SMC2707

lebrikizumab solution for injection in pre-filled syringe or pen (Ebglyss®)

Almirall UK Limited

04 October 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

lebrikizumab (Ebglyss®) is accepted for restricted use within NHSScotland.

Indication under review: for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy.

SMC restriction: patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable and where a biologic would otherwise be offered.

Four phase III studies demonstrated superiority of lebrikizumab in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis.

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.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Lebrikizumab is an immunoglobulin (IgG4) monoclonal antibody that binds to interleukin (IL)-13 and selectively inhibits IL-13 signalling, which is a key contributor to disease pathogenesis in atopic dermatitis. The recommended dose of lebrikizumab is 500 mg (two 250 mg subcutaneous injections) at both week 0 and week 2, followed by 250 mg administered subcutaneously every other week up to week 16. Consideration should be given to discontinuing treatment in patients who have shown no clinical response after 16 weeks of treatment. Some patients with initial partial response may further improve with continued treatment every other week up to week 24. Once clinical response is achieved, the recommended maintenance dose of lebrikizumab is 250 mg every fourth week. Lebrikizumab can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas.[1]

1.2. Disease background

Atopic dermatitis is a chronic, relapsing, inflammatory skin disease that is characterised by eczematous skin lesions, dry and itchy skin. Itch and skin infections are major complications of atopic dermatitis and failure to gain adequate control can result in sleep disturbance, anxiety and depression and has a substantial impact on quality of life.[2, 3]

1.3. Company proposed position

The submitting company requested that lebrikizumab is restricted for use in patients who have failed on, cannot tolerate or are unsuitable for any of the first-line systemic therapies (azathioprine, ciclosporin, methotrexate or mycophenolate mofetil). SMC restricted lebrikizumab to patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable and where a biologic would otherwise be offered.

1.4. Treatment pathway and relevant comparators

The aim of treatment is to bring the signs and symptoms of atopic dermatitis under control. In patients whose symptoms are not adequately controlled by optimised topical therapies, treatments options include phototherapy (which can be time consuming and associated with side effects if used long term), followed by systemic treatments such as azathioprine, methotrexate, mycophenolate mofetil and ciclosporin (which is the only one of these treatments licensed for this use), which are used for severe and recalcitrant disease but can be associated with toxicities that limit their use.[2, 3] There are several targeted systemic treatments licensed for the treatment of moderate to severe atopic dermatitis in patients who are candidates for systemic therapy. Biologic medicines are the most relevant comparators. Dupilumab (SMC2011 for adults; SMC2232 for adolescents) and tralokinumab (SMC2403) have been accepted for restricted use within NHSScotland for patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.

Targeted systemic treatments also include JAK inhibitors: baricitinib (SMC2337), abrocitinib (SMC2431) and upadacitinib (SMC2417) which are accepted for use within NHSScotland with similar restrictions.

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence to support the efficacy and safety of lebrikizumab comes from ADvocate 1, ADvocate 2, ADhere and ADvantage. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant studies[2, 4-8]

Criteria	ADvocate 1 and 2	ADhere	ADvantage
Study design	Randomised, double-blind, phase III study.		

Eligible patients	• Adults and adolescents (≥12 to <18 years of age, weighing ≥40 kg)
	• Moderate to severe atopic dermatitis, defined as:
	  ○ Baseline EASI score of at least 16 (range 0 to 72, with higher values indicating a greater severity and extent of disease)
	  ○ IGA score of at least 3 (range 0 [clear skin] to 4 [severe disease], with the score describing the overall appearance of atopic dermatitis lesions at a given time point)
	  ○ An affected body surface area of at least 10%
	• Chronic atopic dermatitis for at least 1 year for which topical treatment was inadequate.
	• ADvantage only: not adequately controlled by or not eligible for ciclosporin.		

Treatments	<u>Week 0 to week 16</u> Lebrikizumab subcutaneously at a dose of 250 mg (with a 500 mg loading dose given at baseline and at week 2) or placebo every two weeks. Patients were given lebrikizumab or placebo as monotherapy (ADvocate 1 and 2) or in combination with low-to-mid-potency topical corticosteroids (ADhere and ADvantage). <u>Beyond week 16</u> ADvocate 1 and 2: In the 36-week maintenance phase, patients who achieved a response to lebrikizumab were randomised again in a 2:2:1 ratio to receive lebrikizumab 250 mg every two weeks, lebrikizumab 250 mg every four weeks or placebo. Patients who did not achieve a response by week 16 were assigned to receive open-label lebrikizumab 250 mg every two weeks. ADhere: After completion of week 16, patients were offered the option to continue treatment in a separate long-term extension study. ADvantage: After completion of week 16, patients entered the maintenance period during which all patients received lebrikizumab 250 mg every two weeks. Those who had received placebo during the induction period received loading doses of lebrikizumab (500 mg) at weeks 16 and 18; blinding was maintained at weeks 16 and 18.		
Randomisation	Randomised in a 2:1 ratio. Stratified according to geographic region (US versus Europe versus rest of the world) (ADvocate 1 and 2 and ADhere only), age group (adolescents versus adults), disease severity (IGA 3 versus 4) and previous dupilumab use (yes versus no) (ADvantage only).		
Primary outcomes	• EASI 75 (≥75% reduction from baseline in EASI score) at week 16 (ADvocate 1 and 2, ADhere and ADvantage)		

	• IGA score of 0 or 1 with a reduction (indicating improvement) of ≥2 points from baseline at week 16 (ADvocate 1 and 2 and ADhere)
Secondary outcomes	• IGA score of 0 or 1 with a reduction (indicating improvement) of ≥2 points from baseline at week 16 (ADvantage) • EASI 90 (≥90% reduction in EASI score from baseline) • Pruritus NRS (≥4-point improvement) • DLQI (≥4-point improvement).
Statistical analysis	Overall type I error was controlled for primary and key secondary outcomes in ADvocate 1 and 2 (graphical multiple testing strategy) and ADhere (gated multiple testing strategy). The primary analyses of ADvocate 1 and 2 and ADhere handled intercurrent events in the following way: for patients who used rescue medication and for patients who discontinued treatment due to lack of efficacy, patients had their values set to baseline, which implies non-response. Patients who discontinued treatment due to adverse events or any other reason were deemed missing data and were imputed using MCMC-MI.

Abbreviations: DLQI = Dermatology Life Quality Index; EASI = Eczema Area and Severity Index; IGA = Investigator's Global Assessment; NRS = Numerical Rating Scale; MCMC-MI = Markov chain Monte Carlo multiple imputation; US = United States.

Lebrikizumab, as monotherapy or in combination with topical corticosteroids, was associated with significantly improved outcomes compared with placebo in adolescents and adults with moderate to severe atopic dermatitis. See Table 2.2 for more details.

Table 2.2. Key efficacy results at week 16 for ADvocate 1 and 2 (1: ITT, 2: mITT population), ADhere (mITT population) and ADvantage (FAS population).[1, 7]

ADvocate 1		ADvocate 2		ADhere		ADvantage	
LEB (n=283)	**PBO (n=141)**	**LEB (n=281)**	**PBO (n=146)**	**LEB + TCS (n=145)**	**PBO + TCS (n=66)**	**LEB + TCS (n=220)**	**PBO + TCS (n=111)**
IGA 0 or 1 with a reduction of ≥2 points							
43%*	13%	33%*	11%	41%*	22%	42%†	24%
EASI 75 (≥75% reduction in EASI score from baseline)							
59%*	16%	52%*	18%	70%*	42%	68%*	41%
EASI 90 (≥90% reduction in EASI score from baseline)							
38%*	9.0%	31%*	9.5%	41%*	22%	43% †	21%
Pruritus NRS (≥4-point improvement)**							
46%*	13%	40%*	12%	51%*	32%	50% †	30%
DLQI (≥4-point improvement)**							
76%*	34%	66%*	34%	77%*	59%	-	-

* Statistically significant p-value versus placebo.
** The percentage is calculated relative to the number of patients with a baseline Pruritus NRS ≥4 or DLQI ≥4 respectively.
Abbreviations: DLQI = Dermatology Life Quality Index; EASI = Eczema Area and Severity Index; FAS = full analysis set; IGA = Investigator's Global Assessment; ITT = intention-to-treat; LEB = lebrikizumab; mITT = modified intention-to-treat; NRS = Numerical Rating Scale; PBO = placebo; TCS = topical corticosteroids.
† Secondary outcomes in ADvantage were not controlled for multiplicity and therefore the p-values for the secondary outcomes are nominal.

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

2.2. Evidence to support the positioning proposed by the submitting company

ADvantage recruited patients not adequately controlled by or not eligible for ciclosporin. Results are included in Table 2.2 above. The following post hoc subgroup analyses were performed by the submitting company:

- ADvocate 1, ADvocate 2 and ADhere patients with previous exposure to ciclosporin. Results appear to be consistent with those from the full study populations demonstrating efficacy of lebrikizumab when compared with placebo.
- ADhere patients with previous exposure to dupilumab. As patient numbers were low, these results are difficult to interpret and are not presented here.
- Composite outcome EASI 50 and DLQI ≥4-point improvement at week 16 and 52 for the adult and adolescent subgroups in ADvocate 1, ADvocate 2 and ADhere studies were assessed as post hoc subgroup analyses. Results suggest efficacy in both adult and adolescent patients.

2.3. Health-related quality of life outcomes

The Dermatology Life Quality Index (DLQI) and Pruritus Numerical Rating Scale (NRS) outcomes reported in Table 2.2 are patient-reported outcomes. There were additional patient-reported outcomes assessed across the studies: Patient-Orientated Eczema Measure (POEM), Patient-Reported Outcomes Measurement Information System (PROMIS) and EQ-5D-5L. Lebrikizumab-treated patients had a greater reduction in POEM than placebo-treated patients in ADvocate 1 and 2 and ADhere. In PROMIS for anxiety and depression in adults, ADvocate 1 and 2 showed improvements in the lebrikizumab group versus placebo. In ADhere, the difference was smaller.[2] In ADvocate 1 and 2 and ADhere, the improvement in EQ-5D-5L visual analogue scale (VAS) scores at week 16 was greater in the lebrikizumab group than in the placebo group.[10-12]

2.4. Supportive studies

ADjoin is an ongoing long-term extension study that recruited patients who completed one of the following studies: ADvocate 1 and 2, ADhere, ADore (a single-arm study in adolescents only) and ADopt-VA (a US study evaluating the effect of lebrikizumab on vaccine responses in adults with atopic dermatitis). In patients who had responded to lebrikizumab in ADvocate 1 and 2 or ADhere (defined as those patients who achieved either EASI 75 or IGA 0 or 1 following 16 weeks of lebrikizumab treatment without use of rescue therapy), efficacy was maintained through two years in IGA 0 or 1, EASI 75, EASI 90 and Pruritus NRS ≥4-point improvement.[13]

2.5. Indirect evidence to support clinical and cost-effectiveness comparisons

In the absence of direct evidence comparing lebrikizumab with relevant comparators the submitting company presented an indirect treatment comparison. This has been used to inform the economic case. Details are presented in Table 2.3.

Table 2.3: Summary of indirect treatment comparison

Criteria	Overview
Design	Network meta-analysis (NMA)
Population	Adults and adolescents with moderate to severe atopic dermatitis.
Comparators	Abrocitinib, baricitinib, dupilumab, upadacitinib and tralokinumab (with or without TCS).

Studies included	38 studies (22 monotherapy studies and 16 combination therapy studies).
Outcomes	EASI response at week 16, IGA response at week 16 and ≥4-point improvement in pruritus NRS at week 4 and week 16.
Results	As combination therapy, lebrikizumab performed better than baricitinib but not as well as upadacitinib 30 mg. There was no evidence of a difference between lebrikizumab and abrocitinib, dupilumab, tralokinumab or upadacitinib 15 mg.

Abbreviations: EASI = Eczema Area and Severity Index; IGA = Investigator's Global Assessment; NRS = Numerical Rating Scale; TCS = topical corticosteroids.

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

3. Summary of Safety Evidence

In the ADvocate 1 and 2 and ADhere studies (pooled), from week 0 to week 52 or 56, any treatment-emergent adverse event (AE) was reported by 63% (93/147) of patients in the lebrikizumab 250 mg every four weeks (two weekly until week 16) group and 55% (194/352) in the placebo group, and 29% and 11% were considered related to study treatment respectively. In the lebrikizumab and placebo groups respectively, patients with a reported serious AE were 3.4% versus 2.0% and patients discontinuing therapy due to an AE was 2.0% versus 1.4%.[2]

The most frequently reported treatment-emergent AEs of any grade with an incidence >5% in the lebrikizumab 250 mg every four weeks group (two weekly until week 16) versus the placebo group (from week 0 to week 52 or 56) were: COVID-19 (8.8% versus 1.4%), nasopharyngitis (13% versus 3.1%), atopic dermatitis (6.8% versus 21%), allergic conjunctivitis (6.1% versus 0.9%), headache (6.8% versus 2.8%) and conjunctivitis (12.2% versus 2.0%).[2]

Overall, no major safety concerns were identified for lebrikizumab and the regulatory bodies considered the overall safety profile to be manageable.[2]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- Four large phase III studies and a long-term extension study provide evidence to support the efficacy and safety of lebrikizumab in adult and adolescent patients with moderate to severe atopic dermatitis who require systemic treatment.
- Lebrikizumab demonstrated statistically significant and clinically relevant improvements over placebo when used as monotherapy or in combination with topical corticosteroids. The primary outcomes, proportion of patients achieving EASI 75 (all four studies) and IGA 0 or 1 (with ≥2 point reduction from baseline) at week 16 (ADvocate 1 and 2 and ADhere only), were met in all four studies.[2]

4.2. Key uncertainties

- There is no direct evidence comparing lebrikizumab with relevant comparators. The network meta-analysis (NMA) had some limitations: the population was broader than the proposed positioning, there were differences between the study populations that may not

have been accounted for, two head-to-head studies were excluded, EASI 50 and DLQI ≥4 outcomes were not assessed, and outcomes were assessed at 16 weeks meaning relative long-term efficacy and safety is uncertain. Two recently published NMAs[14, 15] provide additional data to suggest that a conclusion of comparable efficacy between lebrikizumab and the other biologic medicines, dupilumab and tralokinumab, may be reasonable. The results of the comparison versus JAK inhibitors remains uncertain.

- There is limited long-term data, especially in patients who have failed on, cannot tolerate or are unsuitable for any of the first-line systemic therapies. The long-term extension study ADjoin has shown that efficacy of lebrikizumab is maintained up to two years in the wider population[13], however ADvantage (patients not adequately controlled by or not eligible for ciclosporin) has only reported on week 16 outcomes and further data are awaited.
- There may be generalisability issues with the ADvocate studies due to lebrikizumab and placebo being administered as monotherapies. Patients in Scottish clinical practice may be likely to receive systemic treatments in combination with topical corticosteroids. ADvocate studies did not inform the economic base case. Moreover, in ADhere and ADvantage, patients requiring rescue treatment were discontinued on study treatment, which may not be reflective of clinical practice but is a common feature of atopic dermatitis studies.
- The subgroup analysis of patients with previous ciclosporin use in the ADvocate and ADhere studies were post hoc and included small patient numbers. Therefore, these results should be interpreted with caution.
- Secondary outcomes in ADvantage were not controlled for multiplicity and are descriptive only.[6]

4.3. Clinical expert input

Clinical experts consulted by SMC consider lebrikizumab to meet an unmet need and to be a therapeutic advancement; although there are a number of treatments available in this setting, the data from clinical studies suggest that lebrikizumab is an efficacious and tolerable treatment. Some patients with moderate to severe atopic dermatitis may have had an inadequate response or experienced adverse effects with currently available treatments.

4.4. Service implications

There are no additional service implications anticipated with the introduction of lebrikizumab.

5. Summary of Patient and Carer Involvement

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

- We received patient group submissions from the National Eczema Society and Eczema Outreach Support. The National Eczema Society is a registered charity and Eczema Outreach Support is a Scottish charitable incorporated organisation.
- The National Eczema Society has received 25% pharmaceutical company funding in the past two years, including from the submitting company. Eczema Outreach Support has received

23% pharmaceutical company funding in the past two years, with none from the submitting company.

- There is no cure for atopic eczema and current treatment options aim to reduce skin inflammation and itch, restore the skin's barrier function and improve quality of life. Atopic eczema affects the whole family. It has substantial physical and mental health impacts on the person experiencing it, but it also affects their parents/carers.
- Since atopic eczema is a heterogeneous condition, with different treatments working effectively for different people, the introduction of lebrikizumab would increase the likelihood that patients with moderate to severe eczema would find a long-term treatment that is effective for them.
- Lebrikizumab appears to be effective in clearing and improving facial and hand eczema, which are challenging areas of the body to manage, and often present specific difficulties for patients. Treatment only needs to be taken every 4 weeks once response is achieved resulting in a reduction in the treatment burden.
- Patients are likely to need fewer visits to out-patient clinics for observation and monitoring when taking lebrikizumab compared to conventional immunosuppressant drugs, which would be welcomed by patients. Potential side effects should be discussed with the patient and parent/carer (if relevant) to enable them to understand the risks before making a treatment decision.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

The submitting company provided an economic case, as described in Table 6.1

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	Lifetime (100 years)
Population	Adults and adolescents 12 years and older, with a body weight of at least 40 kg, who are candidates for systemic therapy to treat moderate to severe atopic dermatitis. In the base case all patients are assumed to have combination treatment with topical corticosteroids.
Comparators	Biologics: dupilumab, tralokinumab, JAK inhibitors: abrocitinib, baricitinib and upadacitinib
Model description	A hybrid decision tree and Markov model was developed. The 1-year decision tree was designed to capture short-term treatment decisions and initial responses to treatment at 16 and 52 weeks. The Markov model reflected the long-term course of AD with treatment response health states starting from year 2 onwards. At baseline, people started treatment with either lebrikizumab or its comparators. People whose condition responded to treatment could continue to have lebrikizumab or its comparators, but people whose condition did not respond proceeded to have best supportive care.

Clinical data	The key effectiveness data for lebrikizumab was taken from ADvocate 1, ADvocate 2 and ADhere. EASI75 was the primary outcome in all three studies. In the model, the composite outcome of EASI50 + DLQI≥4 was the preferred response definition. There were no direct head-to-head studies comparing lebrikizumab with relevant active comparators. ITCs were therefore conducted to compare the efficacy of lebrikizumab with comparator therapies.
Extrapolation	The model used discontinuation data to inform whether people continued to have maintenance treatment with lebrikizumab and its comparators or switched to best supportive care. A drug-class approach was taken regarding applying discontinuation rates in the model. That is, the average of the conditional discontinuation rates for biologics (lebrikizumab, dupilumab and tralokinumab) was applied to these treatments and the same was done for the JAK inhibitors (abrocitinib, baricitinib and upadacitinib). No long-term discontinuation data were available. Hence, short-term discontinuation was converted to an annual rate and applied to lebrikizumab and its comparators.
Quality of life	Utility values applied in the company's model were sourced from the ADhere study. Utilities from the lebrikizumab arm of the ADhere study were applied for lebrikizumab and its comparators. Data from the placebo arm was applied for best supportive care.
Costs and resource use	The economic analysis included costs associated with medicine acquisition, administration, health-state monitoring, adverse events and the costs of managing flares.
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. PAS discounts are in place for all comparator medicines and these were considered in the results used for decision-making. SMC is unable to present the results provided by the company which used an estimate of the PAS price for dupilumab, tralokinumab, baricitinib, upadacitinib and abrocitinib due to commercial confidentiality and competition law issues.

6.2. Results

SMC would wish to present the with-PAS cost-effectiveness estimates that informed the SMC decision. However, owing to the commercial in confidence and competition law concerns regarding the PAS, SMC is unable to publish these results. It should be noted that the base case economic results showed that the cost-effectiveness case for lebrikizumab was better when compared to biologic treatments than when compared to JAK inhibitors.

6.3. Sensitivity analyses

The company provided probabilistic sensitivity analysis, deterministic sensitivity analysis (DSA) and scenario analysis. In the DSA, the parameters with the greatest impact on the incremental cost-effectiveness ratio (ICER) were long-term (annual) treatment discontinuation, placebo (baseline) response rate, conditional discontinuation rates and treatment waning. The parameters tested in key scenario analysis is summarised in Table 6.3.

Table 6.3 Scenario analysis results

	Parameter(s)	Base case	Scenario
1	Choice of endpoint/ outcome	EASI50 + DLQI≥4	EASI 75
2A	% of patients having combination treatment with topical corticosteroids	100%	0%
2B			50%
3A	Combination therapy - second-line systemic treatment	ADhere and ADvantage prior systemic therapy subgroup	ADhere prior systemic therapy subgroup and ADvantage full analysis set
3B			ADhere and ADvantage prior systemic therapy subgroup excluding JAKs and biologics
4A	Health state utility source	ADhere	NICE TA681
4B			NICE TA534
5	Utility decrements for adverse events	Included	Excluded

Abbreviations: JAKs: Janus Kinase inhibtors

6.4. Key strengths

The study data from ADvocate and ADhere is promising and suggests meaningful clinical benefit. Despite the lack of direct comparative evidence and the limitations of the data, the company has used best available methods to perform the NMAs. The economic model is structurally sound and costing has been comprehensive.

6.5. Key uncertainties

The weaknesses in the analysis include the following:

- The results used for decision-making (inclusive of all relevant PAS discounts) indicated higher cost-effectiveness ratios for lebrikizumab versus the JAK inhibitors abrocitinib, baricitinib and upadacitinib compared to lebrikizumab versus the biologics dupilumab and tralokinumab.
- As noted above, in the absence of direct evidence an NMA was used. The results of the NMA are associated with limitations, particularly regarding the comparisons with abrocitinib, baricitinib and upadacitinib.
- The preferred composite outcome of EASI 50 + DLQI ≥ 4 is not published for comparator clinical studies. As a solution, the company indirectly derived composite outcome response rates using EASI75 results from the NMA. Despite the use of proxy data, scenario analysis showed that the choice of outcome measure did not alter cost-effectiveness conclusions versus any of the comparators.
- It would have been preferable to apply individual treatment-specific discontinuation rates. This was not feasible since conditional discontinuation data was not available for all comparator treatments in the model. There remains some empirical uncertainty regarding the average discontinuation rates applied in the model (10% for JAK inhibitors; 3.9% for biologics) albeit these are not drivers of cost-effectiveness. This uncertainty also feeds into estimates of long-term discontinuation as these probabilities were simply annualized estimates for short-term discontinuation due to the absence of long-term discontinuation data.

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

7. Conclusion

After considering all the available evidence the Committee accepted lebrikizumab for restricted use in NHSScotland. Use is restricted to patients who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable and where a biologic would otherwise be offered.

8. Guidelines and Protocols

EuroGuiDerm published the "European guideline (EuroGuiDerm) on atopic eczema: part I – systemic therapy" in August 2022, which updates a previous guideline from May 2018.[3]

9. Additional Information

9.1. Product availability date

31 January 2024

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year
lebrikizumab	**500 mg (two 250 mg subcutaneous injections) at week 0 and week 2, followed by 250 mg administered subcutaneously every other week up to week 16. Once clinical response is achieved, the recommended maintenance dose of lebrikizumab is 250 mg every fourth week.**	**First year: £22,713** **Subsequent years: £14,763**

Costs from MIMS online on 02 August 2024. Costs calculated using the full cost of vials/ampoules assuming wastage. 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 2,139 patients eligible for treatment with lebrikizumab in year 1 and 4,048 patients in year 5, to which confidential estimates of treatment uptake were applied.

SMC is unable to publish the with PAS budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget with the PAS. This template does not incorporate any PAS discounts associated with comparator medicines or PAS associated with medicines used in a combination regimen.

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

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This assessment is based on data submitted by the applicant company up to and including 13 September 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.