



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport  
PO Box 20350  
2500 EJ THE HAGUE

**National Health Care  
Institute**

Care  
Medicinal Products

Willem Dudokhof 1  
1112 ZA Diemen  
PO Box 320  
1110 AH Diemen  
[www.zorginstituutnederland.nl](http://www.zorginstituutnederland.nl)  
[info@zinl.nl](mailto:info@zinl.nl)

T +31 (0)20 797 85 55

2024031717

Date 12 September 2024  
Subject Package advice on the lock procedure medicinal product lebrikizumab (Ebglyss®) for atopic eczema

**Our reference**  
2024031717

Dear Ms Agema,

The National Health Care Institute is hereby advising you about the assessment of lebrikizumab (Ebglyss®) for treating moderate to severe atopic dermatitis (AD). The reason for this advice was lebrikizumab being placed in the lock procedure for expensive medicinal products.

Licensed indication

Lebrikizumab is indicated for the treatment of moderate to severe atopic eczema in adults and adolescents aged 12 and above with a bodyweight of at least 40 kg who are eligible for systemic treatment.

Clinical picture

Atopic dermatitis (AD, also known as constitutional or atopic eczema) is a chronic, recurring and very common skin condition. In about 80% of cases, AD arises before the age of five. The localisation of AD changes with age; in children aged under two, the face and scalp are generally affected and from age two upwards, the backs of the knees, insides of the elbows, wrists and ankles are affected. The severity and scope can vary a great deal. The clinical course of AD is chronic and intermittent, with remissions and exacerbations, for several years (childhood) or decades (adolescents and adults).

In 2021, there were an estimated 396,700 people with AD either under treatment for the condition by their GP or whose GP knew that the patient was receiving care from the secondary healthcare system. The majority of patients who are eligible for systemic treatment are currently treated with dupilumab.

Claim by the marketing authorisation holder

Lebrikizumab is equivalent to dupilumab in terms of its value for treating moderate to severe atopic dermatitis (AD) in adults and adolescents aged 12 and over who are eligible for systemic treatment.

**Package advice**

The National Health Care Institute advises you to include lebrikizumab in the basic health insurance package for treating moderate to severe atopic dermatitis in

adults and adolescents aged 12 and above who are eligible for systemic treatment. Based on the evidence currently available, the National Health Care Institute concludes that lebrikizumab is equivalent to dupilumab in terms of its value for treating moderate to severe atopic dermatitis in patients aged 12 and over who are eligible for systemic treatment. Lebrikizumab is therefore in line with established medical science and medical practice. Including lebrikizumab in the basic health insurance package should not lead to additional costs, given its equivalent value.

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We have explained below how we reached this package advice.

### General

At your request, the National Health Care Institute assesses whether care should be part of the standard health insurance package from the perspective of the basic health insurance package paid from joint premiums.

The National Health Care Institute assesses against the four package criteria<sup>1</sup> of effectiveness<sup>2</sup>, cost-effectiveness<sup>3</sup>, necessity<sup>4</sup> and feasibility<sup>5</sup>. The Scientific Advisory Board (WAR) advises the National Health Care Institute about the basis (scientific support) and the conclusion of the assessment. If there are risks regarding accessibility and affordability, the assessment of the package criterion of effectiveness (established medical science and medical practice) will be placed in the wider social context of the four package criteria. The Insured Package Advisory Committee advises the Executive Board of the National Health Care Institute in this regard. This society-oriented weighing up results in the package advice. Stakeholders are consulted during the process.

### **Comprehensive weighting of package criteria**

#### *Effectiveness – Established medical science and medical practice*

The effectiveness and safety of lebrikizumab have been investigated in three phase 3, double-blind, randomised, placebo-controlled studies. Those studies showed that after a 16-week follow-up, a statistically significantly higher percentage achieved a clinically relevant response in the intervention groups than in the placebo groups on the endpoints measuring eczema severity, itching and quality of life. No direct comparative studies are available and a naive indirect comparison was therefore made. The efficacy and safety of dupilumab have been investigated in four studies. The study designs and endpoints are similar to the studies with lebrikizumab. The results of these studies were similar to those of the studies with lebrikizumab. Based on the available data, it seems likely that there are no relevant differences between lebrikizumab and dupilumab in terms of eczema severity, itching and quality of life. The beneficial effects of the two drugs can therefore be said to be similar. The adverse effects are also similar. The

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<sup>1</sup> *Pakketbeheer in de praktijk 4* (Real-world package management 4, 2023). National Health Care Institute, Diemen. Via [www.zorginstituutnederland.nl](http://www.zorginstituutnederland.nl).

<sup>2</sup> *Beoordeling Stand van de Wetenschap en Praktijk* (Assessment of established medical science and medical practice, 2023). National Health Care Institute. Via [www.zorginstituutnederland.nl](http://www.zorginstituutnederland.nl).

<sup>3</sup> Cost-effectiveness report (2015). National Health Care Institute, Diemen. Via [www.zorginstituutnederland.nl](http://www.zorginstituutnederland.nl).

<sup>4</sup> Necessity is related to both the medical need due to the severity of a disease for the patient (burden of disease) and the need for an item to be insured. See the report 'Real-world package management 4' (2023).

<sup>5</sup> The package criterion of feasibility deals with whether it is feasible or sustainable to include a specific form of care in the basic health insurance package. It is therefore mainly a test of various implementation aspects, such as the healthcare organisation, the support base, ethical and legal aspects, budget impact, etc. See the report 'Real-world package management 4' (2023).

National Health Care Institute is therefore sufficiently confident that this indirect comparison has established the equivalent value of lebrikizumab and dupilumab for treating patients with moderate to severe atopic dermatitis (AD) who are eligible for systemic treatment.

#### *Cost-effectiveness*

Because of the equivalent values of lebrikizumab and dupilumab, an analysis of the cost-effectiveness is not necessary.

#### *Budget impact analysis*

The National Health Care Institute estimates that approximately 1,199 patients will be treated with lebrikizumab in the third year after it is introduced onto the market. A proportion will start this as new treatment and incur additional costs due to induction treatment; the remainder will be treated with maintenance treatment throughout the year. The overall costs of lebrikizumab therefore come to €18.1 million in the third year after inclusion in the health insurance package. If allowance is made for substitution, the additional costs of lebrikizumab therefore come to €0.5 million in the third year after inclusion in the health insurance package. The difference in costs is largely driven by the difference in induction treatments for the different medicinal products. For patients on maintenance treatment, though, lebrikizumab yields cost savings compared to the weighted average cost of other systemic treatments (€12,909 versus €14,821). The estimated additional costs and cost savings here are based on list prices. As a point of principle, including lebrikizumab in the health insurance package should not lead to additional costs.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as appendices (pharmacotherapeutic assessment and budget impact analysis).

Yours sincerely,

Sjaak Wijma  
Chair of the Executive Board

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