Australia. However, access is limited as JAKis are not currently subsidised on the Pharmaceutical Benefits Scheme for this indication. This study aimed to establish expert consensus on criteria for initiating and continuing subsidised JAKi therapy for AA.

Methods: An eDelphi study was conducted with 26 Australian specialists in hair and scalp disorders, who participated in two online survey rounds. A third round, held as a virtual meeting, facilitated discussion. Consensus was defined as ≥ 75% agreement or disagreement.

Results: Twenty-six, twenty-two, and twenty-five experts completed the first, second, and third rounds, respectively. Experts agreed that JAKis were nearly always the best treatment for cases with ≥ 50% scalp hair loss and usually the best treatment for 21%–49% scalp hair loss. The most important additional factors when assessing eligibility for JAKis were refractory disease, rapid progression, psychosocial morbidity, poorly camouflaged hair loss, ophiasis pattern, and impaired quality of life. Treatment failure was defined as < 50% improvement in scalp hair loss after 12 months of therapy. Indicators of remission included achieving SALT 0, regrowth of facial hair, improved DLQI scores, patient satisfaction, negative hair pull test, and reduced psychosocial impairment.

Conclusions: This expert consensus provides a framework for determining eligibility for subsidised JAKi therapy in Australian AA patients. Future research, supported by patient registries, should incorporate patient perspectives to further refine these criteria, ensure equitable access to treatment, and assess real-world impact, safety, and effectiveness.

1 | Introduction

Alopecia areata (AA) is a chronic autoimmune condition that causes non-scarring hair loss [1]. According to the Alopecia Areata Investigator Global Assessment (AA-IGA) Scale, severe AA is defined as at least 50% scalp hair loss [2]. The Alopecia Areata Severity and Morbidity Index (ASAMI) Study was a global expert consensus project which formed the foundation of the present exercise and identified various determinants of alopecia severity beyond scalp hair loss, including facial hair loss, relapsing AA, prolonged episode duration, and rapidly progressing disease [3].

Prior to baricitinib receiving TGA approval for the treatment of AA in May 2023, no approved systemic therapies existed [4]. Off-label systemic treatments include oral corticosteroids and steroid-sparing agents such as azathioprine, methotrexate, and ciclosporin. The 2020 international Alopecia Areata Consensus of Experts (ACE) study recommended oral or topical corticosteroids as first-line therapy, regardless of disease severity [5]. Since then, the approval of JAK inhibitors (JAKis) has transformed AA management, necessitating updated guidelines. A Cochrane network meta-analysis found that baricitinib is the only AA treatment with strong evidence for hair regrowth [6]. Currently, despite TGA approval, there is no subsidy available for JAKis in treating AA in Australia. A one-month supply of baricitinib on a private prescription costs over $1000 AUD [7], rendering it inaccessible to most.

In the United Kingdom, as of March 2024, patients with severe AA can access subsidised ritlecitinib via the National Health Service. Severe AA has been defined by the British Association of Dermatologists as either a SALT score ≥ 50, or a SALT score between 21–49 with at least one of the following factors: negative impact on psychosocial functioning, noticeable eyebrow or eyelash involvement, inadequate response to at least 6 months of treatment, or a diffuse positive hair pull test [8].

With baricitinib (May 2023) [4] and ritlecitinib (July 2024) [9] approved by the TGA for severe AA, it is essential to establish criteria for subsidised prescriptions. This survey builds upon the work of the ASAMI exercise and presents recommendations from Australian experts on the subgroups of AA patients most suitable for treatment, as well as criteria defining disease remission and treatment failure.

2 | Materials and Methods

This study was reported according to a checklist developed by Sinha et al., which included recommended items to include in studies [10] using the Delphi technique and the SQUIRE 2.0 guidelines [11]. Whilst the Delphi technique requires a minimum of two rounds of face-to-face interactions, the eDelphi process allows anonymous engagement online [5].

2.1 | Expert Panel Selection

A total of thirty-three Australian hair and scalp disorder specialists were invited to participate. Invitations were extended based on self-reported interest and expertise in AA, experience with JAKi prescribing for AA, involvement in the ASAMI study, and a history of publication on AA-related research and/or conference presentations regarding AA.

2.2 | eDelphi Survey

Participants completed two rounds of an online questionnaire, followed by a third round conducted via a virtual meeting. The first survey included a total of 29 questions, the second 21 questions, and the third round 10 questions (Figure 1). The initial questionnaire was developed by a panel of five clinicians and researchers with extensive clinical and research experience with AA, including members of the Australian research team behind the ASAMI study.

Most questions on AA severity were adapted from ASAMI [3]. Irrelevant or repetitive questions, and those with limited value in the Australian context, were removed or revised. Additional questions were included regarding the impact of younger age and female gender on AA severity. This was based on studies showing that AA has a greater impact on quality of life in females [12–14], and that childhood onset is correlated with increased chronicity and severe forms of alopecia [15]. Six questions were added in round two based on expert suggestions.

Consensus for Likert-type and multiple-choice statements was defined as a minimum of 75% agreement or disagreement. This threshold was chosen based on previous eDelphi studies, which determined consensus levels within the 70%–80% range [16, 17]. Questions that did not achieve consensus in rounds 1 or 2 were included in the subsequent round.

2.3 | Statistical Analysis

Categorical data were reported using frequencies and percentages, while responses to free-text questions were presented descriptively.

3 | Results

3.1 | Expert Panel

Of the 33 invited experts, 26 (79%) completed round 1, 22 (67%) completed round 2, and 25 (76%) completed round 3. The majority practice in Victoria (20; 77%), 4 practice in Queensland (15%), and the remaining 2 currently practice overseas (8%). 17 experts (65%) are fellows of the Australasian College of

Dermatologists, 3 (12%) are international dermatologists completing the Australian Specialist fellowship pathway, 4 (15%) are international dermatologists completing Australian hair fellowships, and 2 (8%) are international dermatologists who recently completed Australian hair fellowships (Figure 2).

3.2 | Findings

Key consensus outcomes are described in Table 1.

3.3 | Assessment of Disease Severity and Eligibility for Subsidised JAKi

3.3.1 | Extent of Scalp Hair Loss and Other Clinical Findings

The majority of participants in round 1 (21, 81%) agreed with the AA-IGA interpretation of AA disease severity [2]. Only 5 participants (19%) offered alternative SALT values (Table 2). There was consensus that JAKis are nearly always the best management option for patients with a SALT score ≥ 50, usually the best option if the SALT is between 21–49, and sometimes the best option if the SALT is lower than that.

There was agreement that hair loss in an ophiasis distribution should increase eligibility, as should non-scalp involvement, including ClinRo 2 or 3 loss of eyebrows or eyelashes, significant beard hair loss in males, and ClinRo 2 or 3 nail involvement. There was agreement that a strong positive hair pull test increases eligibility, whereas adverse trichoscopic findings do not.

3.3.2 | Disease Course

Rapid progression of scalp hair loss, defined as an increase of more than 10 SALT points over six weeks, was agreed to increase suitability for subsidised JAKi therapy. A history of previous AA episodes or a history of alopecia totalis or universalis (AT/AU) also increased suitability. Experts agreed that a current episode exceeding one year, or total disease duration (time from first episode of AA) exceeding 10 years, increased eligibility.

3.3.3 | Treatment History

Experts reached consensus that refractory disease, defined as failure to respond to intralesional corticosteroids (at least three treatments at 4–6 week intervals), a six-week tapering course of oral corticosteroids (starting at 20 mg/day), or steroid-sparing agents like azathioprine, methotrexate, or cyclosporine (used at adequate doses for a minimum of three months), increased suitability for JAKis. A positive response to prior JAKi use via compassionate supply or private prescription was identified as increasing suitability.

Consensus was not reached in the first two rounds regarding failure to respond to topical corticosteroids. In round 3, experts wanted to stratify by age. They noted that while topical corticosteroids are rarely trialled in adults, given limited treatment options for children, they are often used in paediatric cases. Despite this stratification, no consensus was achieved on whether failure to respond to topical corticosteroids influences JAKi eligibility in any age group.

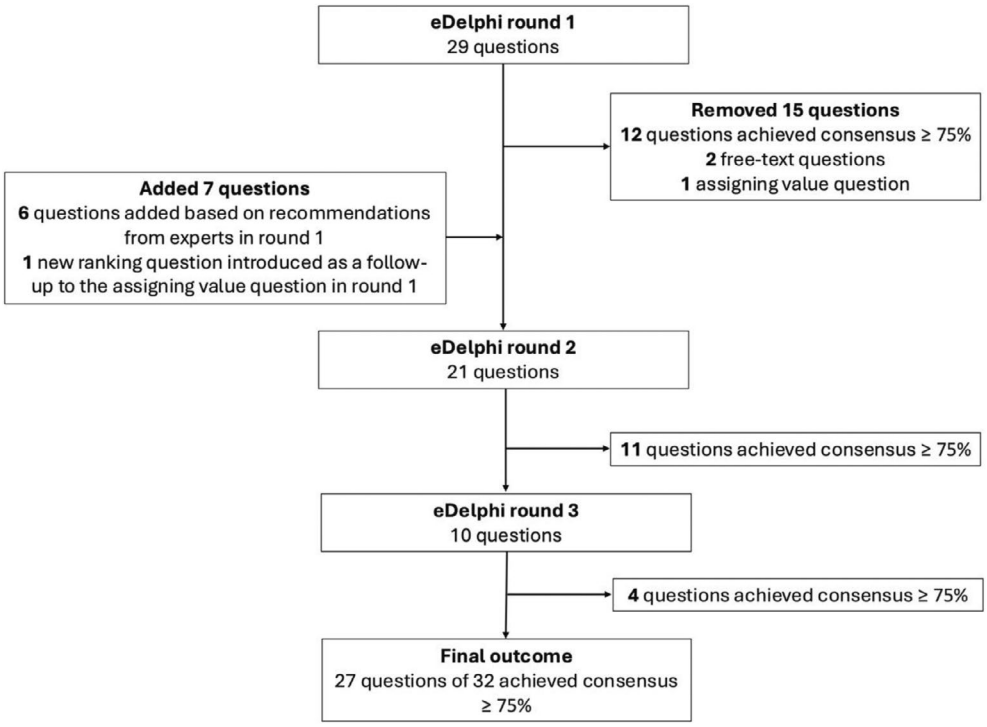

FIGURE 1 | Summary of the eDelphi survey rounds.

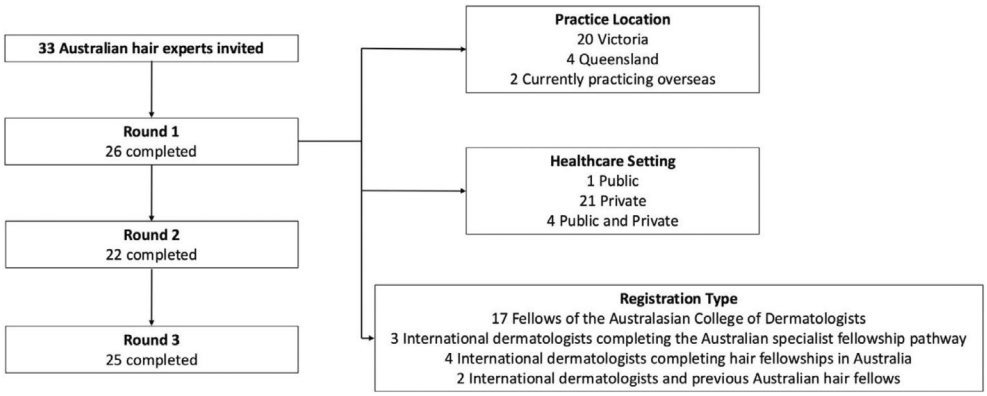

FIGURE 2 | Characteristics of the Australian hair experts who participated in the consensus exercise.

3.3.4 | Psychosocial and Quality of Life Impairment

Psychosocial factors, including a history of anxiety, depression, suicidal ideation, or social impairment exacerbated by AA, were deemed important, as was a Dermatology Life Quality Index (DLQI) score greater than or equal to 11. The cultural significance of scalp or facial hair was considered to increase suitability for JAKi therapy, as was hair loss in difficult-to-conceal areas.

3.3.5 | Age and Gender

Experts agreed that patients aged 5–17 were more likely to benefit from JAKi therapy than adults. There was no consensus on whether females would benefit more than males.

3.3.6 | Comorbidities

Consensus was not achieved as to whether the presence of co-existing atopic dermatitis or other autoimmune diseases increases eligibility for JAK inhibitor therapy.

3.3.7 | Relative Importance of Severity Factors

Experts considered refractory disease to be the most important factor to consider when assessing AA severity beyond scalp hair loss (Table 3). In the context of one point being equivalent to 1% scalp hair loss, a mean of 16.6 points was assigned to refractory disease. The other top-scoring items were: psychosocial factors (14.2 points), rapid disease progression (13.8 points), poorly camouflaged scalp hair loss (13.6 points), DLQI > 11 (13 points), and ophiasis pattern of hair loss (13 points). The lowest scoring factors were: loss of beard hair (9.2 points), female gender (7 points), adverse trichoscopy findings (7 points), patient age 5–11 (6.8 points), and Clin RO 2 or 3 nail changes (6.8 points). In round 2, experts ranked the top 10 severity factors, and their order of importance remained unchanged.

3.4 | Disease Remission

The experts identified several clinical parameters that could indicate AA disease remission: achieving SALT 0, facial hair regrowth, improvement in DLQI scores, patient satisfaction, negative hair pull, and reduced psychosocial impairment related to AA. Parameters deemed not indicative of disease remission included SALT 10, SALT 20, improvement in nail changes, and improvement in trichoscopy findings. Experts agreed that the ideal time point for reassessing JAK inhibitor therapy after remission, to decide on stopping or down-titrating treatment, was after 6 months.

3.5 | Treatment Failure

Experts reached a consensus on the definition of treatment failure that would warrant discontinuation of subsidised JAK inhibitor therapy: failure to achieve at least a 50% improvement in scalp hair loss from baseline. It was agreed that this assessment should be conducted 12 months after initiation of JAK inhibitor treatment.

4 | Discussion

The consensus outcomes presented in this study provide guidance for the development of eligibility criteria for subsidised JAKi therapy in Australia. By incorporating both clinical and psychosocial factors, treatment can be prioritised for patients with the greatest need.

81% of surveyed experts supported the AA-IGA scale, which defines severe disease as a SALT score ≥ 50 [2]. In Canada and the UK, JAKis are reimbursed for adult patients with more than 50% scalp hair loss [8, 18]. However, our experts agreed that JAKi therapy is usually also the best management option for patients with a SALT score between 21–49. They also recommended that children as young as five should be eligible for subsidised JAKis if data supports safety and efficacy in this group.

There was agreement that clinical features beyond scalp involvement contribute to disease severity. Refractory disease emerged as the most critical non-scalp determinant, underscoring the need for JAKis in patients unresponsive to other treatments. Psychosocial morbidity, rapid disease progression, poorly camouflaged scalp hair loss, ophiasis pattern, and high DLQI scores were also deemed important. These were also identified as important severity determinants in the ASAMI exercise [3].

TABLE 1 | Key consensus outcomes.

Questionnaire domain	Agree/disagree	Consensus (%)	Round in which the consensus was reached
Degree of Scalp Hair Loss			
I agree with the AA-IGA interpretation of AA disease severity.	Agree	81	1
Rapid progression			
Rapid progression of hair loss (greater than 10-point increase in SALT over 6 weeks) increases suitability for subsidised JAKi.	Agree	84	1
Number of AA episodes and Relapse History			
Previous episode/episodes of AA increase suitability for subsidised JAKi.	Agree	77	1
Refractory Disease			
Failure to respond to intralesional corticosteroid (minimum 3 treatments at 4–6 weekly intervals) increases suitability for subsidised JAKi.	Agree	96	1
Failure to respond to a tapering course of oral corticosteroids (minimum 6 weeks, commencing at 20 mg/day) increases suitability for subsidised JAKi.	Agree	93	1
Failure to respond to a steroid-sparing agent such as azathioprine, methotrexate, or cyclosporin (adequate dose for a minimum of 3 months) increases suitability for subsidised JAKi.	Agree	100	1
Hair Pull Test			
A strong positive hair pull test increases suitability for subsidised JAKi.	Agree	91	2
Trichoscopy			
Broken hairs, black dots, exclamation mark hairs, and tapering hairs on trichoscopy increase suitability for subsidised JAKi.	Disagree	79	3
Ophiasis distribution			
Hair loss in an ophiasis distribution increases suitability for subsidised JAKi.	Agree	92	1
Cosmetic camouflage			
Inability to conceal hair loss despite careful styling increases suitability for subsidised JAKi.	Agree	96	1
Non-scalp involvement			
ClinRO 2 or 3 loss of eyelashes increases suitability for subsidised JAKi.	Agree	76	1
ClinRO 2 or 3 loss of eyebrows increases suitability for subsidised JAKi.	Agree	88	1
Significant or complete loss of beard hair in males increases suitability for subsidised JAKi.	Agree	81	2
ClinRO 2 or 3 nail involvement increases suitability for subsidised JAKi.	Agree	76	2

(Continues)

TABLE 1 | (Continued)

Questionnaire domain	Agree/disagree	Consensus (%)	Round in which the consensus was reached
Quality of Life and Psychosocial Morbidity			
A history of anxiety, depression, suicidal ideation, or impairment in social functioning, precipitated or exacerbated by AA, increases suitability for subsidised JAKi.	Agree	88	1
A DLQI score > 11 increases suitability for subsidised JAKi.	Agree	89	1
Age			
Patient age of 5–11 years increases my assessment of AA severity and therefore increases suitability for subsidised JAKi.	Agree	84	3
Patient age of 12–18 years increases my assessment of AA severity and therefore increases suitability for subsidised JAKi.	Agree	76	2
Cultural factors			
Racial, ethnic, or cultural importance of scalp or facial hair increases suitability for subsidised JAKi.	Agree	76	2
Episode/Disease duration			
Prolonged duration of the current episode of AA (> 1 year) increases suitability for subsidised JAKi therapy.	Agree	91	2
Prolonged duration of disease (> 10 years) increases suitability for JAKi therapy.	Agree	91	3
Alopecia totalis/universalis (AT/AU)			
Previous alopecia totalis or universalis increases suitability for subsidised JAKi therapy.	Agree	90	2
Previous JAKi use			
Response to previous oral JAKi via compassionate supply or private prescription increases suitability for subsidised JAKi therapy.	Agree	81	2
Treatment failure			
Treatment failure that would mandate discontinuation of subsidised JAKi therapy can be best defined by failure to achieve a 50% improvement from baseline in scalp hair loss.	Agree	95	2
After commencing a JAKi, treatment failure should be assessed at 12 months.	Agree	81	2
Remission			
Once AA disease remission has been achieved, JAKi therapy should be re-evaluated and possibly stopped or titrated down after 6 months.	Agree	84	3

Previous studies have found that the psychological burden of AA does not correlate linearly with the extent of scalp hair loss [14, 19, 20]. As such, JAKi therapy may offer substantial benefits in patients with less than 50% scalp hair loss but significant psychological distress. Given that camouflage techniques improve the quality of life in AA patients [21], poorly concealed hair loss can reasonably be assumed to exacerbate the psychological burden. Ophiasis-distribution AA is notoriously resistant to pre-JAKi era treatments such as intralesional corticosteroids and minoxidil [22], likely explaining why experts are keen to initiate JAKis in this subgroup.

Our results show that quality of life (QOL) is an important consideration when assessing eligibility for JAKis; however,

TABLE 2 | Alternative definitions for AA severity based on SALT score, proposed by five experts who disagreed with AA-IGA definitions.

	Limited	Moderate	Severe	Very severe
SALT score range	1–10	11–30	31–70	71–100
	1–5	6–10	11–20	21–100
	1–5	6–20	21–40	41–100
	1–5	6–19	21–50	51–100
	1–5	6–20	21–80	81–100

TABLE 3 | Relative importance of other factors in assessing AA severity, compared to scalp hair loss. Experts were asked to assign a point value to each severity factor, with one point equivalent to 1% scalp hair loss.

Severity factor	Average points assigned
Refractory disease	16.6
Psychosocial factors (anxiety, depression, suicidal ideation, or social impairment due to AA)	14.2
Rapid disease progression	13.8
Poorly camouflaged scalp hair loss	13.6
DLQI > 11	13
Ophiasis pattern of hair loss	13
Clin RO 2 or 3 loss of eyebrows	12.8
Disease relapse	12.8
Clin RO 2 or 3 loss of eyelashes	11.2
Strong positive hair pull	10.8
Patient age 12–18	9.6
Large gaps in, or complete loss of beard in males	9.2
Female gender	8.4
Adverse trichoscopy findings	7
Patient age 5–11	6.8
ClinRO 2 or 3 nail changes	6.8

AA-specific measures are necessary [23]. This finding aligns with the 2024 ASAMI global expert consensus exercise, where it was determined that the DLQI is an inadequate tool for evaluating QoL in individuals with AA [3]. While the DLQI offers a general assessment of dermatology-related QoL, it does not accurately reflect the unique psychosocial burden experienced by patients with AA. Notably, the DLQI was developed using a cohort of 120 patients, only two of whom were diagnosed with AA [24], limiting its relevance and validity in this population.

A key outcome of this study was establishing criteria for treatment failure and remission. Experts agreed that failure to achieve ≥ 50% improvement in scalp hair loss after 12 months of therapy constitutes treatment failure, warranting discontinuation of JAKis. Conversely, achieving SALT 0, regrowth of facial hair, a negative hair pull test, patient satisfaction, and improvements in psychosocial impairment and DLQI scores were identified as indicators of remission.

5 | Limitations

The expert panel primarily represented clinicians from Victoria and Queensland, which may limit generalisability to other states. A fundamental limitation of the eDelphi method is that the opinions of individual experts may not always be based on established evidence. Additionally, this eDelphi process relied solely on expert opinion, which may not fully capture patient perspectives. Given that patients' self-perceived disease severity has been shown to correlate reliably with quality-of-life impact [25], incorporating patient beliefs is essential to comprehensively assess AA severity.

6 | Conclusion

This expert consensus provides guidance on criteria for initiating and continuing subsidised JAKi therapy in Australian AA patients. Further assessment of the sensitivity of these criteria in identifying eligible patients is warranted before their implementation in clinical practice and reimbursement decisions. In addition, the establishment of a dedicated patient registry for AA disease severity and treatment safety will facilitate this process, while also enabling the comparative analysis of real-world impact, effectiveness, and safety of emerging and existing AA therapies [5, 26, 27].

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Ethics Statement

Reviewed and approved by the Bellberry Human Research Ethics Committee.

Conflicts of Interest

Professor Rodney Sinclair is an Editorial Board member of the Australasian Journal of Dermatology and a co-author of this article. To minimise bias, he was excluded from all editorial decision-making

related to the acceptance of this article for publication. Samantha Eisman has been an investigator in clinical trials and/or affiliated with (Presentations/Promotional work/Advisory boards) for AbbVie, Arena Pharmaceutical, Boston Pharmaceuticals, Botanix, Bristol-Myers Squibb, Celldex Therapeutics, Dermaliq Therapeutics, Dermira, Eli Lilly and Company, Evelo Biosciences, Hope Medicine, Immunic Therapeutics, Janssen, Kobiolabs, Kymab, LEO Pharma, L'Oréal, Nektar Therapeutics, Novartis, Pfizer Inc., Regeneron, Samson Pharmaceuticals, Sanofi, Suzhou Connect Biopharmaceuticals, Takeda Pharmaceuticals, TEVA Pharmaceuticals, Tigermed, and Zai Lab. S.E. is Treasurer and Board Member of the Australian Hair and Wool Research Society (2019 to present). Leona Yip is a consultant, advisory board member, or key opinion leader for L'Oréal, Galderma, Eli Lilly, Pfizer, LEO Pharma, and CryoMed. Dmitri Wall reports receiving honoraria for consultancy from Bristol Myers Squibb, Eli Lilly, Pfizer, AbbVie, and Sun Pharma; has received speaker fees from Almirall, Lilly, and L'Oreal; and has received support from AbbVie to attend conferences. He is a shareholder in Samson Clinical. He is an employee of National and International Skin Registry Solutions (NISR) and a director of Hair Restoration Blackrock, Dublin, Ireland. He is a steering committee member of the Global Registry of Alopecia Areata Disease Severity and Treatment Safety (GRASS) International and PI of GRASS Ireland. Professor Kiarash Khosrotehrani is a former editor-in-chief of the Australasian Journal of Dermatology. He received research funding from la Roche Posay, Novartis, Lilly for investigator-initiated studies. Dr. David Orchard is an Editorial Board member of the Australasian Journal of Dermatology and a co-author of this article. To minimise bias, they were excluded from all editorial decision-making related to the acceptance of this article for publication. All other authors have no conflicts of interest.

Data Availability Statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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