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
Tafasitamab (new therapeutic indication: follicular lymphoma, after ≥ 1 prior therapy, combination with lenalidomide and rituximab)

From 2 July 2026

At their session on 2 July 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 number 4 to the information on the benefit assessment of tafasitamab in accordance with the resolution of 3 March 2022:

Tafasitamab

Resolution of: 2 July 2026
Entry into force on: 2 July 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 December 2025):

Minjuvi is indicated in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) (Grade 1-3a) after at least one line of systemic therapy.

Therapeutic indication of the resolution (resolution of 2 July 2026):

See new therapeutic indication according to marketing authorisation.

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

Tafasitamab 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 their 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).

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

Extent of the additional benefit and significance of the evidence of tafasitamab in combination with lenalidomide and rituximab:

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

Extent of the additional benefit and significance of the evidence of tafasitamab in combination with lenalidomide and rituximab:

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Study results according to endpoints:[1]

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

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	↔	No relevant difference 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		

inMIND study:

- Double-blind, randomised, controlled phase III study
- Tafasitamab in combination with lenalidomide and rituximab *versus* lenalidomide in combination with rituximab
- Treatment phase comprising a maximum of 12 cycles, each spanning 28 days
- Ongoing study, planned end: August 2028
- Relevant sub-population: subjects who have undergone one prior therapy

[1] Data from the dossier assessment of the G-BA (published on 15 April 2026), and from the amendment to the dossier assessment from 12 June 2026, unless otherwise indicated.

Mortality

Endpoint	Tafasitamab + lenalidomide + rituximab		Lenalidomide + rituximab		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					
	147	n.c. [26.8; n.c.] 5 (3.4)	153	n.c. [n.c.; n.c.] 7 (4.6)	0.71 [0.22; 2.22]; 0.55

Morbidity

Endpoint	Tafasitamab + lenalidomide + rituximab		Lenalidomide + rituximab		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 (%)*	Hazard ratio [95% CI] p value Absolute difference (AD)[a]
Progression-free survival[b]					
	147	24.0 [19.2; n.c.][c] 35 (23.8)	153	15.4 [12.0; 25.8][c] 64 (41.8)	0.40 [0.26; 0.62]; < 0.0001 + 8.6 months

Endpoint	Tafasitamab + lenalidomide + rituximab			Lenalidomide + rituximab			Intervention vs control
	n/N	Baseline median (min; max)	Mean change from baseline (%)	n/N	Baseline median (min; max)	Mean change from baseline (%)	p value
Health status (EQ-5D VAS)[d]							
	117/121	80.0 (11; 100)	0.1 (5.6)	122/128	80 (30; 100)	-2.5 (0.9)	0.37

Endpoint	Tafasitamab + lenalidomide + rituximab			Lenalidomide + rituximab			Intervention vs control
	n/N	Base-line me-dian (min; max)	Mean change from baseline (%)	n/N	Base-line me-dian (min; max)	Mean change from baseline (%)	p value
Symptomatology (EORTC QLQ-C30)[e]							
Fatigue	118/ 121	22.0 (0; 100)	4.8 (33.04)	125/ 128	22.0 (0; 100)	9.2 (32.0)	0.36
Nausea and vomiting	118/ 121	0.0 (0; 33)	1.2 (-84.9)	125/ 128	0.0 (0; 67)	2.5 (-18.1)	0.64
Pain	118/ 121	0.0 (0; 100)	3.8 (-23.5)	125/ 128	0.0 (0; 100)	10.2 (22.7)	0.09
Dyspnoea	118/ 121	0.0 (0; 100)	0.7 (-52.13)	125/ 128	0 (0; 100)	5.7 (-25.77)	0.26
Insomnia	118/ 121	33.0 (0; 100)	-2.3 (-27.06)	125/ 128	33 (0; 100)	4.7 (-9.00)	0.06
Loss of appetite	118/ 121	0.0 (0; 100)	3.6 (-9.60)	125/ 128	0.0 (0; 67)	1.9 (-49.9)	0.47
Constipation	118/ 121	0.0 (0; 100)	0.7 (-42.03)	125/ 128	0 (0; 100)	1.6 (-33.6)	0.98
Diarrhoea	118/ 121	0 (0; 100)	7.0 (-4.63)	125/ 128	0 (0; 67)	9.4 (-4.63)	0.23

Health-related quality of life

Endpoint	Tafasitamab + lenalidomide + rituximab			Lenalidomide + rituximab			Intervention vs control
	n/N	Baseline median (min; max)	Mean change from baseline (%)	n/N	Baseline median (min; max)	Mean change from baseline (%)	p value
EORTC QLQ-C30 – Functional scales[f]							
General health status	118/121	75.0 (17; 100)	0.5 (7.4)	124/128	71.0 (0; 100)	-2.3 (1.9)	0.60
Physical functioning	118/121	93.0 (0; 100)	-4.6 (2.95)	125/128	93 (7; 100)	-5.6 (-5.6)	0.81
Role functioning	118/121	100.0 (0; 100)	-7.2 (-3.32)	125/128	100.0 (0; 100)	-11.9 (-8.30)	0.35
Emotional functioning	117/121	83.0 (17; 100)	0.5 (6.5)	125/128	83.0 (17; 100)	-0.4 (3.70)	1.00
Cognitive functioning	118/121	100.0 (17; 100)	-4.6 (-0.52)	124/128	100;0 (0; 100)	-6.8 (-6.1)	0.67
Social functioning	118/121	100.0 (17; 100)	-4.1 (-2.03)	125/128	100 (0; 100)	-4.0 (0.51)	0.73
FACT-Lym[g]							
Total score	113/121	137.8 (27; 164)	-2.4 (1.8)	120/128	135.0 (81; 166)	-3.9 (1.88)	0.99

Side effects

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Tafasitamab + lenalidomide + rituximab**		**Lenalidomide + rituximab**		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value [h]
Total adverse events (presented additionally)	147	147 (100)	153	152 (99.3)	1.00 [0.99; 1.02]; 0.33
Serious adverse events (SAEs)	147	46 (31.3)	153	38 (24.8)	1.2 [0.85; 1.75]; 0.29
Severe adverse events (CTCAE grade 3 or 4)	147	102 (69.4)	153	94 (61.4)	1.1 [0.96; 1.33]; 0.15
Therapy discontinuation due to adverse events	147	22 (15.0)	153	14 (9.2)	1.6 [0.86; 3.11]; 0.13
Severe adverse events according to MedDRA (with an incidence ≥ 5% and at least 1% in at least one study arm and statistically significant difference between the treatment arms; SOC and PT)					
Infections and infestations, SOC	147	26 (17.7)	153	14 (9.2)	1.9 [1.01; 3.47]; 0.04
COVID-19 pneumonia, PT	147	8 (5.4)	153	1 (0.7)	8.1 [0.99; 66.74]; 0.02
Pneumonia, PT	147	11 (7.5)	153	3 (2.0)	3.9 [1.10; 13.45]; 0.02
SAEs according to MedDRA (with an incidence ≥ 5% in at least one study arm and statistically significant difference between the treatment arms; SOC and PT)					
Infections and infestations, SOC	147	25 (17.0)	153	13 (8.5)	2.0 [1.03; 3.68]; 0.03
COVID-19 pneumonia, PT	147	8 (5.4)	153	1 (0.7)	8.1 [0.99; 66.74]; 0.02

a. Estimation of the HR using a stratified Cox proportional hazards model; calculation of the p value using a stratified log-rank test; data on absolute difference (AD) only in the case of statistically significant difference; own calculation
b. Primary endpoint of the inMIND study, estimation by the investigators
c. Median PFS estimated using the Kaplan-Meier method; two-sided 95% CI calculated using the Brookmeyer and Crowley method (log-log transformation)
d. Scale: 0–100. A higher score means better health status.
e. Scale from 0 to 100 points transformed. Higher values mean more severe symptomatology.
f. Scale from 0 to 100 points transformed. Higher values correspond to better functioning or health/ quality of life.
g. A scale of 0–168 points. Higher values mean higher quality of life.
h. Relative risk and p value calculated post hoc using the stratified Cochran-Mantel-Haenszel test

Abbreviations used:

Endpoint MedDRA system organ classes/ preferred terms/ AEs of special interest	Tafasitamab + lenalidomide + rituximab		Lenalidomide + rituximab		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value [h]
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PT = preferred term; SOC = system organ class; vs = versus					

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

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	↔	No relevant difference 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		

inMIND study:

- Double-blind, randomised, controlled phase III study
- Tafasitamab in combination with lenalidomide and rituximab *versus* lenalidomide in combination with rituximab
- Treatment phase comprising a maximum of 12 cycles, each spanning 28 days
- Ongoing study, planned end: August 2028
- Relevant sub-population: Subjects who have undergone at least two prior therapies

Mortality

Endpoint	Tafasitamab + lenalidomide + rituximab		Lenalidomide + rituximab		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					
	126	n.c. [27.9; n.c.] 10 (7.9)	122	n.c. [n.c.; n.c.] 16 (13.1)	0.51 [0.22; 1.15]; 0.10

Morbidity

Endpoint	Tafasitamab + lenalidomide + rituximab		Lenalidomide + rituximab		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 (%)*	Hazard ratio [95% CI] p value Absolute difference (AD)[a]
Progression-free survival[b] (presented additionally)					
	126	22.4 [15.0; n.c.] 40 (31.7)	122	11.5 [8.57; 15.2] 67 (54.9)	0.44 [0.29; 0.66]; < 0.0001 + 10.9 months

Endpoint	Tafasitamab + lenalidomide + rituximab			Lenalidomide + rituximab			Intervention vs control
	n/N	Base-line median (min; max)	Mean change from baseline (%)	n/N	Base-line median (min; max)	Mean change from baseline (%)	p value
Health status (EQ-5D VAS)[d]							
	97/ 101	70 (30; 100)	1.2 (5.7)	100/ 103	72 (0; 100)	-0.7 (7.1)	0.84
Symptomatology (EORTC QLQ-C30)[e]							
Fatigue	98/ 101	33.0 (0; 89)	1.2 (14.1)	101/ 103	33.0 (0; 100)	0.2 (-7.6)	0.63
Nausea and vomiting	98/ 101	0.0 (0; 33)	0.8 (-11.78)	101/ 103	0 (0; 83)	0.4 (-41.2)	0.98
Pain	98/ 101	17.0 (0; 100)	-0.8 (-20.2)	101/ 103	17.0 (0; 100)	-3.1 (-36.9)	0.65
Dyspnoea	98/ 101	0.0 (0; 100)	0.8 (-23.01)	101/ 103	0.0 (0; 100)	-0.9 (-53.42)	0.68
Insomnia	98/ 101	33.0 (0; 100)	-0.4 (-24.4)	101/ 103	33 (0; 100)	-0.8 (15.2)	0.34
Loss of appetite	98/ 101	0.0 (0; 100)	0.4 (-60.9)	101/ 103	0.0 (0; 67)	1.7 (-52.6)	0.92
Constipation	98/ 101	0.0 (0; 100)	4.4 (-27.13)	101/ 103	0.0 (0; 67)	-0.9 (-52.2)	0.051
Diarrhoea	98/ 101	0.0 (0; 33)	5.6 (-6.3)	101/ 103	0.0 (0; 67)	3.9 (-36.5)	0.59

Health-related quality of life

Endpoint	Tafasitamab + lenalidomide + rituximab			Lenalidomide + rituximab			Intervention vs control
	n/N	Base-line me-dian (min; max)	Mean change from baseline (%)	n/N	Base-line median (min; max)	Mean change from baseline (%)	p value
EORTC QLQ-C30 – Functional scales[f]							
General health status	98/ 101	67.0 (17; 100)	-1.6 (10.8)	101/ 103	67 (0; 100)	1.4 (17.2)	0.27
Physical functioning	98/ 101	87.0 (40; 100)	-2.9 (-1.70)	101/ 103	87.0 (0; 100)	-2.7 (-0.73)	0.99
Role functioning	98/ 101	83.0 (17; 100)	-4.6 (3.3)	101/ 103	83 (0; 100)	-1.6 (3.6)	0.36
Emotional functioning	98/ 101	75 (0; 100)	0.3 (5.3)	101/ 103	83 (8; 100)	-1.3 (7.2)	0.65
Cognitive functioning	98/ 101	91.5 (0; 100)	-3.0 (-1.67)	101/ 103	83 (0; 100)	-1.7 (-0.75)	0.56
Social functioning	98/ 101	83.0 (17; 100)	-5.2 (-2.1)	101/ 103	83.0 (17; 00)	1.3 (17.5)	0.26
FACT-Lym[g]							
Total score	95/ 101	127.0 (52; 159)	1.2 (2.5)	99/ 103	125.2 (47; 163)	-2.0 (0.43)	0.75

Side effects

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Tafasitamab + lenalidomide + rituximab**		**Lenalidomide + rituximab**		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value [h]
Total adverse events (presented additionally)	127	125 (98.4)	119	118 (99.2)	1.0 [0.96; 1.02]; 0.55
Serious adverse events (SAEs)	127	53 (41.7)	119	48 (40.3)	1.1 [0.81; 1.47]; 0.57
Severe adverse events (CTCAE grade 3 or 4)	127	94 (74.0)	119	96 (80.7)	0.9 [0.81; 1.07]; 0.31
Therapy discontinuation due to adverse events	127	21 (16.5)	119	19 (16.0)	1.1 [0.61; 1.89]; 0.80
Severe adverse events according to MedDRA (with an incidence ≥ 5% and ≤ 1% in at least one study arm and statistically significant difference between the treatment arms; SOC and PT)					
Febrile neutropenia, PT	127	9 (7.1)	119	2 (1.7)	4.5 [0.94; 21.06]; 0.04
SAEs according to MedDRA (with an incidence ≥ 5% in at least one study arm and statistically significant difference between the treatment arms; SOC and PT)					
Gastrointestinal disorders, SOC	127	1 (0.8)	119	7 (5.9)	0.1 [0.02; 1.11]; 0.03

a. Estimation of the HR using a stratified Cox proportional hazards model; calculation of the p value using a stratified log-rank test; data on absolute difference (AD) only in the case of statistically significant difference; own calculation
b. Primary endpoint of the inMIND study, estimation by the investigators
c. Median PFS estimated using the Kaplan-Meier method; two-sided 95% CI calculated using the Brookmeyer and Crowley method (log-log transformation)
d. Scale: 0–100. A higher score means better health status.
e. Scale from 0 to 100 points transformed. Higher values mean more severe symptomatology.
f. Scale from 0 to 100 points transformed. Higher values correspond to better functioning or health/ quality of life.
g. A scale of 0–168 points. Higher values mean higher quality of life.
h. Relative risk and p value calculated post hoc using the stratified Cochran-Mantel-Haenszel test

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PT = preferred term; SOC = system organ class; vs = versus

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

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

Approx. 680 to 1,510 patients

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

Approx. 370 to 840 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 Minjuvi (active ingredient: tafasitamab) at the following publicly accessible link (last access: 30 April 2026):

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

Therapy with tafasitamab should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with follicular lymphoma.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The EMA will assess new information on this medicinal product at least annually and update the product information as necessary.

4. Treatment costs

Annual treatment costs:

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tafasitamab in combination with lenalidomide and rituximab	
Tafasitamab	€ 92,565.00
Lenalidomide	€ 428.68
Rituximab	€ 21,714.40
Total:	€ 114,708.08
Additionally required SHI costs	€ 10.49

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 May 2026)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 4 Cycle 2-5: 1	8	€ 800

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 relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic 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.

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

- 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 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 2 July 2026.

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

Berlin, 2 July 2026

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

Dr Optendrenk