

Drug assessment at a glance: A25-134¹

Donanemab (early Alzheimer's disease)

10 August 2026

¹ This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A25-134. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Adults with clinically diagnosed mild cognitive impairment due to Alzheimer's disease with confirmed amyloid pathology who are ApoE ε4 non-carriers or heterozygotes
Intervention	donanemab
Comparator	watchful waiting
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 1

	Size of the effects		Informative value of the effects	
Mortality	∅		–	
Morbidity	∅		–	
Symptoms	∅		–	
Health-related quality of life	∅		–	
Side effects	∅		–	
	∅	No (suitable) data	–	Not applicable
	↔	No advantage or disadvantage	★	Low
	↑ / ↓	Small advantage/disadvantage	★★	Moderate
	↑↑ / ↓↓	Moderate advantage/disadvantage	★★★	High
	↑↑↑ / ↓↓↓	Large advantage/disadvantage		

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 1

- No suitable data were available. The data from the AACI randomized controlled trial comparing donanemab with placebo were unsuitable for the following reasons:
- No provision was made for a differentiated diagnosis between mild cognitive impairment and mild dementia due to Alzheimer's disease. Subsequent attempts to identify the patient population with mild cognitive impairment on the basis of concomitant antidementia treatment and the results of disease-specific questionnaires completed by the patients were unable to provide a sufficient approximation of the population with mild cognitive impairment.
- In particular, based on a score of 0.5 in the CDR-GS questionnaire, it could not be assumed that patients with mild Alzheimer's dementia (untreated) had been sufficiently excluded from the population for research question 1. This is of importance, because the population with mild Alzheimer's dementia potentially biases the effect estimate in favour of the intervention. As it is likely that a high proportion of patients with mild Alzheimer's dementia were included in the patient population that was analysed as a population with mild cognitive impairment, the available data were not suitable for drawing conclusions about the population of patients with mild cognitive impairment.

Research question 2 of the benefit assessment

Population	Adults with clinically diagnosed mild dementia due to Alzheimer's disease with confirmed amyloid pathology who are ApoE ϵ 4 non-carriers or heterozygotes
Intervention	donanemab
Appropriate comparator therapy	donepezil or galantamine or rivastigmine
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 2

	Size of the effects	Informative value of the effects
Mortality	↔	–
Morbidity	↔	–
Symptoms	↔	–
Health-related quality of life	∅	–
Side effects	↓↓	★
	<div> <div>∅</div> <div>↔</div> <div>↑ / ↓</div> <div>↑↑ / ↓↓</div> <div>↑↑↑ / ↓↓↓</div> </div> <div> <div>No (suitable) data</div> <div>No advantage or disadvantage</div> <div>Small advantage/disadvantage</div> <div>Moderate advantage/disadvantage</div> <div>Large advantage/disadvantage</div> </div>	<div>–</div> <div>★</div> <div>★★</div> <div>★★★</div> <div>Not applicable</div> <div>Low</div> <div>Moderate</div> <div>High</div>

Overall: no advantage or disadvantage

Evidence base and noteworthy aspects – research question 2

- Evidence base: subpopulation of the AACI randomized controlled trial comparing donanemab with placebo.
- Subsequent attempts to identify the patient population with mild Alzheimer's dementia using the patients' concomitant treatment and results of the disease-specific CDR (Clinical Dementia Rating) questionnaire were able to provide a sufficient approximation of the population with mild Alzheimer's dementia.
- In contrast to research question 1, it was assumed that the patient population analysed as a population with mild Alzheimer's dementia did not contain a relevant proportion of patients with mild cognitive impairment. This is because the proportion of patients with mild cognitive impairment with a score of at least 1 on the CDR-GS questionnaire or at least 4.5 on the CDR-SB was generally considered to be low. It should be noted, however, that a potentially large proportion of patients receiving AChEI treatment and with mild Alzheimer's dementia, but who have different CDR scores – in particular a CDR-GS of 0.5 – was not included in the presented analyses.

Key study findings – research question 2

Study Outcome category Outcome	donanemab + AChEI		placebo + AChEI		donanemab + AChEI vs. placebo + AChEI
	N	Median time to event (weeks) [95% CI] Patients with event n (%)	N	Median time to event (weeks) [95% CI] Patients with event n (%)	HR [95% CI]; p-value
AACI					
Morbidity					
Symptoms (CDR-SB – time to permanent deterioration)					
Subpopulation CDR-GS 1 or 2	122	77.3 [77.00; NC] 36 (29.5)	110	77.0 [75.71; NC] 45 (40.9)	0.80 [0.51; 1.25]; 0.320
Subpopulation CDR-SB 4.5 to 9.0	119	79.0 [77.00; NC] 33 (27.7)	107	77.0 [75.71; NC] 42 (39.3)	0.75 [0.47; 1.19]; 0.218
Cognition (ADAS-Cog13 – time to permanent deterioration)					
Subpopulation CDR-GS 1 or 2	122	NA [78.14; NC] 20 (16.4)	110	79.9 [76.71; NC] 33 (30.0)	0.60 [0.34; 1.06]; 0.079
Subpopulation CDR-SB 4.5 to 9.0	119	NA [78.14; NC] 19 (16.0)	107	NA [76.71; NC] 30 (28.0)	0.56 [0.31; 0.9997]; 0.0499

Study Outcome category Outcome	donanemab + AChEI		placebo + AChEI		donanemab + AChEI vs. placebo + AChEI
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p-value
AACI					
Side effects					
SAEs					
Subpopulation CDR-GS 1 or 2	120	27 (22.5)	110	17 (15.5)	1.46 [0.84; 2.52]; 0.184
Subpopulation CDR-SB 4.5 to 9.0	117	25 (21.4)	107	16 (15.0)	1.43 [0.81; 2.53]; 0.231
Discontinuation due to AEs	117	19 (16.2)	107	5 (4.7)	3.48 [1.34; 8.98]; 0.008
Subpopulation CDR-GS 1 or 2	120	20 (16.7)	110	6 (5.5)	3.06 [1.27; 7.33]; 0.011
Subpopulation CDR-SB 4.5 to 9.0	117	19 (16.2)	107	5 (4.7)	3.48 [1.34; 8.98]; 0.008
Infusion-related reactions (PT, AEs)					
Subpopulation CDR-GS 1 or 2	120	7 (5.8)	110	0 (0)	13.76 [0.80; > 100]; 0.015
Subpopulation CDR-SB 4.5 to 9.0	117	8 (6.8)	107	0 (0.0)	15.56 [0.91; > 100]; 0.007

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Donanemab (frühe Alzheimer-Krankheit); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 15.04.2026]. URL: <https://doi.org/10.60584/A25-134>.

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Donanemab (frühe Alzheimer-Krankheit); Addendum zum Projekt A25-134 (Dossierbewertung) [online]. 2026 [Accessed: 16.04.2026]. URL: <https://doi.org/10.60584/A26-29>.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Donanemab (frühe Alzheimer-Krankheit) [online]. 2026 [Accessed: 16.04.2026]. URL: <https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1278/>.

English translations for this project are published at <https://www.iqwig.de/en/projects/a25-134.html> and <https://www.iqwig.de/en/projects/a26-29.html>.

Publisher details

Publisher

Institute for Quality and Efficiency in Health Care (IQWiG)

Address

Siegburger Str. 237

50679 Köln

Germany

Phone: +49 221 35685-0

Fax: +49 221 35685-1

Email: info@iqwig.de

Internet: www.iqwig.de