Gemeinsamer Bundesausschuss

# Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Baricitinib (new therapeutic indication: atopic dermatitis, ≥ 2 to < 18 years)

of 2 May 2024

At its session on 2 May 2024, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. **In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Baricitinib in the version of the resolution of 2 May 2024 on the therapeutic indication "polyarticular juvenile idiopathic arthritis, RF+ or RF– polyarticular and extended oligoarticular, ≥ 2 years":**

**Baricitinib**

Resolution of: 2 May 2024
Entry into force on: 2 May 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

**New therapeutic indication (according to the marketing authorisation of 18 October 2023):**

Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy.

**Therapeutic indication of the resolution (resolution of 2 May 2024):**

Treatment of moderate to severe atopic dermatitis in children and adolescents 2 to 17 years of age who are candidates for systemic therapy.

## 1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

a) Children 2 to 11 years of age with moderate atopic dermatitis who are candidates for systemic therapy

**Appropriate comparator therapy:**

A patient-individual optimised treatment regimen depending on the manifestation of the disease and taking into account the previous therapy and the following therapies:

- topical glucocorticoids of classes 1 to 3
- topical calcineurin inhibitors

The respective authorisation status of the medicinal products must be taken into account.

**Extent and probability of the additional benefit of baricitinib compared to the appropriate comparator therapy**

An additional benefit is not proven.

b) Children 2 to 11 years of age with severe atopic dermatitis who are candidates for systemic therapy

**Appropriate comparator therapy:**

dupilumab (in combination with TCS and/or TCI if required)

**Extent and probability of the additional benefit of baricitinib compared to dupilumab:**

An additional benefit is not proven.

c) Adolescents 12 to 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

**Appropriate comparator therapy:**

dupilumab (in combination with TCS and/or TCI if required)

**Extent and probability of the additional benefit of baricitinib compared to dupilumab:**

An additional benefit is not proven.

**Study results according to endpoints:**[1]

a) Children 2 to 11 years of age with moderate atopic dermatitis who are candidates for systemic therapy

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | ∅ | No data available. |
| Morbidity | ∅ | No data available. |
| Health-related quality of life | ∅ | No data available. |
| Side effects | ∅ | No data available. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

b) Children 2 to 11 years of age with severe atopic dermatitis who are candidates for systemic therapy

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | ∅ | No data available. |
| Morbidity | ∅ | No data available. |
| Health-related quality of life | ∅ | No data available. |
| Side effects | ∅ | No data available. |
| Explanations: | | |

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-109) unless otherwise indicated.

| |
|---|
| ↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable |

c) Adolescents 12 to 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
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| Mortality | ∅ | No data available. |
| Morbidity | ∅ | No data available. |
| Health-related quality of life | ∅ | No data available. |
| Side effects | ∅ | No data available. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

## 2. Number of patients or demarcation of patient groups eligible for treatment

a) Children 2 to 5 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

Approx. 2,700 to 3,900 patients

b) Children 6 to 11 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

Approx. 9,700 to 14,100 patients

c) Adolescents 12 to 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

Approx. 5,300 to 10,600 patients

## 3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Olumiant (active ingredient: baricitinib) at the following publicly accessible link (last access: 24 April 2024):

https://www.ema.europa.eu/en/documents/product-information/olumiant-epar-product-information_en.pdf

Treatment with baricitinib should only be initiated and monitored by doctors experienced in treating atopic dermatitis.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card).

In particular, the training material contains information and warnings on the risk of serious and opportunistic infections including tuberculosis and herpes zoster. It also points out the need for an effective contraceptive method.

## 4. Treatment costs

**Annual treatment costs:**

a) Children 2 to 11 years of age with moderate atopic dermatitis who are candidates for systemic therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Baricitinib<br>Additionally required SHI services:<br>Total: | € 14,205.65<br>€ 181.82<br>€ 14,387.47 |
| Appropriate comparator therapy: | |
| Prednisolone[2] | Different from patient to patient |
| Hydrocortisone butyrate[3] | Different from patient to patient |
| Methylprednisolone[4] | Different from patient to patient |
| Tacrolimus | Different from patient to patient |
| Pimecrolimus | Different from patient to patient |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

[2] Prednisolone is presented as an example for class I topical glucocorticoids.
[3] Hydrocortisone butyrate is presented as an example for class II topical glucocorticoids.
[4] Methylprednisolone is presented as an example for class III topical glucocorticoids.

b) Children 2 to 11 years of age with severe atopic dermatitis who are candidates for systemic therapy

and

c) Adolescents 12 to 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Baricitinib<br>Additionally required SHI services:<br>Total: | € 14,205.65<br>€ 181.82<br>€ 14,387.47 |
| Appropriate comparator therapy: | |
| Dupilumab | € 8,060.52 - € 16,121.04 |
| Hydrocortisone butyrate | Different from patient to patient |
| Methylprednisolone | Different from patient to patient |
| Tacrolimus | Different from patient to patient |
| Pimecrolimus | Different from patient to patient |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

## 5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Children 2 to 11 years of age with moderate atopic dermatitis who are candidates for systemic therapy

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Children 2 to 11 years of age with severe atopic dermatitis who are candidates for systemic therapy

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

c) Adolescents 12 to 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

– No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 2 May 2024.**

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 2 May 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken