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: juvenile psoriatic arthritis, ≥ 2 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 "enthesitis-related arthritis, ≥ 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 15 September 2023):

Baricitinib is indicated for the treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs:

- Juvenile psoriatic arthritis.

Baricitinib may be used as monotherapy or in combination with methotrexate.

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

See new therapeutic indication according to marketing authorisation.

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

Children and adolescents 2 years of age and older with active juvenile psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic DMARDs

Appropriate comparator therapy for baricitinib, alone or in combination with MTX:

- Etanercept (≥ 12 years) or secukinumab (≥ 6 years) or tofacitinib

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Children and adolescents 2 years of age and older with active juvenile psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic DMARDs

No data available.

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-113) unless otherwise indicated.

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

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

Children and adolescents 2 years of age and older with active juvenile psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic DMARDs

approx. 140 - 240 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: 10 January 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 the therapy of juvenile psoriatic arthritis.

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:

Children and adolescents 2 years of age and older with active juvenile psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic DMARDs

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Baricitinib Methotrexate[2] Combination therapy	€ 14,205.65 € 181.38 - € 610.92 € 14,387.03 - € 14,816.57
Appropriate comparator therapy:	
Etanercept	€ 10,129.09 - € 12,405.01
Secukinumab Methotrexate[3] Combination therapy	€ 4,852.92 - € 9,304.06 € 64.66 - € 181.38 € 4,917.58 - € 9,485.44
Tofacitinib Methotrexate[2] Combination therapy	€ 7,680.67 - € 11,720.23 € 181.38 - € 610.92 € 8,291.59 - € 11,901.61

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

Costs for additionally required SHI services: not applicable

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:

Children and adolescents 2 years of age and older with active juvenile psoriatic arthritis who have had an inadequate response or intolerance to one or more conventional synthetic or biologic DMARDs

- 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.

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

[2] For the calculation of the annual treatment costs, the parenteral dosage form is used to represent the lower limit (children ≥ 2 years).
[3] For the calculation of the annual treatment costs, the oral dosage form is used to represent the range.

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