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
Momelotinib (reassessment of an orphan drug after exceeding the EUR 30 million limit (myelofibrosis))

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. In Annex XII, the information on the active ingredient Momelotinib in the version of the resolution of 15 August 2024 (Federal Gazette, BAnz AT 01.10.2024 B2) shall be replaced by the following information:

Momelotinib

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

New therapeutic indication (according to the marketing authorisation of 25 January 2024):

Omjjara is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

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

See therapeutic indication according to marketing authorisation.

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

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

Appropriate comparator therapy:

− Ruxolitinib

or

− Fedratinib

Extent and probability of the additional benefit of momelotinib compared to ruxolitinib:

An additional benefit is not proven.

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Appropriate comparator therapy:

− Fedratinib

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	↔	No relevant difference for the benefit assessment.
Health-related quality of life	↔	No relevant difference for the benefit assessment.
Side effects	↓	Disadvantage in the endpoint of therapy discontinuation due to adverse events.
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		

SIMPLIFY-1

- Randomised, controlled, double-blind phase III study, completed
- Momelotinib versus ruxolitinib
- Final data cut-off: 1 July 2019
- Relevant sub-population: Subjects with a haemoglobin level < 10 g/dl at baseline

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-139), unless otherwise indicated.

Mortality

Endpoint	**Momelotinib**		**Ruxolitinib**		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	Hazard ratio [95% CI] p value[a]
Overall survival					
	86	n.r. [5.68; n.c.] 5 (5.8)	94	n.r. 1 (1.1)	6.04 [0.69; 53.18] 0.080

Morbidity

Endpoint	**Momelotinib**		**Ruxolitinib**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[a]
Leukaemic transformation					
	86	n.r. 1 (1.2)	94	n.r. 0 (0)	– 0.14
Endpoint	**Momelotinib**		**Ruxolitinib**		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value Absolute difference (AD)[b]
Transfusion independence [c] – (presented additionally)					
	86	33 (38.4)	94	19 (20.2)	2.13 [1.33; 3.33] 0.001 + 18.2%

Endpoint	Momelotinib		Ruxolitinib		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value Absolute difference (AD)[b]
Symptomatology (MPN-SAF – Improvement[d] at week 24)					
Early satiety	86	17 (19.8)	94	30 (31.9)	0.60 [0.36; 1.00] 0.050
Abdominal pain	86	16 (18.6)	94	22 (23.4)	0.79 [0.45; 1.41] 0.531[e]
Abdominal discomfort	86	21 (24.4)	94	23 (24.5)	1.00 [0.60; 1.67] > 0.999[e]
Inactivity	86	13 (15.1)	94	23 (24.5)	0.63 [0.34; 1.16] 0.14
Problems with headaches	86	14 (16.3)	94	13 (13.8)	1.18 [0.59; 2.36] 0.720[e]
Concentration problems	86	14 (16.3)	94	22 (23.4)	0.70 [0.38; 1.27] 0.254[e]
Dizziness	86	19 (22.1)	94	16 (17.0)	1.22 [0.68; 2.22] 0.50
Numbness in the hands and feet	86	17 (19.8)	94	16 (17.0)	1.16 [0.63; 2.15] 0.720[e]
Insomnia	86	24 (27.9)	94	29 (30.9)	0.88 [0.56; 1.37] 0.57
Depression or sad mood	86	13 (15.1)	94	18 (19.1)	0.80 [0.41; 1.51] 0.533[e]
Sexual dysfunction	86	12 (14.0)	94	11 (11.7)	1.19 [0.55; 2.56] 0.67
Cough	86	10 (11.6)	94	19 (20.2)	0.60 [0.30; 1.18] 0.14
Night sweats	86	27 (31.4)	94	33 (35.1)	0.92 [0.61; 1.39] 0.68
Itching	86	15 (17.4)	94	17 (18.1)	0.96 [0.51; 1.81] 0.966[e]
Bone pain (not joint pain or arthritis)	86	21 (24.4)	94	18 (19.1)	1.18 [0.68; 2.04] 0.56

Endpoint	Momelotinib		Ruxolitinib		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value Absolute difference (AD)[b]
Fever (> 37.8 degrees Celsius)	86	4 (4.7)	94	6 (6.4)	0.73 [0.21; 2.50] 0.627[e]
Unintentional weight loss over the last 6 months	86	28 (32.6)	94	28 (29.8)	1.10 [0.71; 1.69] 0.69
Overall quality of life	86	15 (17.4)	94	24 (25.5)	0.67 [0.38; 1.19] 0.17
Symptomatology (PGIC – Any improvement in symptoms[f] at week 24)					
	86	55 (64.0)	94	70 (74.5)	0.84 [0.69; 1.03] 0.088
Fatigue (BFI total score – Improvement[g] at week 24)					
	86	21 (24.4)	94	26 (27.7)	0.88 [0.54; 1.45] 0.718[e]
Health status (EQ-5D VAS – Improvement[h] at week 24)					
	86	20 (23.3)	94	21 (22.3)	1.04 [0.61; 1.78] 0.905[e]

Health-related quality of life

Endpoint	Momelotinib		Ruxolitinib		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value [b]
SF-36v2 – Improvement[i] at week 24					
Physical Component Summary (PCS) score	86	13 (15.1)	94	9 (9.6)	1.49 [0.68; 3.33] 0.32
Mental Component Summary (MCS) score	86	6 (7.0)	94	10 (10.6)	0.66 [0.25; 1.73] 0.531[e]

Endpoint	Momelotinib		Ruxolitinib		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value [b]
Physical functioning	86	22 (25.6)	94	24 (25.5)	0.98 [0.60; 1.61]
Physical role functioning	86	20 (23.3)	94	17 (18.1)	1.28 [0.72; 2.27]
Physical pain	86	18 (20.9)	94	22 (23.4)	0.84 [0.49; 1.45]
Perception of general health status	86	21 (24.4)	94	19 (20.2)	1.20 [0.70; 2.08]
Vitality	86	13 (15.1)	94	24 (25.5)	0.59 [0.32; 1.09]
Social functioning	86	12 (14.0)	94	17 (18.1)	0.77 [0.39; 1.52]
Emotional role functioning	86	13 (15.1)	94	18 (19.1)	0.79 [0.41; 1.52]
Psychological well-being	86	16 (18.6)	94	16 (17.0)	1.10 [0.58; 2.04]

Side effects

Endpoint	Momelotinib		Ruxolitinib		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value Absolute difference (AD)[b]
Total adverse events (AEs, presented additionally)					
	86	81 (94.2)	94	91 (96.8)	–
Serious adverse events (SAEs)					
	86	26 (30.2)	94	23 (24.5)	1.24 [0.77; 1.99] 0.531[e]
Severe adverse events (CTCAE grade 3 or 4)					
	86	42 (48.8)	94	52 (55.3)	0.88 [0.67; 1.17] 0.531[e]
Therapy discontinuation due to adverse events					
	86	17 (19.8)	94	5 (5.3)	3.72 [1.43; 9.64] 0.003[e]

Endpoint	Momelotinib		Ruxolitinib		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value Absolute difference (AD)[b]
					+ 14.5%
Specific adverse events					
Nausea (PT, AEs)	86	19 (22.1)	94	3 (3.2)	6.92 [2.12; 22.57] < 0.001[e] + 18.9%
Anaemia (PT, severe AEs)	86	10 (11.6)	94	26 (27.7)	0.42 [0.22; 0.82] 0.007[e] -16.1%

a. HR, CI from Cox proportional hazards model stratified by the stratification factors of TD at baseline (yes, no) and baseline platelet count (< 100, 100–200, > 200 × 109/l), p value: stratified log-rank test

b. In Module 4A, the pharmaceutical company presented the inverse effect estimate for the endpoints on morbidity and health-related quality of life (values < 1 indicate an advantage for the intervention). For the present table, IQWiG converted the effect estimators by forming the inverse value (values > 1 indicate an advantage for the intervention). RR, CI and p value: Poisson regression model with reliable sandwich matrix estimators, including the covariates of treatment, TD at baseline (yes, no) and baseline platelet count (< 100, 100–200, > 200 × 10^9/l). Indication of absolute difference (AD) only in case of statistically significant difference; own calculation.

c. Defined as the percentage of patients who did not receive a red blood cell transfusion during the 24-week randomised controlled treatment phase

d. A reduction by ≥ 15% in the respective individual items compared with the start of the study is considered as clinically relevant improvement (scale range: 0 to 10).

e. Unadjusted RR and CI. p value: IQWiG's calculation, unconditional exact test (CSZ method according to Martin Andrés A. et al. 1994)

f. Defined as "very much improved", "much improved" or "minimally improved"

g. A decrease in the BFI total score by ≥ 15% compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 10).

h. An increase in the score by ≥ 15% compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 100).

i. An increase in the PCS by ≥ 9.4 points or the MCS by ≥ 9.6 points compared to the start of the study is considered as clinically relevant improvement (scale range: 7.3 to 70.1 for PCS and 5.8 to 69.9 for MCS; determined using the 2009 normative sample, see Maruish ME, 2011).

Abbreviations used:
AD = absolute difference; BFI = Brief Fatigue Inventory; CTCAE = Common Terminology Criteria for Adverse Events; Hb = haemoglobin; HR = hazard ratio; CI = confidence interval; MPN-SAF = Myeloproliferative Neoplasm Symptom Assessment Form; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PGIC = Patient Global Impression of Change; PT = preferred term; RR = relative risk; SF-36v2 = Short Form-36 Health Survey Version 2; SAE = serious adverse event; TD = transfusion dependence; AE = adverse event; VAS = visual analogue scale; vs = versus

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

No data are available to allow an assessment of the additional benefit.

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

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

Approx. 470 to 1,500 patients

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Approx. 210 to 1,180 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 Omjjara (active ingredient: momelotinib) at the following publicly accessible link (last access: 22 January 2026):

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

Treatment with momelotinib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with myelofibrosis.

4. Treatment costs

Annual treatment costs:

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Momelotinib	€ 53,358.13
Appropriate comparator therapy:	
Ruxolitinib	€ 24,673.09 - € 73,290.96
Fedratinib Additionally required SHI costs	€ 43,732.48 € 143.64

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

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Momelotinib	€ 53,358.13
Appropriate comparator therapy:	
Fedratinib Additionally required SHI costs	€ 43,732.48 € 143.64

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

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

- 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.

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

- 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 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 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