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[C2H2406] Donanemab (Kisunla)

1. Purpose of use

Suppression of disease progression in patients with mild cognitive impairment and mild dementia due to Alzheimer's disease

2. Price of the drug

Donanemab has been reimbursed since November 2024, and the drug price for Kisunla Intravenous Infusion 350 mg is JPY 66,948 as of July 2026. The price was determined using the similar efficacy comparison method (I) with a usefulness premium (II) of 5%. The product was designated as an item for cost-effectiveness evaluation with H1 classification.

3. Scope of cost-effectiveness evaluation

This product is used to suppress disease progression in patients with mild cognitive impairment and mild dementia due to Alzheimer’s disease. The scope of the evaluation agreed upon by the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below:

Target population	Patients with mild cognitive impairment and mild dementia due to Alzheimer's disease who have the following: (a) Mini-Mental State Examination (MMSE) scores of 22–28 (b) MMSE scores of 20–21
Comparator	(a) Lecanemab plus non-pharmacological therapy with or without donepezil (Evaluated technology: Donanemab plus non-pharmacological therapy with or without donepezil) (b) Non-pharmacological therapy with or without donepezil (Evaluated technology: Donanemab plus non-pharmacological therapy with or without donepezil)

4. Evaluation of additional benefits

Population (a): Patients with MMSE scores of 22–28

The manufacturer concluded that the additional benefits of donanemab over lecanemab were not demonstrated based on currently available evidence, as directly comparing the two clinical trials for donanemab and lecanemab was difficult because of differences in eligibility criteria and baseline patient characteristics. The academic group accepted the manufacturer's claim.

Population (b): Patients with MMSE scores of 20–21

In the subgroup analysis of patients with MMSE scores of 20–21 from the pivotal TRAILBLAZER-ALZ 2 trial, the decline from baseline to Week 76 in the Integrated Alzheimer's Disease Rating Scale (iADRS) score (primary endpoint) was smaller with donanemab, although the result was not statistically significant. The increase in Clinical Dementia Rating-Sum of Boxes (CDR-SB) score from baseline to Week 76 was significantly smaller in the donanemab group. The manufacturer claimed that although no statistically significant difference was observed in the change in iADRS score because of the limited sample size, these results were consistent with those observed in the overall study population. The academic group accepted the manufacturer’s claim that the additional benefit of donanemab over the comparator was demonstrated based on these findings.

5. Results of the cost-effectiveness analysis

The manufacturer conducted a cost-minimization analysis using a decision tree model for target population (a) and a cost-utility analysis using a Markov model for target population (b). The Markov model accounted for Alzheimer’s disease severity, institutionalization, and mortality. The academic group conducted a re-analysis of the efficacy of donanemab, the long-term treatment effects after discontinuation, caregiver utility, and patient proportions. The parameters for patient proportions were based on data from a post-marketing survey collected from the manufacturer under the ECCEE’s instructions.

The results are shown below.

[Public healthcare payer's perspective]

Target population	Comparator	Additional benefit	ICER (JPY/QALY)
(a) Patients with MMSE scores of 22–28	Lecanemab + non-pharmacological therapy ± donepezil	Not shown	Cost reduction
(b) Patients with MMSE scores of 20–21	Non-pharmacological therapy ± donepezil	Shown	17,840,060

[Public healthcare and long-term care payer's perspective]

Target population	Comparator	Additional benefit	ICER (JPY/QALY)
(a) Patients with MMSE scores of 22–28	Lecanemab + non-pharmacological therapy ± donepezil	Not shown	--*
(b) Patients with MMSE scores of 20–21	Non-pharmacological therapy ± donepezil	Shown	17,228,267

*The manufacturer did not perform an analysis from Public healthcare and long-term care payer's perspective

[Drug Price Corresponding to an ICER of JPY 5,000,000 per QALY]

The drug price corresponding to an ICER of JPY 5,000,000 per QALY (2) is as follows. The listed price of Kisunla Intravenous Infusion 350 mg is JPY 66,948 (1) as of July 2026.

Target population	Perspective	Drug price (2)	1-((2)÷(1))
(a) Patients with MMSE scores of 22–28	Public healthcare payer	66,948	0%
	Public healthcare and long-term care payer	66,948	0%
(b) Patients with MMSE scores of 20–21	Public healthcare payer	15,315	77.1%
	Public healthcare and long-term care payer	15,669	76.6%