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
Vimseltinib (symptomatic tenosynovial giant cell tumours)

of 16 April 2026

At their session on 16 April 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. Annex XII shall be amended in alphabetical order to include the active ingredient Vimseltinib as follows:

Vimseltinib

Resolution of: 16 April 2026
Entry into force on: 16 April 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 September 2025):

Romvimza is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability.

Therapeutic indication of the resolution (resolution of 16 April 2026):

See therapeutic indication according to marketing authorisation.

1. Extent of the additional benefit and significance of the evidence

Vimseltinib is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan drugs. In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The G-BA determine the extent of the additional benefit for the number of patients and patient groups for which there is a therapeutically significant additional benefit in accordance with Chapter 5 Section 12, paragraph 1, number 1, sentence 2 of its Rules of Procedure (VerfO) in conjunction with Section 5, paragraph 8 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), indicating the significance of the evidence. This quantification of the additional benefit is based on the criteria laid out in Chapter 5 Section 5, paragraph 7, numbers 1 to 4 of the Rules of Procedure (VerfO).

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

Extent of the additional benefit and significance of the evidence of vimseltinib:

Indication of a considerable additional benefit

Study results according to endpoints:[1]

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No deaths occurred.
Morbidity	↑↑	Advantages in the endpoints "physical functioning" (using PROMIS-PF and PGIC/PGIS-PF), "worst pain" and "moderate pain", "limitations in range of motion" (using NRS stiffness and PGIC-ROM), "PGIC disease symptomatology" and "health status"
Health-related quality of life	∅	No data available.
Side effects	↓↓	Disadvantages in severe AEs.
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		

MOTION study:

- Ongoing two-part randomised, multicentre, placebo-controlled study
  - The comparative part 1 of the study up to week 25 is taken into account
    - Vimseltinib + best supportive care (BSC) vs placebo + BSC
  - Non-comparative part 2 of the study up to week 49: Patients in the placebo arm may receive vimseltinib
- Data cut-off from 22.05.2025 (completion of study part 1: 22.08.2023)

[1] Data from the dossier assessment of the G-BA (published on 2 February 2026), and from the amendment to the dossier assessment from 26 February 2026, unless otherwise indicated.

Mortality

Endpoint	Vimseltinib (+BSC)		Placebo (+BSC)		Vimseltinib (+BSC) vs Placebo (+BSC)
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Effect estimator [95% CI] p value
Overall survival					
	No deaths occurred.				

Morbidity

Endpoint	Vimseltinib (+BSC)		Placebo (+BSC)		Vimseltinib (+BSC) vs Placebo (+BSC)
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
Objective response rate[a] according to IRR based on RECIST (presented additionally)[b]					
	83	33 (39.8)	33	0	32.7 [2.06; 520.5] 0.01

Endpoint	Vimseltinib (+BSC)			Placebo (+BSC)			Vimseltinib (+BSC) vs Placebo (+BSC)
	N	*Baseline* MV (SD)	*Change from baseline to week 25* LS mean (SE)	N	*Baseline* MV (SD)	*Change from baseline to week 25* LS mean (SE)	LS mean difference [95% CI][c]; p value Hedges' g [95% CI]
Physical functioning using PROMIS-PF[d]							
	63[e]	39.0 (6.14)	4.6 (0.96)	30[e]	38.5 (5.98)	1.3 (0.88)	3.3 [1.4; 5.2] 0.0007 0.764 [0.319; 1.210].
Endpoint	**Vimseltinib (+BSC)**			**Placebo (+BSC)**			**Vimseltinib (+BSC) vs Placebo (+BSC)**
	N	*Patients with event n (%)*		N	*Patients with event n (%)*		RR [95% CI] p value
Physical functioning using PGIC and PGIS-PF							

Improvement[f] in the PGIC-PF	83	55 (66.3)	40	9 (22.5)	2.95 [1.63; 5.35] 0.0004
Improvement by ≥ 1 point in the PGIS-PF	83	36 (43.4)	40	8 (20.0)	2.10 [1.09; 4.06] 0.03

Endpoint	**Vimseltinib (+BSC)**		**Placebo (+BSC)**		**Vimseltinib (+BSC) vs Placebo (+BSC)**
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
Limitation of range of motion using NRS-stiffness[g]					
Improvement by ≥ 2 points at week 25	83	32 (38.6)	40	6 (15.0)	2.65 [1.21; 5.82] 0.01
Limitation of range of motion using PGIC and PGIS-ROM					
Improvement in the PGIC-ROM[f]	83	53 (63.9)	40	8 (20.0)	3.24 [1.71; 6.13] 0.0003
Improvement by ≥ 1 point in the PGIS-ROM	83	32 (38.6)	40	8 (20.0)	1.93 [0.98; 3.79] 0.06

Endpoint	**Vimseltinib (+BSC)**			**Placebo (+BSC)**			**Vimseltinib (+BSC) vs Placebo (+BSC)**
	N	*Baseline* MV (SD)	*Change from baseline to week 25* LS mean (SE)	N	*Baseline* MV (SD)	*Change from baseline to week 25* LS mean (SE)	LS mean difference [95% CI][c]; p value Hedges' g [95% CI]
Active range of motion (ROM)[h] (presented additionally)							
	73[e]	63.0 (29.4)	18.4 (6.46)	33[e]		3.8 (7.19)	14.6 [4.0; 25.3] 0.008

Endpoint	**Vimseltinib (+BSC)**			**Placebo (+BSC)**			**Vimseltinib (+BSC) vs Placebo (+BSC)**
	N	*Baseline* MV (SD)	*Change from baseline to week 25*	N	*Baseline* MV (SD)	*Change from baseline to week 25*	LS mean difference [95% CI][c]; p value Hedges' g [95% CI]

			LS mean (SE)			LS mean (SE)	
"Worst pain" and "moderate pain" using BPI-SF items							
Worst pain	68[e]	5.5 (2.11)	-2.6 (0.33)	31[e]	6.0 (1.78)	-1.0 (0.39)	-1.6 [-2.3; -0.8] < 0.0001 -0.90 [-1.34; -0.46]
Moderate pain	68[g]	4.62 (2.00)	-2.4 (0.30)	31[g]	5.19 (1.96)	-1.0 (0.36)	-1.4 [-2.1; -0.7] 0.0001 -0.86 [-1.29; -0.42]
Endpoint	**Vimseltinib (+BSC)**			**Placebo (+BSC)**			**Vimseltinib (+BSC) vs Placebo (+BSC)**
	N	*Patients with event n (%)*		N	*Patients with event n (%)*		RR [95% CI] p value
Health status using EQ-5D-VAS[i]							
Improvement by ≥ 15 points at week 25	83	26 (31.3)		40	4 (10.0)		3.20 [1.21; 8.44] 0.02
General disease symptomatology using PGIC							
Improvement[e]	83	55 (66.3)		40	9 (22.5)		2.95 [1.63; 5.35] 0.0004

Health-related quality of life

No data available.

Side effects

Endpoint MedDRA system organ classes/ preferred terms/ AEs of special interest	**Vimseltinib (+BSC)**		**Placebo (+BSC)**		**Vimseltinib (+BSC) vs Placebo (+BSC)**
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
Total adverse events (presented additionally)	83	83 (100)	39	37 (94.9)	-
Serious adverse events (SAEs)	83	6 (7.2)	39	1 (2.6)	2.82 [0.35; 22.62] 0.33
Severe adverse events (CTCAE grade 3 or 4)	83	31 (37.3)	39	4 (10.3)	3.64 [1.38; 9.60] 0.01

Therapy discontinuation due to adverse events	83	5 (6.0)	39	0 (0.0)	5.24 [0.30; 92.4] 0.26
Severe adverse events according to MedDRA (with an incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No significant differences					
SAEs according to MedDRA (with an incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No significant differences					
Adverse events of special interest (with statistically significant difference between the treatment arms)					
No determination of AEs of special interest in the MOTION study					

a. Defined as CR or PR
b. Primary endpoint of the MOTION study
c. MMRM using the sandwich estimator to assess the variance-covariance matrix. The dependent variable was the change from the baseline value. Each of these models included fixed effects for the treatment group, time, and the interaction between treatment group and time. The analyses were stratified according to the stratification factors "tumour localisation" and "region". In addition, the baseline value of the corresponding endpoint was adjusted for as a cofactor.
d. T-transformed values, MV = 50, SD = 10. Higher values indicate better physical functioning.
e. Number of subjects for whom values are available for week 25.
f. An improvement in the PGIC was defined as "very much improved", "much improved" and "minimally improved".
g. Values from 0 to 10; higher values indicate greater stiffness.
h. Values expressed as a percentage relative to the AMA reference values; lower values indicate a greater deviation from the reference standard.
i. Values ranging from 0 to 100; higher values correspond to the best possible health status.

Abbreviations used:
AMA = American Medical Association; BPI-SF = Brief Pain Inventory – Short Form; BSC = Best Supportive Care; CR = complete remission; CTCAE = Common Terminology Criteria for Adverse Events; EQ-5D-VAS = visual analogue scale of the European Quality of Life 5-Dimensions; CI = confidence interval; LS = least squares; MMRM = Mixed Model for Repeated Measures; MV = mean value; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; NRS = Numerical Rating Scale; PGIC = Patient Global Impression of Change; PGIS = Patient Global Impression of Severity; PR = partial remission; PROMIS-PF = Patient-Reported Outcomes Measurement Information System Physical Function; RR = relative risk; SD = standard deviation; SE = standard error; vs = versus

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

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

Approx. 160 – 1,140 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 Romvimza (active ingredient: vimseltinib) at the following publicly accessible link (last access: 8 April 2026):

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

Therapy with vimseltinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, who are experienced in the treatment of patients with tenosynovial giant cell tumours as well as specialists in orthopaedics and trauma surgery, and other doctors from other specialist groups participating in the Oncology Agreement.

4. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Vimseltinib	€ 335,979.11

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

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:

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

- 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product vimseltinib is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5 per cent of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant percentage within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the G-BA website on 16 April 2026.

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

Berlin, 16 April 2026

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

Prof. Hecken