SMC2610

ritlecitinib hard capsules (Litfulo®)

Pfizer Ltd

08 March 2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a full submission

ritlecitinib (Litfulo®) is accepted for use within NHSScotland.

Indication under review: For the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.

In a randomised, double-blind, phase IIb/III study in patients with severe alopecia areata, ritlecitinib was associated with statistically significant improvements in scalp hair regrowth versus placebo at week 24.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.

Overleaf is the detailed advice on this product.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Ritlecitinib inhibits Janus kinase (JAK) 3 and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) kinase family in an irreversible and selective manner, disrupting adenosine triphosphate (ATP) binding. In cellular settings, it targets γ-common cytokine signalling. In addition, TEC family kinases inhibition leads to reduced natural killer cell and CD8+ T cell cytolytic activity. Both JAK3 and TEC pathways are involved in alopecia areata, though the full pathophysiology is still not understood. [1]

The recommended dose is ritlecitinib 50 mg orally once daily. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 36 weeks. [1]

1.2. Disease background

Alopecia areata is a chronic immune-mediated disorder leading to non-scarring hair loss, primarily affecting the scalp but potentially involving other areas like eyebrows and body hair. The three main types of alopecia areata are patchy with localised hairless areas, alopecia totalis (AT) that is complete scalp hair loss, and alopecia universalis (AU) that is loss of all body hair. Whilst spontaneous hair regrowth is common, multiple disease episodes are typical, and 10 to 25% of patients progress to AT or AU. The condition carries a significant psychological burden, and the treatment goal is to achieve lasting hair regrowth with an acceptable appearance from the patient's viewpoint. [2]

1.3. Treatment pathway and relevant comparators

According to clinical experts consulted by SMC, presently, there is no satisfactory treatment for severe alopecia areata in Scotland and access to some treatment options may vary widely. Potential pharmacological options include corticosteroids (topical, intralesional, or systemic), topical minoxidil or dithranol, contact immunotherapy, systemic psoralen plus ultraviolet radiation, and immunosuppressive agents such as methotrexate and ciclosporin. Most available pharmacological treatments are not licensed for use in severe alopecia areata, generally demonstrate limited efficacy, and may be associated with considerable side effects. Wigs and other prostheses are used in the management of alopecia areata. Some patients may not pursue treatment initially, as spontaneous hair regrowth is possible in certain cases.[2, 3]

Baricitinib (Olumiant®) is licensed for the treatment of severe alopecia areata in adult patients.[4] Following a full submission, SMC issued advice (SMC2572) in August 2023 that it is not recommended for use within NHSScotland.

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence to support the efficacy and safety of ritlecitinib for the treatment of severe alopecia areata in adult patients comes from the ALLEGRO-2b/3 study. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant study [1, 2, 5]

Criteria	ALLEGRO-2b/3 (B7981015)
Study design	International, randomised, double-blind, placebo-controlled, dose-ranging, phase IIb/III study which comprised a 24-week placebo-controlled period and a 24-week extension period.
Eligible patients	• Male or female patients aged 12 years and older. Within Voluntary Harmonisation Procedure in countries regulated by the EMA (Czech Republic, Germany, Hungary, Poland, and Spain) patients were between the ages 18 and 74 years. • Have a clinical diagnosis of alopecia areata with no other aetiology of hair loss (such as telogen effluvium, androgenetic alopecia). • Confirmed ≥50% hair loss of the scalp according to SALT, including AT and AU, without evidence of terminal hair regrowth within 6 months of both the screening and baseline visits. • Current episode of hair loss ≤10 years.
Treatments	• a loading dose of 200 mg of ritlecitinib once daily for 4 weeks followed by ritlecitinib 50 mg once daily to week 48 (n=132) • a loading dose of 200 mg of ritlecitinib once daily for 4 weeks followed by ritlecitinib 30 mg once daily to week 48 (n=130) • ritlecitinib 50 mg once daily to week 48 (n=130) • ritlecitinib 30 mg once daily to week 48 (n=132) • ritlecitinib 10 mg once daily to week 48 (n=63) • placebo to week 24 followed by a loading dose of 200 mg ritlecitinib once daily for 4 weeks then 50 mg ritlecitinib once daily to week 48 (n=65) • placebo to week 24 followed by 50 mg ritlecitinib once daily to week 48 (n=65)
Randomisation	Patients were randomised in a 2:2:2:2:1:1:1 manner to the treatments in the order listed above. Randomisation was stratified by scalp hair loss (AT/AU versus not AT/AU) and age (<18 years and ≥18 years).[6]
Primary outcome	Proportion of participants who achieve an absolute SALT score ≤10 at Week 24. SALT score assesses alopecia areata severity based on scalp hair loss, ranging from 0 = no scalp hair loss to 100 = total scalp hair loss. SALT ≤10 response represents less than or equal to 10% of scalp hair loss.
Selected secondary outcomes	• PGI-C response defined as a score of “moderately improved” or “greatly improved” at week 24 (key secondary outcome). PGI-C response rate is a patient-reported outcome evaluating the improvement or worsening of their alopecia areata. • SALT ≤20 response at week 24 • EBA response, defined as ≥2-grade improvement from baseline or normal EBA score (range 0 to 3=normal) in patients with abnormal eyebrows at baseline. • ELA response, defined as ≥2-grade improvement from baseline or normal ELA score (range 0 to 3=normal) in patients with abnormal eyelashes at baseline.
Statistical analysis	Efficacy analyses were performed in the Full Analysis Set population, which included all patients who underwent randomisation, regardless of whether they received study medication. The primary outcome measures were the difference in the proportion of participants who achieved a SALT score of ≤10 at week 24 in each treatment arm compared with placebo. The two placebo groups were pooled for this analysis, and the 10 mg group comparison to placebo was excluded. A hierarchical statistical testing strategy was applied in the study with no formal testing of outcomes after the first non-significant outcome in the hierarchy. Eight hypotheses (for the primary and key secondary outcomes in combination with four dosing schemes [10 mg group comparison to placebo not included]) were tested as part of a hierarchical testing strategy. There were different hierarchical testing orders for the different regulatory authorities. Results in this document are presented as per the MHRA’s preferred hierarchical testing

	order. Only results for the licensed dose of ritlecitinib (50 mg without loading dose) are reported.

Abbreviations: AT = alopecia totalis, AU = alopecia universalis, EBA = eyebrow assessment, ELA = eyelash assessment, PGI-C = Patient Global Impression of Change, SALT = Severity of Alopecia Tool

A significantly greater proportion of patients achieved Severity of Alopecia Tool (SALT) ≤10 response (primary outcome) and Patient Global Impression of Change (PGI-C) response (key secondary outcome) with the licensed dose of ritlecitinib (50 mg once daily) compared with placebo at Week 24. [1, 2, 6, 7] Results are summarised in Table 2.2.

The SALT ≤10, SALT ≤20 and PGI-C response rates increased further at week 48 with ritlecitinib 50mg (N=125; 31%, 43% and 56%, respectively). [1, 2, 6, 7]

Table 2.2. Primary and selected secondary outcome results at week 24[1, 2, 6, 7]

	Ritlecitinib 50 mg (N=130)	**Pooled placebo (N=131)**
Primary outcome		
SALT ≤10 response, %	13%	1.5%
Difference versus placebo (95% CI)	12% (5.4 to 18)	
p-value	<0.001	
Key secondary outcome		
PGI-C response, %	49%	9.2%
Difference versus placebo (95% CI)	40% (29 to 51)	
p-value	<0.001	
Selected secondary outcome		
SALT ≤20 response, %	23%	1.5%
EBA response, %	29% (29/100)	4.7% (5/107)
ELA response, %	29% (26/90)	5.2% (5/97)
Abbreviations EBA = eyebrow assessment; ELA = eyelash assessment; CI = confidence interval; N = total number of patients; PGI-C = Patient Global Impression of Change; SALT = Severity of Alopecia Tool		

2.2. Health-related quality of life outcomes

Health Related Quality of Life (HRQoL) outcomes included the Alopecia Areata Patient Priority Outcomes (AAPPO) scale, the Hospital Anxiety and Depression Scale (HADS), the EuroQoL 5 Dimensions (EQ-5D-5L) and the 36-Item Short Form Health Survey version 2 Acute (SF36v2). However, no meaningful quality of life (QoL) differences were observed for ritlecitinib 50mg versus placebo. [7]

2.3. Supportive studies

ALLEGRO-LT (B7981032) is an ongoing Phase III, uncontrolled, open-label, international, long-term study to evaluate the safety and efficacy of ritlecitinib in adults and adolescents ≥12 years of age with alopecia areata. [2, 8]

Eligible patients from ALLEGRO-2a (B7931005) a Phase IIa proof of concept study in adult patients who had ≥50% terminal scalp hair loss, or ALLEGRO-2b/3 (B7981015, described in Table 2.1 above) had an opportunity to enrol in this study, as well as de novo adult patients who had ≥25% terminal scalp hair loss due to alopecia areata and adolescents (aged 12 to <18 years) who had ≥50% terminal scalp hair loss due to alopecia areata.

Patients who had previously received ritlecitinib in B7931005 or ALLEGRO-2b/3, were administered 50 mg once daily for up to 60 months in the ALLEGRO-LT study. De novo patients were administered a loading dose of 200 mg ritlecitinib once daily for 4 weeks, followed by 50 mg given once daily for up to 60 months in the ALLEGRO-LT study.

The study primarily assessed safety; however, secondary efficacy outcomes were descriptively assessed. Preliminary results suggest SALT ≤10 and PGI-C responses is sustained or continue to increase up to Month 30 to 32 of treatment with ritlecitinib 50mg.[2, 8]

3. Summary of Safety Evidence

In the 24-week, placebo-controlled period of ALLEGRO-2b/3 (B7981015) any treatment-emergent adverse event (AE) was reported by 75% (98/130) of patients in the ritlecitinib 50 mg daily group (licensed dose) and 71% (93/131) in the pooled placebo group. In the ritlecitinib 50 mg and pooled placebo groups respectively, patients with a reported serious AE were 0 versus 2.3%, patients with a temporary dose interruption due to AEs were 10% versus 5.3%, and AEs led to permanent discontinuations in two patients in each group. [6]

During the placebo-controlled period, the most frequently reported treatment emergent AEs of any grade with an incidence > 5% in the ritlecitinib 50 mg daily group or pooled placebo group were, respectively: upper respiratory tract infection (6.2% versus 7.6%), nasopharyngitis (10% versus 6.1%), headache (9.2% versus 8.4%), nausea (2.3% versus 5.3%), diarrhoea (9.2% versus 3.8%), acne (6.2% versus 4.6%) and urticaria (4.6% versus 2.3%). [6]

During the overall 48-weeks study period, any AE was reported by 85% (110/130) of patients in the ritlecitinib 50 mg group. In the ritlecitinib 50 mg, 2 patients reported a serious AE, patients with a temporary dose interruption due to AEs were 15%, and AEs led to permanent discontinuations in four patients. The most frequently reported treatment emergent AEs were in the ritlecitinib 50 mg group: headache (12% in both groups), nasopharyngitis (13% versus 6.1%), upper respiratory tract infection (8.5% versus 9.1%), nausea (2.3% versus 1.5%), and acne (9.2% versus 12%). [6] During the overall study period, in the ritlecitinib 50 mg group, AEs of special interest included herpes zoster (reported in five patients) pulmonary embolism (reported in one patient, not related to treatment), and malignancies (reported in one patient, related to treatment per the investigator]). No serious infections occurred in the 50 mg or placebo to 50 mg groups. No deaths, major cardiovascular events, or opportunistic infections were reported during the study. Audiology evaluation did not reveal any central hearing disorder from ritlecitinib, and no serious neurological AEs were observed. [6]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- In ALLEGRO-2b/3, a significantly greater proportion of patients in the ritlecitinib 50 mg group compared with the placebo group achieved a SALT ≤10 response at week 24. The treatment effect in SALT ≤10 response was numerically small but still considered clinically relevant by regulators due to the stringency of the measure and the short 24-week duration of the placebo-controlled period.[2]

- Results for this primary outcome were supported by larger treatment effects in patient reported subjective key secondary outcome, PGI-C, and in the less stringent secondary outcome, SALT ≤20.
- Open-label and uncontrolled longer-term data indicate there is no apparent reduction in the treatment effect on prolonged use and may suggest sustained or increased efficacy with up to 2.5 years of treatment. [2]

4.2. Key uncertainties

- The QoL outcomes in ALLEGRO 2b/3 did not demonstrate meaningful differences between ritlecitinib and placebo and the overall quality of life benefits for the Scottish population remain uncertain.
- The placebo-controlled data are limited to 24 weeks from ALLEGRO-2b/3, so there is uncertainty about the longer-term effectiveness of ritlecitinib.
- There are limited data on the impact of interrupting treatment for responders. The limited clinical data available and simulation data suggest that interruptions for less than 6 weeks may not significantly affect regrown scalp hair, though loss of response is likely with longer interruptions. Regular re-assessment of the benefit-risk profile is recommended. [2]
- Trends suggested ritlecitinib may be less effective in patients with AT/AU (3.6% difference in SALT ≤10 response with ritlecitinib compared with placebo at Week 24) compared with those without AT/AU (19% difference). [2] However, the study was not designed to statistically test in subgroups and due to the low patient numbers, subgroup analysis results should be interpreted with caution.
- According to the submitting company, the relevant comparator is best supportive care (BSC), defined as non-pharmacological therapy alongside disease management. They assumed it includes wigs and other prosthetic supports alongside routine appointments with healthcare professionals. The key study employed a placebo-controlled design, and the placebo arm appeared to adequately mirror BSC without pharmacological intervention. Clinical experts noted that pharmacological treatments may be used in the management of alopecia areata, but most of these are not licensed for this indication and have limited efficacy.
- The pivotal study was designed as a dose-ranging one, which resulted in a limited number of patients in each treatment group, with only 130 patients randomised to ritlecitinib 50mg daily and 131 patients to placebo during the controlled 24-week period. However, it was considered satisfactory by regulators to support the 50 mg daily dose without a loading dose, which was proposed primarily based on safety considerations. [2]
- Regulators have deemed the safety of ritlecitinib 50 mg generally acceptable and manageable. However, uncertainties exist regarding long-term exposure, neuro-safety, and potential class effects shared with other JAK inhibitors approved for chronic inflammatory disorders, as well as the use in adolescents. These have been highlighted in the Summary of products characteristics (SPC) and will be monitored post-approval. [2]

4.3. Clinical expert input

Clinical experts consulted by SMC considered that ritlecitinib fills an unmet need in this therapeutic area, namely as there are no reliably effective treatments currently available to treat severe alopecia areata. They considered ritlecitinib is a therapeutic advancement due to its novel mechanism of action and positive effect on hair growth.

4.4. Service implications

Clinical experts consulted by SMC generally considered that there would be no significant service implications associated with the introduction of ritlecitinib.

5. Summary of Patient and Carer Involvement

The following information reflects the views of the specified Patient Group.

- We received a patient group submission from Alopecia UK, which is a registered charity.
- Alopecia UK has received 13.4% pharmaceutical company funding in the past two years, including from the submitting company.
- Alopecia areata is not just cosmetic, it is an autoimmune condition. People with alopecia areata describe feelings of shock, trauma, and disrupted identity. It is not only about the degree of hair loss, there is also a big impact on the quality of life lived with a non-curable and unpredictable visible difference. It can lead to debilitating mental health conditions (depression, anxiety) and psychosocial impacts (isolation, panic, absenteeism, diminished life outcomes and even suicidal ideation).
- There are very limited treatment options for alopecia areata. Only 1 in 4 patients are referred from their GP to dermatology, and many with severe alopecia areata will be told there is nothing that can be done. Patients accept there is no cure but are frustrated and despair that limited treatments are available with limited success in terms of patient numbers who respond and percentage hair growth.
- The patient group described how they are aware of patients who have accessed JAK inhibitors that have experienced hair regrowth and as a result experienced improvements in the psychosocial impacts of alopecia.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

The economic case is summarised in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	Lifetime – 66 years based on an assumed starting age of 34

Population	Adults and children (aged 12 and above) with severe alopecia areata. Within the modelling, the company classified severe as having a Severity of Alopecia Tool (SALT) score of 50 or greater.
Comparators	Ritlecitinib was compared against best supportive care (BSC), which was defined as no pharmacological treatment. Patients had access to wigs and other prosthetic supports.
Model description	A 9 state semi-Markov model was used. The alive health states were defined based on four separate ranges of SALT score: ≥50, 21-49, 11-20 and ≤10. Separate states at each SALT level were included to capture whether a patient was on ritlecitinib treatment or not, generating 8 alive health states in total. Additionally, there was a death state. Patients entered the model in the SALT ≥50 state and could transition in the alternative states in each of the subsequent 12-week cycles.
Clinical data	The main sources of clinical data were the ALLEGRO 2b/3 study[7] and the ALLEGRO-LT study[9]. Within the ritlecitinib arm, transitions between health states within the first 48 weeks were matched to those observed in the ALLEGRO 2b/3 study. Continued treatment with ritlecitinib up to 48 weeks was subject to 2 stopping rules. Patients were assumed to stop treatment if their hair loss increased at week 24 or they did not achieve a SALT score of 20 or less at week 48. Between weeks 48 and 96, data from the ALLEGRO-LT study was used to model movement in the ritlecitinib arm. During this period, if a patient transitioned to a SALT score >20, they would discontinue treatment. Data from the placebo arm of the ALLEGRO 2b/3 study were used to model state transitions during the first 24 weeks of the model.
Extrapolation	At week 96, due to the applied stopping rules, all patients receiving ritlecitinib would be within the SALT≤10 or SALT 11-20 states. They were assumed to remain there, as long as treatment continued. From week 48, a discontinuation rate was applied to patients receiving treatment with ritlecitinib, in addition to the SALT score-based stopping rules. This was modelled by applying an exponential survival curve to time to treatment discontinuation data observed in the ALLEGRO LT study. Throughout the model, upon discontinuation, ritlecitinib patients transitioned to the SALT≥50 state, unless part of a small group who achieved spontaneous remission. The rate of spontaneous remission was in line with the rate of patients achieving SALT≤10 in the placebo arm of the ALLEGRO 2b/3 study (value listed as Academic in Confidence (AiC)). In the BSC arm, after week 24, any patient outside of the SALT ≥50 state transitioned to that state unless achieving spontaneous remission in the same proportion as the ritlecitinib arm. Alopecia areata was not assumed to impact upon mortality, and so an age-specific general population morality rate was applied equally across all states in each cycle.
Quality of life	The company collected data from various standardised health related quality of life (HRQoL) instruments during the ALLEGRO 2b/3 study. However, it judged these as inappropriate to use in the modelling, given their perceived insensitivity towards hair loss. Instead, the company developed vignettes based on desk research, input from alopecia areata patients and retrospective analysis of data collected in the clinical studies. These vignettes were validated with clinicians before being valued using the time trade off method with members of the public. The estimated values were classed as AiC by the company.
Costs and resource use	Medicine costs included in the model covered the acquisition costs for ritlecitinib and the treatment of adverse events. Ritlecitinib is an oral treatment and so no administration cost was included. Wider health costs covered monitoring costs, dermatology consultation costs and the supply and fitting of wigs.
PAS	A Patient Access Scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHSScotland. Under the PAS, a discount was offered on the list price.

*Other data were also assessed but remain confidential.**

6.2. Results

The economic analysis estimated that the incremental cost-effectiveness ratio for ritlecitinb, inclusive of the PAS, was £7,842. Disaggregated results showed that the main difference in estimated total costs between the treatment arms was the acquisition costs of ritlecitinib. The main difference in the total quality adjusted life years (QALYs) was from greater occupancy of the SALT ≤10 state by the ritlecitinib patients.

6.3. Sensitivity analyses

To explore areas of uncertainty one-way and probabilistic sensitivity analyses were undertaken alongside scenario analyses. Scenario analyses suggested that utility values used were one of the main drivers of the economic results.

A selection of scenario analyses is presented below, which again are inclusive of the PAS discount on ritlecitinib.

Table 6.3: Scenario analysis results (PAS discount on ritlecitinib applied)

	Parameter	Base-case	Scenarios	ICER (£/QALY)
	Base case	-	-	7,842
1	**Time horizon**	Lifetime (66 years)	15 years	8,313
2	**Age group**	≥12 years	≥18 years	8,306
3			≥12 to <18 years	7,722
4	**48 week stopping rule threshold for ritlecitinib**	SALT≤20	SALT≤10	8,318
5	**Final stopping rule point**	48 weeks	36 weeks	7,919
6	**Patients considered in transition matrices for long-term response**	Full sample of ALLEGRO LT study	Only patients receiving licenced 50mg dose before and during ALLEGRO LT study	8,079
7	**Utility values**	Vignette study values	Adapted Vañó-Galván utility[10]: SALT <10: 0.89 SALT 11-20: 0.89 SALT 21-49: 0.85 SALT 50+: 0.77	22,418
8	**Health state costs**	BSC patients are monitored indefinitely	BSC patients generate no monitoring costs 5 years after initiation (wig costs continue)	10,656

Abbreviations: BSC, best supportive care; ICER, incremental cost-effectiveness ratio

6.4. Key strengths

- The economic modelling matches the licensed indication.
- The clinical studies indicated that ritlecitinib had a statistically significant treatment effect on hair regrowth at week 24 and that this appeared to be sustained up to 2.5 years.

6.5. Key uncertainties

- The company collected HRQoL through various instruments as part of the ALLEGRO studies. These suggested that hair regrowth was associated with very small changes in quality of life. The company attributed this to both characteristics of the study population and the inability of standardised instruments to capture the effects of alopecia areata on daily living. Instead, for the base case, the company estimated utility from a vignette study. Despite following good practice guidance,[11] the estimated utility values from the vignette study lacked face validity, suggesting very large disutilities from hair loss. Despite challenges in measuring the quality of life for people with alopecia areata through standardised instruments, such an approach was viewed as leading to the most appropriate utility value estimates in this case. Using utility values from external studies which used the EQ-5D instrument led to large increases in the estimated ICER value (See Scenario 7 in Table 6.3).
- The base case analysis assumed that the second stopping rule would be applied at week 48. The SPC recommends that treatment be reviewed at 36 weeks. A scenario applying the second stopping rule at 36 weeks led to a very small increase in the ICER (Scenario 5).
- The company has used data from the full ALLEGRO LT study to inform transitions in the ritlecitinib arm between weeks 48 and 96. This includes people who received alternatives to the licensed dose of 50 mg. Restricting the analysis to just those patients who received the 50 mg dose before and during the ALLEGRO LT study led to a small increase in the ICER (Scenario 6).

7. Conclusion

The Committee considered the benefits of ritlecitinib in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and agreed that the criterion for the absence of other treatments of proven benefit was satisfied.

After considering all the available evidence, and after application of the appropriate SMC modifiers, the Committee accepted ritlecitinib for use in NHSScotland.

8. Guidelines and Protocols

Relevant information is included in:

- British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Published in May 2012 [Update in progress].[3]
- National Institute for Health and Care Excellence (NICE), Clinical Knowledge Summaries: Alopecia areata. Last updated in March 2023.[12]
- Primary Care Dermatological Society (PCDS). Alopecia areata.[13] Last updated in May 2022.

9. Additional Information

9.1. Product availability date

January 2024.

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year (£)
ritlecitinib	**50 mg orally once daily**	**11,520**

Costs from eMC Dictionary of Medicines and Devices Browser on 08 January 2024. Costs do not take any patient access schemes into consideration.

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimated there would be 3,230 patients eligible for treatment with ritlecitinib in each year. Taking uptake and discontinuations into account the company estimate that 47 patients would receive treatment in year 1 rising to 746 patients in year 5.

SMC is unable to publish the PAS budget impact due to this being commercial in confidence. A budget impact assessment is provided in confidence to Scottish Health Boards to enable them to estimate the predicted budget impact of the new treatment.

*Other data were also assessed but remain confidential.**

References

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This assessment is based on data submitted by the applicant company up to and including 16 February 2024.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.