HTA370

A Multi-Country Evaluation of Access to Biologics for Atopic Dermatitis in Europe: Evidence from the Lebrikizumab Case Study

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BACKGROUND & OBJECTIVE

- Biologic therapies have expanded treatment options for patients with moderate-to-severe atopic dermatitis (AD) with inadequate response to conventional therapies
- Lebrikizumab, a monoclonal antibody binding with high affinity to interleukin-13, is approved by the European Medicines Agency (EMA) for adults and adolescents (≥12 years, ≥40 kg) with moderate-to-severe AD who are candidates for systemic therapy[1]
- Here, we compare national reimbursement criteria for lebrikizumab use as AD treatment across European countries with the population defined in the EMA-approved SmPC[1] and identify differences in reimbursement access criteria that may restrict access beyond the EMA-approved indication

CONCLUSIONS

- Patient access to lebrikizumab for moderate-to-severe AD varies across Europe, reflecting heterogeneity in national reimbursement policies, treatment positioning and healthcare decision-making frameworks
- These disparities contribute to unequal therapeutic opportunities for patients, despite shared regulatory approval and substantial burden of disease across European countries[1,2]
- This highlights the opportunity for a more harmonised approach to access, potentially supported by greater alignment in health technology assessment (HTA) methodologies, reimbursement criteria and clinical guideline implementation
- Improving consistency in access pathways could help ensure that treatment decisions are driven primarily by clinical need rather than geographic location, supporting equity of care, optimised disease control and improved long-term outcomes for patients with AD across European healthcare systems

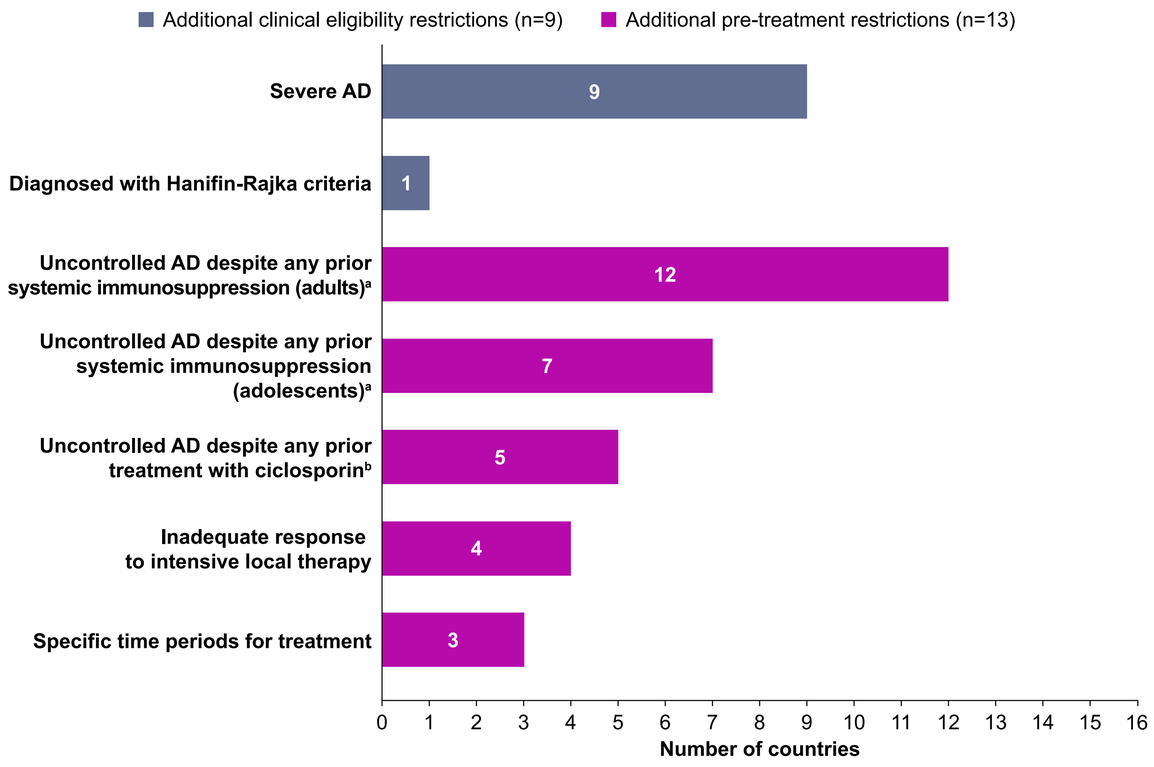
KEY FINDINGS

Table 1: Alignment of national reimbursement criteria for lebrikizumab with the EMA label across European countries[a]

	Austria	Belgium	Czech Republic	England[b]	Finland	France	Germany	Ireland	Italy	The Netherlands	Poland	Portugal	Scotland[b]	Spain	Sweden	Switzerland[c]	Overall n/N (%)
Aligned with EMA							✓			✓							2/16 (12.5)
Clinical eligibility restrictions beyond the EMA label	✓	✓	✓		✓			✓	✓		✓			✓	✓		9/16 (56.3)
Pre-treatment eligibility restrictions beyond the EMA label	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		✓	13/16 (81.3)

[a]Norway, Denmark, Liechtenstein and Luxembourg have access to lebrikizumab but have not conducted a HTA. [b]England and Scotland are not a part of the European Union and follow the decisions of the UK's regulatory body 'Medicines & Healthcare products Regulatory Agency'. [c]Switzerland is not a part of the European Union and follows the decisions of the Swiss authorisation authority for medicinal products 'Swissmedic'.

Figure 1: Additional pre-treatment and clinical eligibility restrictions for accessing lebrikizumab nationally compared with the EMA label



Blue bars show additional clinical eligibility restrictions across 9 countries (n=9); pink bars show additional pre-treatment eligibility restrictions across 13 countries (n=13). As countries may have more than one restriction, categories are not mutually exclusive and values should not be summed. [a]Uncontrolled AD includes intolerance, inadequate response or contraindication to conventional systemic immunosuppression. [b]Uncontrolled AD includes intolerance, inadequate response or contraindication to ciclosporin.

Table 2: Clinical eligibility restrictions beyond the EMA label, by country

Country	Additional clinical eligibility restrictions
Austria	• Severe AD with persistent eczema
Belgium	• Diagnosis with AD as per Hanifin-Rajka criteria; meet severe thresholds in P-NRS (≥3) and EASI (≥21.1) and/or SCORAD (≥50)
Czech Republic	• Severe AD
Finland	• Severe AD
Ireland	• Adults and adolescents with moderate-to-severe AD, defined as EASI ≥16

Italy	• Adults with severe AD (EASI ≥24)
	• Adolescents with at least one of the following:
	  • EASI >24;
	  • localisation in visible areas (face, hands) and/or sensitive areas (genitals, perianal/perineal);
	  • itch NRS >7;
	  • CDLQI >10

Poland	• Severe AD (EASI ≥20)
Spain	• Adults with severe AD (EASI ≥21, PGA ≥3, body surface area involvement ≥10%) • Adolescents with severe AD (EASI ≥21)
Sweden	• Severe AD

These criteria are consistent with the EMA label (moderate-to-severe AD) but are narrower: each country restricts eligibility beyond the label, by disease severity and/or by defined score thresholds.

METHODS

- A targeted review of HTA and payer decision documents was conducted across 16 European countries that completed local HTA processes for lebrikizumab by May 2026
- The countries involved were:
  - Austria, Belgium, Czech Republic, England, Finland, France, Germany, Ireland, Italy, The Netherlands, Poland, Portugal, Scotland, Spain, Sweden and Switzerland
- The clinical and pre-treatment restrictions for accessing lebrikizumab were compared with the EMA-approved indication
  - **Clinical restrictions:** Defined levels of disease severity (moderate, severe or both), required responder rates (percentage thresholds), absolute or relative changes in Eczema Area and Severity Index (EASI), Investigator's Global Assessment (IGA), Dermatology Life Quality Index (DLQI), Children's DLQI (CDLQI), Peak Pruritus Numerical Rating Scale (PP-NRS) and any mandatory improvement criteria to maintain therapy
  - **Pre-treatment restrictions:** Assessment of mandatory step-up treatment approaches prior to biologic eligibility, including topical-only pre-treatment (systemic-naïve patients) and failure or intolerance of conventional systemic therapy (non-biologic systemic-naïve and prior use of any biologic agents)
- Data were analysed descriptively

RESULTS

Restrictive criteria

- 14 of the 16 countries assessed for their lebrikizumab access criteria had more restrictive reimbursement criteria than the EMA label (excluding Germany and The Netherlands)

Additional restrictions

- Over half of the countries assessed (n=9/16; **Table 1**) impose clinical eligibility restrictions beyond the EMA label (e.g. specific disease severity thresholds using tools such as EASI, SCORing AD [SCORAD], or CDLQI; **Table 2**)
- More than two-thirds (n=13/16; **Table 1**) of countries have additional pre-treatment restrictions compared with the EMA label, such as failure or intolerance of conventional systemic therapy, before patients become eligible for lebrikizumab
- Some countries restrict eligible populations to patients who have had an inadequate response to intensive local therapy (n=4/13; **Figure 1**) or failure of advanced treatments (e.g., phototherapy)
- Pre-treatment restrictions beyond the EMA label can be viewed via the QR code

Access for adolescents

- Nearly all countries (n=12/13) with pre-treatment restrictions limit the eligible population to adults whose disease is not adequately controlled by systemic immunosuppressive therapy, with most of these countries applying this restriction to the adolescent population (n=7/13)
- In countries that do not restrict to adolescents who have received systemic immunosuppressive therapy, other restrictions are:
  - Continuous local therapy for at least 4 months within the last 12 months prior to reimbursement request (Belgium)
  - Disease remains uncontrolled after maximal local therapy and more advanced treatments, such as phototherapy or balneotherapy (Czech Republic)

Abbreviations: *AD=atopic dermatitis; AE=adverse event; CDLQI=Children's Dermatology Life Quality Index; DLQI=Dermatology Life Quality Index; EASI=Eczema Area and Severity Index; EMA=European Medicines Agency; HTA=health technology assessment; IGA=Investigator's Global Assessment; PGA=Physician's Global Assessment; NRS=Numerical Rating Scale; P-NRS=Pruritus Numerical Rating Scale; PP-NRS=Peak Pruritus Numerical Rating Scale; SCORAD=SCORing Atopic Dermatitis; SmPC=Summary of Product Characteristics.* **Acknowledgements:** The authors thank Nahin Kazi, PhD, Costello Medical, London, for providing medical writing support, and the Costello Medical Creative team for design support, in accordance with Good Publication Practice (GPP) 2022 guidelines. **References:** 1. European Medicines Agency. Ebglyss Summary of Product Characteristics. Accessed August 2026. 2. Augustin M, et al. J Eur Acad Dermatol Venereol 2022;36(12):2316–24. **Disclosures: TB** is/was speaker and/or consultant for AbbVie, Aclaris, Almirall, AnaptysBio, Apogee, Aristea, Attovia, Belenos, Biocryst, Biogeneration, BioVerSys, Bluefine, Böhringer-Ingelheim, Bristol-Myers Squibb, BYOME Labs, Cantargia, CellDex, Choate, Dermavant, DirigentBio, Domain Therapeutics, EMD Serono, EngImmune, Ennovate, Evommune, Forbion, Formycon, Galderma, Gilead, GSK, ImagGeneBio, Janssen, Kyowa/Kirin, Kymera, LEO, LG Chem, Lilly, Mabylon, MSD, Micreos, Nektar, Nextech, Novartis, Numab, Ornavi, Overtone, Pfizer, Pierre Fabre, Protagonist Tx, Samsung Bioepis, Sanofi/Regeneron, Scienta Lab, Serono, SwitchKine, TIRmed, Triton, Triveni, UCB, Union Therapeutics, UPStream Bio, WinWard, YUHAN, Zurabio. He is founder and chairman of the board of the non-profit biotech "Davos Biosciences AG" within the international Kühne-Foundation. He is also the founder and senior medical advisor of the consulting firm "Bieber Dermatology Consulting". **BA**, **LS-F** and **MDBG** are employees of Almirall, S.A. **Funding:** This study was funded by Almirall, S.A. Medical writing support, provided by Costello Medical, was funded by Almirall, S.A. Almirall, S.A. has licensed the rights to develop and commercialise lebrikizumab for the treatment of dermatology indications, including atopic dermatitis, in Europe. Lilly has exclusive rights for the development and commercialisation of lebrikizumab in the United States and the rest of the world outside of Europe.

Scan the QR code for additional pre-treatment restrictions compared with the EMA label, by country

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