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 Lecanemab (Early Alzheimer's disease)

of 19 February 2026

At their session on 19 February 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, information on the active ingredient Lecanemab shall be added in alphabetical order as follows:

Lecanemab

Resolution of: 19 February 2026
Entry into force on: 19 February 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 15 April 2025):

Leqembi is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer's disease (Early Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology.

Therapeutic indication of the resolution (resolution of 19 February 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 a clinical diagnosis of mild cognitive impairment due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

Appropriate comparator therapy:

Best supportive care

Extent and probability of the additional benefit of lecanemab compared to best supportive care:

An additional benefit is not proven.

b) Adults with a clinical diagnosis of mild dementia due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

Appropriate comparator therapy:

Donepezil *or* galantamine *or* rivastigmine

Extent and probability of the additional benefit of lecanemab compared to acetylcholinesterase inhibitors (AChEIs):

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with a clinical diagnosis of mild cognitive impairment due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

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 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		

CLARITY AD study: randomised controlled phase III study, lecanemab versus placebo

Mortality

Endpoint	Lecanemab		Placebo		Lecanemab vs Placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Overall mortality[a]					
	252	0 (0)	245	3 (1.2)	0.14 [0.01; 2.68] 0.080

[1] Data from the dossier assessment of the IQWiG (A25-111) and from the addendum (A26-01), unless otherwise indicated.

Morbidity

Endpoint	Lecanemab			Placebo			Lecanemab vs Placebo
	N	Patients with event n (%)		N	Patients with event n (%)		RR [95% CI] p value
Symptoms using CDR-SB (responder analysis)							
Deterioration at month 18[b]	216	22 (10.2)		217	25 (11.5)		0.85 [0.51; 1.44] 0.547
Endpoint	**Lecanemab**			**Placebo**			**Lecanemab vs Placebo**
	N[c]	Values at the start of the study MV (SD)	Change at month 18 MV (SE)	N[c]	Values at the start of the study MV (SD)	Change at month 18 MV (SE)	MD [95% CI] p value
Symptoms using CDR-SB *(continuous analysis, presented additionally)*							
Change at month 18[d]	*242*	*2.6* (1.07)	*0.92 (0.12)*	*240*	*2.7 (1.09)*	*1.05 (0.12)*	*-0.13 [-0.47; 0.20] 0.434*
Endpoint	**Lecanemab**			**Placebo**			**Lecanemab vs Placebo**
	N	Patients with event n (%)		N	Patients with event n (%)		RR [95% CI] p value
Cognition using ADAS-Cog14							
Deterioration at month 18[e]	213	11 (5.2)		215	12 (5.6)		0.86 [0.39; 1.89] 0.705
Health status using EQ-5D VAS							
Deterioration at month 18[f]	216	37 (17.1)		218	36 (16.5)		1.02 [0.67; 1.55] 0.923

Health-related quality of life

Endpoint	Lecanemab		Placebo		Lecanemab vs Placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
QOL-AD					
Deterioration at month 18[g]	216	21 (9.7)	217	21 (9.7)	1.00 [0.57; 1.78] 0.992

Side effects

Endpoint	Lecanemab		Placebo		Lecanemab vs Placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Total adverse events (presented additionally)[h]					
	252	226 (89.7)	245	207 (84.5)	–
Serious adverse events (SAE)[h]					
	252	37 (14.7)	245	28 (11.4)	1.28 [0.81; 2.03] 0.293
Therapy discontinuation due to adverse events					
	252	11 (4.4)	245	7 (2.9)	1.53 [0.60; 3.88] 0.530
Specific adverse events					
Symptomatic ARIA events[i]	252	6 (2.4)	245	0 (0)	12.64 [0.72; 223.18] 0.016
Infusion-related reactions (AE)[j]	252	67 (26.6)	245	19 (7.8)	3.43 [2.13; 5.53] < 0.001

a. The results on overall mortality are based on the data on fatal AEs.
b. An increase in CDR-SB by ≥ 2.7 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 18).
c. Number of patients considered in the effect estimate.
d. Lower (decreasing) values mean better symptomatology; negative effects (intervention minus comparison) mean an advantage for the intervention (scale range: 0 to 18).
e. An increase by ≥ 13.5 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 90).
f. A decrease by ≥ 15 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
g. A decrease by ≥ 5.85 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 13 to 52).
h. Without disease-related events
i. The following events are considered: symptomatic ARIA-E, symptomatic ARIA-H, serious ARIA-E and serious ARIA-H.
j. Operationalised via a PT list compiled by the pharmaceutical company

Abbreviations
AChEI = acetylcholinesterase inhibitors; ADAS-Cog14 = Alzheimer's Disease Assessment Scale – Cognitive subscale 14-item version; ARIA = amyloid-related imaging abnormalities; ARIA-E = ARIA with oedema; ARIA-H = ARIA with haemosiderin deposition; CDR-SB = Clinical Dementia Rating – Sum of Boxes; CI = confidence interval; MV = mean value; n = number of patients with (at least 1) event; N = number of patients evaluated; PT = preferred term; pU = pharmaceutical company; QOL-AD = Quality of Life in Alzheimer's Disease Scale; RCT = randomised controlled trial; RR = relative risk; SD = standard deviation; SE = standard error; SAE = serious adverse event(s); AE = adverse event(s); VAS = visual analogue scale

b) Adults with a clinical diagnosis of mild dementia due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
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Health-related quality of life	↔	No relevant differences for the benefit assessment.
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CLARITY AD study: randomised controlled phase III study, lecanemab versus placebo (each in combination with AChEI)

Mortality

Endpoint	Lecanemab + AChEI		Placebo + AChEI		Lecanemab + AChEI vs Placebo + AChEI
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Overall mortality[a]					
	139	1 (0.7)	138	1 (0.7)	0.99 [0.06; 15.71] > 0.999

Morbidity

Endpoint	**Lecanemab + AChEI**			**Placebo + AChEI**			**Lecanemab + AChEI vs Placebo + AChEI**
	N	Patients with event n (%)		N	Patients with event n (%)		RR [95% CI] p value
Symptoms using CDR-SB (responder analysis)							
Deterioration at month 18[b]	103	28 (27.2)		115	39 (33.9)		0.84 [0.56; 1.27] 0.410
Endpoint	**Lecanemab + AChEI**			**Placebo + AChEI**			**Lecanemab + AChEI vs Placebo + AChEI**
	N[c]	Values at the start of the study MV (SD)	Change at month 18 MV (SE)	N[c]	Values at the start of the study MV (SD)	Change at month 18 MV (SE)	MD [95% CI] p value
Symptoms using CDR-SB *(continuous analysis, presented additionally)*							
Change at month 18[d]	*136*	*3.7 (1.29)*	*1.87 (0.24)*	*137*	*3.7 (1.38)*	*2.61 (0.23)*	*-0.74 [-1.40; -0.09] 0.026* *SMD[e] -0.30 [-0.57; -0.03]*
Endpoint	**Lecanemab + AChEI**			**Placebo + AChEI**			**Lecanemab + AChEI vs Placebo + AChEI**
	N	Patients with event n (%)		N	Patients with event n (%)		RR [95% CI] p value
Cognition using ADAS-Cog14							
Deterioration at month 18[f]	99	14 (14.1)		111	26 (23.4)		0.63 [0.35; 1.14] 0.130
Health status using EQ-5D VAS							
Deterioration at month 18[g]	103	16 (15.5)		113	25 (22.1)		0.66 [0.38; 1.17] 0.155

Health-related quality of life

Endpoint	Lecanemab + AChEI		Placebo + AChEI		Lecanemab + AChEI vs Placebo + AChEI
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
QOL-AD					
Deterioration at month 18[h]	104	10 (9.6)	113	19 (16.8)	0.56 [0.28; 1.15] 0.115

Side effects

Endpoint	Lecanemab + AChEI		Placebo + AChEI		Lecanemab + AChEI vs Placebo + AChEI
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Total adverse events (presented additionally)[i]					
	139	127 (91.4)	138	111 (80.4)	–
Serious adverse events (SAE)[i]					
	139	20 (14.4)	138	14 (10.1)	1.42 [0.75; 2.70] 0.293
Therapy discontinuation due to adverse events					
	139	10 (7.2)	138	4 (2.9)	2.48 [0.80; 7.73] 0.126
Specific adverse events					
Symptomatic ARIA events[j]	139	7 (5.0)	138	1 (0.7)	6.95 [0.87; 55.74] 0.034
Infusion-related reactions (AE)[k]	139	32 (23.0)	138	10 (7.2)	3.18 [1.63; 6.21] < 0.001
Urinary tract infections (PT, AE)	139	5 (3.6)	138	17 (12.3)	0.29 [0.11; 0.77] 0.008

a. The results on overall mortality are based on the data on fatal AEs.
b. An increase in CDR-SB by ≥ 2.7 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 18).
c. Number of patients considered in the effect estimate.
d. Lower (decreasing) values mean better symptomatology; negative effects (intervention minus comparison) mean an advantage for the intervention (scale range: 0 to 18).
e. The SMD is considered in order to check the relevance of the result. Here, the 95% CI of the SMD is not completely below the irrelevance threshold of -0.2. Thus, it cannot be inferred that the effect is relevant.
f. An increase by ≥ 13.5 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 90).
g. A decrease by ≥ 15 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
h. A decrease by ≥ 5.85 points (15% of the scale range) compared to the start of the study is considered as clinically relevant deterioration (scale range: 13 to 52).
i. Without disease-related events

j. The following events are considered: symptomatic ARIA-E, symptomatic ARIA-H, serious ARIA-E and serious ARIA-H.
k. Operationalised via a PT list compiled by the pharmaceutical company

Abbreviations
AChEI = acetylcholinesterase inhibitors; ADAS-Cog14 = Alzheimer's Disease Assessment Scale – Cognitive subscale 14-item version; ARIA = amyloid-related imaging abnormalities; ARIA-E = ARIA with oedema; ARIA-H = ARIA with haemosiderin deposition; CDR-SB = Clinical Dementia Rating – Sum of Boxes; CI = confidence interval; MV = mean value; n = number of patients with (at least 1) event; N = number of patients evaluated; PT = preferred term; pU = pharmaceutical company; QOL-AD = Quality of Life in Alzheimer's Disease Scale; RCT = randomised controlled trial; RR = relative risk; SD = standard deviation; SE = standard error; SMD = standardised mean difference; SAE = serious adverse event(s); AE = adverse event(s); VAS = visual analogue scale

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

a) Adults with a clinical diagnosis of mild cognitive impairment due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

and

b) Adults with a clinical diagnosis of mild dementia due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

Approx. 131,000 to 440,000 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 Leqembi (active ingredient: lecanemab) at the following publicly accessible link (last access: 5 January 2026):

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

Treatment with lecanemab should only be initiated and monitored by specialists in neurology or specialists in psychiatry and psychotherapy who are experienced in the treatment of Alzheimer's disease and have timely access to Magnetic Resonance Imaging (MRI) diagnostics.

Prior to initiating treatment with lecanemab, testing for ApoE ε4 status must be performed and the presence of amyloid beta (Aβ) pathology must be confirmed using an appropriate test.

During treatment with lecanemab, cognitive function should be reviewed and clinical symptoms assessed approximately every 6 months.
Treatment with lecanemab should be discontinued as soon as the patient has progressed to moderate Alzheimer's disease.
In accordance with Annex III No. 10a of the Pharmaceuticals Directive, the prevention of progression to moderate Alzheimer's disease must therefore be reviewed every 6 months for the continued prescription of lecanemab. The type, duration and outcome of the use of lecanemab must be documented.

Lecanemab may cause amyloid-related imaging abnormalities (ARIA). In addition to ARIA, intracerebral haemorrhages with a diameter of more than 1 cm have occurred in patients treated with lecanemab.

Prior to initiating treatment with lecanemab, a current (no older than 6 months) baseline brain MRI should be obtained to assess for pre-existing ARIA. Furthermore, an MRI scan must be performed before the 3rd, 5th, 7th and 14th infusion. A clinical assessment, including MRI, should be performed if a patient develops symptoms indicative of ARIA at any time during treatment.

Treatment with lecanemab should not be initiated in patients receiving ongoing therapy with anticoagulants.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients including patient card.
The training material contains, in particular, information on the above-mentioned requirements for treatment with lecanemab and warnings about the risks of ARIA.

Treatment should be initiated for all patients via a mandatory central registration system as part of a Controlled Access Programme (CAP).

4. Treatment costs

Annual treatment costs:

a) Adults with a clinical diagnosis of mild cognitive impairment due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lecanemab Additionally required SHI services: Total:	€ 38,838.89 € 652.50 € 39,491.39
Best supportive care	Different from patient to patient

Designation of the therapy	Annual treatment costs/ patient
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

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

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Lecanemab	Surcharges for the preparation of parenteral solutions containing monoclonal antibodies	€ 100	1	26.1	€ 2,610

b) Adults with a clinical diagnosis of mild dementia due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lecanemab Additionally required SHI services: Total:	€ 38,838.89 € 652.50 € 39,491.39
Appropriate comparator therapy:	
Donepezil	€ 213.41 - € 223.99
Galantamine	€ 227.17 - € 232.38
Rivastigmine	€ 413.88 - € 432.59

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

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Lecanemab	Surcharges for the preparation of parenteral solutions containing monoclonal antibodies	€ 100	1	26.1	€ 2,610

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 a clinical diagnosis of mild cognitive impairment due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

- 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.

b) Adults with a clinical diagnosis of mild dementia due to Alzheimer's disease who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygotes with confirmed amyloid pathology

- 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.

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 Leqembi 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% 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 extent within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 February 2026.

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

Berlin, 19 February 2026

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

Prof. Hecken