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: polymyalgia rheumatica)

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. 5 to the information on the benefit assessment of Sarilumab in the version of the resolution of 7 August 2025 on the therapeutic indication "polyarticular juvenile idiopathic arthritis (pJIA), ≥ 2 years":

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 25 November 2024):

Kevzara is indicated for the treatment of polymyalgia rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper.

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

Adults with polymyalgia rheumatica who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper

Appropriate comparator therapy:

- An individualised therapy with selection of systemic glucocorticoids and the combination of glucocorticoids with methotrexate

Extent and probability of additional benefit of sarilumab compared with prednisone, if applicable with methotrexate:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with polymyalgia rheumatica who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper

[1] Data from the dossier assessment of the IQWiG (A25-13) and from the addendum (A25-18), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No deaths occurred.
Morbidity	↔	No relevant differences for the benefit assessment.
Health-related quality of life	↔	No relevant differences for the benefit assessment.
Side effects	↔	No relevant differences for the benefit assessment.

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

SAPHYR study: Randomised controlled trial over 52 weeks; sarilumab + prednisone vs placebo + prednisone (each with methotrexate if applicable)

Mortality

Endpoint	Sarilumab + prednisone		Placebo + prednisone		Intervention versus control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Overall mortality[a]					
	60	0 (0)	58	0 (0)	-

Morbidity

Endpoint	Sarilumab + prednisone		Placebo + prednisone		Intervention versus control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Pain (HAQ-DI VAS – improvement[b])					
	60	20 (33)	58	20 (34)	0.97 [0.58; 1.61] 0.896
Physical functional status (HAQ-DI – improvement[c])					
	60	19 (32)	58	10 (17)	1.84 [0.93; 3.63] 0.081
Patient-reported global assessment of disease activity (HAQ-DI VAS – improvement[d])					
	60	21 (35)	58	14 (24)	1.45 [0.81; 2.58] 0.208
Fatigue (FACIT-Fatigue – improvement[e])					
	60	24 (40)	58	17 (29)	1.36 [0.82; 2.28] 0.233
Health status (EQ-5D VAS –improvement[f])					
	60	16 (27)	58	9 (16)	1.72 [0.82; 3.60] 0.152

Endpoint	Active ingredient A			Control			Active ingredient A vs control
	N	Values at the start of the study MV (SD)	Mean change at week 52 MV (SE)	N	Values at the start of the study MV (SD)	Change at week 52 MV[a] (SE)	MD [95% CI]; p value
Duration of morning stiffness (individual component of PMR-AS) [in min]							
	48	66.35 (64.86)	-75.61 (5.87)	46	106.30 (216.84)	-53.18 (5.98)	−22.43 [−39.09; −5.77]; 0.009
Mobility of the upper limbs (individual component of the PMR-AS)[g]							
	48	0.52 (0.80)	-0.47 (0.06)	46	0.46 (0.62)	-0.23 (0.06)	−0.24 [−0.40; −0.08]; 0.004 SMD: -0.60 [-1.00; -0.19]

Health-related quality of life

Endpoint	Sarilumab + prednisone		Placebo + prednisone		Intervention versus control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]
SF-36v2					
Physical component summary score (improvement[h])	60	14 (23)	58	10 (17)	1.35 [0.65; 2.82] 0.419
Mental component summary score (improvement[h])	60	11 (18)	58	5 (9)	2.13 [0.78; 5.80] 0.141

Side effects

Endpoint	Sarilumab + prednisone		Placebo + prednisone		Intervention versus control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]
Total adverse events (presented additionally)					
	59	56 (95)	58	49 (84)	-
Serious adverse events (SAE)					
	59	8 (14)	58	12 (21)	0.66 [0.29; 1.50] 0.316
Therapy discontinuation due to adverse events					
	59	7 (12)	58	4 (7)	1.72 [0.53; 5.63] 0.370
Specific adverse events					
Infections (SOC, AE)	59	22 (37)	58	29 (50)	0.75 [0.49; 1.14] 0.173
Serious infections (SOC, SAE)	59	3 (5)	58	3 (5)	0.98 [0.20; 4.75] 0.983

a. The results on overall mortality are based on the data on fatal AEs.
b. A decrease in score by ≥ 1.5 points at week 52 compared to the start of the study is considered a clinically relevant improvement (scale range 0 to 10).
c. A decrease in score by ≥ 0.45 points at week 52 compared to the start of the study is considered a clinically relevant improvement (scale range: 0 to 3).
d. A decrease in score by ≥ 15 points at week 52 compared to the start of the study is considered a clinically relevant improvement (scale range: 0 to 100).
e. An increase in score by ≥ 7.8 points at week 52 compared to the start of the study is considered a clinically relevant improvement (scale range: 0 to 52).
f. An increase in score by ≥ 15 points at week 52 compared to the start of the study is considered a clinically relevant improvement (scale range: 0 to 100).
g. Lower values mean better symptomatology; negative effects mean an advantage for the intervention (scale range: 0 to 3).
h. An increase in score by ≥ 10 points at week 52 compared to the start of the study is considered a clinically relevant improvement (scale range: 0 to 100).

Abbreviations used:
FACIT = Functional Assessment of Chronic Illness Therapy; HAQ-DI = Health Assessment Questionnaire – Disability Index; CI = confidence interval; MD = mean difference; MV = mean value; n = number of patients with (at least 1) event; N = number of patients evaluated; PMR = polymyalgia rheumatica; PMR-AS = PMR activity score; RR = relative risk; SD = standard deviation; SMD = standardised mean difference; SE = standard error; SF-36 = short form 36; SOC = system organ class; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale

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

Adults with polymyalgia rheumatica who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper

Approx. 10,300 – 14,200 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: 02 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 polymyalgia rheumatica.

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:

Adults with polymyalgia rheumatica who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sarilumab Additionally required SHI services Total	€ 17,300.56 € 71.45 € 17,372.01
Prednisone	Different from patient to patient
Appropriate comparator therapy:	
Therapy according to doctor's instructions, taking into account systemic glucocorticoids and the combination of glucocorticoids with methotrexate	
Glucocorticoids monotherapy	
Prednisone	Different from patient to patient
Glucocorticoids in combination with methotrexate	
Prednisone	Different from patient to patient
Methotrexate	€ 52.46 - € 65.06

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

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:

Adults with polymyalgia rheumatica who have had an inadequate response to glucocorticoids or who experience a relapse during glucocorticoid taper

- 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