

SUMMARY

lebrikizumab

EBGLYSS 125 mg/ml**solution for injection (P/2 pre-filled pens and P/2 pre-filled syringes)****Inclusion on list: First listing****Range supplement****Adopted by the Transparency Committee on 4 September 2024****Summary of opinion****→ In adults**

Favourable opinion for reimbursement only in “the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy, in the event of inadequate response, intolerance or contraindication to ciclosporin.”

Unfavourable opinion for reimbursement in adults with inadequate response to topical therapies and who are ciclosporin-naïve, in the absence of comparative data.

No clinical added value of the new EBGLYSS (lebrikizumab) 125 mg/ml solution for injection in pre-filled pen and pre-filled syringe (pack of 2) forms compared to the pre-filled pen and pre-filled syringe (pack of 1) forms already listed.

→ In adolescents ≥ 12 years (weighing at least 40 kg)

Favourable opinion for reimbursement in the MA indication “treatment of moderate to severe atopic dermatitis in adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy.”

No clinical added value of the new EBGLYSS (lebrikizumab) 125 mg/ml solution for injection in pre-filled pen and pre-filled syringe (pack of 2) forms compared to the pre-filled pen and pre-filled syringe (pack of 1) forms already listed.

This document and its bibliographic reference are available to download at www.has-sante.fr 

This opinion is published subject to intellectual property rights

Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

© Haute Autorité de santé – September 2024

Transparency Committee's conclusions

Clinical Benefit

In adults

- Atopic dermatitis is not usually a serious disease, but in its moderate to severe forms it has a significant impact on the quality of life of patients and marked psychosocial repercussions.
- EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2) is intended to have a suspensive effect on symptoms.
- In the absence of direct comparison with ciclosporin, the efficacy/adverse effects ratio of lebrikizumab has not been established in adults with moderate to severe atopic dermatitis with inadequate response to topical treatments and who are ciclosporin-naïve. In patients with inadequate response, intolerance or contraindication to ciclosporin, its efficacy/adverse effects ratio is high.
- This medicinal product is a second-line systemic therapy to be reserved for adults with moderate to severe atopic dermatitis, in the event of inadequate response, intolerance or contraindication to ciclosporin.

→ Public health benefit

EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2) is:

- substantial only in the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy, in the event of inadequate response, intolerance or contraindication to ciclosporin,
- insufficient to justify public funding in view of the available alternatives in the other situations covered by the MA in adults.

The Committee issues:

- a favourable opinion for inclusion of EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only in the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy, in the event of inadequate response, intolerance or contraindication to ciclosporin and at the MA dosages,
- an unfavourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the treatment of moderate to severe atopic dermatitis in adults with inadequate response to topical treatments and who are ciclosporin-naïve, in the absence of comparative data.

- **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

In adolescents ≥ 12 years

- Atopic dermatitis is not usually a serious disease but in its moderate to severe forms, it has a significant impact on the quality of life of patients and marked psychosocial repercussions.
- EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2), is intended to have a suspensive effect on symptoms.
- The efficacy/adverse effects ratio is high.
- It is a first-line systemic therapy to be reserved for adolescents (12 years or older) with moderate to severe atopic dermatitis, in the event of inadequate response to topical treatments (see 5.1. of the Transparency Committee's opinion of 29 May 2024).

→ Public health benefit

EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pre-filled pen (pack of 2) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of EBGLYSS 125 mg/ml (lebrikizumab) solution for injection in pre-filled syringe or pen (pack of 2) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in adolescents 12 years and older (body weight ≥ 40 kg) and at the MA dosages.

- **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

These medicinal products are range supplements that do not provide any clinical added value (CAV V) compared to the forms already listed.