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
Ixekizumab (new therapeutic indication: enthesitis-related arthritis (ERA), ≥ 6 years)

From 19 March 2026

At their session on 19 March 2026, 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 Ixekizumab in accordance with the resolution of 19 March 2026:

Ixekizumab

Resolution of: 19 March 2026
Entry into force on: 19 March 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 August 2025):

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active ERA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Therapeutic indication of the resolution (resolution of 19 March 2026):

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 6 years of age and older with active enthesitis-related arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

Appropriate comparator therapy for ixekizumab, alone or in combination with methotrexate:

- Adalimumab or etanercept (≥ 12 years) or secukinumab

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Children and adolescents 6 years of age and older with active enthesitis-related arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

No data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-121), 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 6 years of age and older with active enthesitis-related arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

Approx. 240 – 290 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 Taltz (active ingredient: ixekizumab) at the following publicly accessible link (last access: 17 November 2025):

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

Treatment with ixekizumab should only be initiated and monitored by specialists who are experienced in the treatment of patients with enthesitis-related arthritis.

4. Treatment costs

Annual treatment costs:

Children and adolescents 6 years of age and older with active enthesitis-related arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Ixekizumab Methotrexate Total combination therapy	€ 8,911.24 – € 17,279.38 € 65.06 – € 182.57 € 8,976.30 – € 17,461.95
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services	€ 6,148.64 – € 11,218.91 € 82.45
Etanercept Additionally required SHI services	€ 9,514.25 – € 10,176.09 € 82.45
Secukinumab Methotrexate Total combination therapy	€ 4,203.84 – € 8,040.52 € 65.06 – € 182.57 € 4,268.90 – € 8,223.09

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 January 2026)

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 6 years of age and older with active enthesitis-related arthritis and a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy

- No medicinal product with new active ingredients for use in combination therapy in compliance with 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 statutory 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 G-BA website on 19 March 2026.

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

Berlin, 19 March 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken