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)
Sarilumab (new therapeutic indication: polyarticular juvenile idiopathic arthritis (pJIA), ≥ 2 years)

of 7 August 2025

At their session on 7 August 2025, 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. 4 to the information on the benefit assessment of Sarilumab in the version of the resolution of 15 February 2018:

Sarilumab

Resolution of: 7 August 2025
Entry into force on: 7 August 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 13 January 2025):

Kevzara is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA; rheumatoid factor positive or negative polyarthritis and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with conventional synthetic DMARDs (csDMARDs). Kevzara may be used as monotherapy or in combination with MTX.

Therapeutic indication of the resolution (resolution of 7 August 2025):

See new therapeutic indication according to marketing authorisation.

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

a) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to previous therapy with conventional synthetic DMARDs

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

- Adalimumab or etanercept or golimumab or tocilizumab, each in combination with MTX; if applicable, as monotherapy, taking into account the respective authorisation status in the case of MTX intolerance or unsuitability

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

An additional benefit is not proven.

b) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to one or more biologic DMARDs

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

- Abatacept or adalimumab or etanercept or golimumab or tocilizumab, each in combination with MTX; if applicable, as monotherapy, taking into account the respective authorisation status in case of MTX intolerance or unsuitability, depending on prior therapy

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to previous therapy with conventional synthetic DMARDs

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable data.
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		

b) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to one or more biologic DMARDs

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable data.

[1]Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-19) unless otherwise indicated.

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

a) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to previous therapy with conventional synthetic DMARDs

Approx. 990 – 1,070 patients

b) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to one or more biologic DMARDs

Approx. 380 – 410 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 Kevzara (active ingredient: sarilumab) at the following publicly accessible link (last access: 24 April 2025):

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

Treatment with sarilumab should only be initiated and monitored by specialists who are experienced in the treatment of patients with polyarticular juvenile idiopathic arthritis.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide a patient identification card. This contains instructions on how to deal with the possible side effects caused by sarilumab, in particular serious infections, neutropenia and gastrointestinal perforation.

4. Treatment costs

Annual treatment costs:

a) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to previous therapy with conventional synthetic DMARDs

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sarilumab[2] Methotrexate Total combination therapy	Not calculable € 182.57 – € 611.91 Not calculable
Appropriate comparator therapy:	
Adalimumab Methotrexate[3] Total combination therapy Additionally required SHI services	€ 6,148.64 – € 11,218.91 € 182.57 – € 611.91 € 6,760.55 – € 11,401.48 € 10.49
Etanercept Additionally required SHI services	€ 4,757.12 – € 10,176.09 € 10.49
Golimumab Methotrexate Total combination therapy Additionally required SHI services	€ 9,375.28 – € 20,904.36 € 182.57 – € 611.91 € 9,557.85 – € 21,516.27 € 10.49
Tocilizumab Methotrexate Total combination therapy	€ 6,237.40 – € 10,535.96 € 182.57 – € 611.91 € 6,849.31 - € -10,718.53

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2025)

b) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to one or more biologic DMARDs

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sarilumab Methotrexate Total combination therapy	Not calculable € 182.57 – € 611.91 Not calculable

[2] Sarilumab 270 mg vial with 175mg/ml solution for injection is currently unavailable on the German market, therefore a cost representation is not possible.
[3] For the calculation of the annual treatment costs, the parenteral dosage form is used to represent the lower limit (children ≥ 2 years).

Designation of the therapy	Annual treatment costs/ patient
Appropriate comparator therapy:	
Abatacept Methotrexate Total combination therapy Additionally required SHI services	€ 9,385.16 – € 22,646.78 € 182.57 – € 611.91 € 9,997.07 – € 22,829.35 € 10.49
Adalimumab Methotrexate Total combination therapy Additionally required SHI services	€ 6,148.64 – € 11,218.91 € 182.57 – € 611.91 € 6,760.55 – € 11,401.48 € 10.49
Etanercept Additionally required SHI services	€ 4,757.12 – € 10,176.09 € 10.49
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Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2025)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Tocilizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300.00

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 and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to previous therapy with conventional synthetic 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.

b) Children and adolescents 2 years of age and older with active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), who have responded inadequately to one or more biologic DMARDs

– 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 7 August 2025.

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

Berlin, 7 August 2025

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

Prof. Hecken