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# [C2H2308] Summary of cost-effectiveness evaluation of lecanemab (LEQEMBI®)

1. Indications

To slow the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease

2. Price of the drug

Lecanemab (LEQEMBI®) has been reimbursed from December 2024 at JPY 45,777 for 200 mg, and JPY 114,443 for 500 mg (as of June 2025). The price was calculated based on the cost-calculation method and this product was designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for the treatment of mild cognitive impairment and mild dementia caused by Alzheimer's disease. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

| | |
|---|---|
| Population | (a) Mild cognitive impairment due to Alzheimer's disease<br>(b) Mild dementia due to Alzheimer's disease |
| Comparator | (a) Non-pharmacological intervention<br>(b) Donepezil + non-pharmacological intervention |

4. Evaluation of additional benefits

In assessing additional benefits, the manufacturer referred to the results of subgroup analyses of mild cognitive impairment and mild dementia due to

Alzheimer's disease and of patients with and without concomitant use of symptom-modifying drugs, in addition to the results of the overall population of the primary study, Study 301.

The manufacturer reported that the primary endpoint, the change in the CDR-SB from baseline to 18 months, showed that, compared with placebo, lecanemab significantly reduced deterioration. In addition, the results of the subgroup analyses of mild cognitive impairment and mild dementia due to Alzheimer's disease and of patients treated with and without symptom-modifying drugs were not heterogeneous with the results of the overall population. On the basis of these findings, the manufacturer reported additional benefits of lecanemab in the following target populations: (a) mild cognitive impairment due to Alzheimer's disease and (b) mild Alzheimer's dementia.

The ATAG accepted the manufacturer's claim of additional benefits on the basis of these results but considered with concern that the treatment efficacy of lecanemab observed in Study 301 was less than the minimal clinically important difference for the CDR-SB. In addition, the comparator in the target population (b) was donepezil, whereas the comparator in Study 301 was placebo, and since donepezil was not administered to the entire population, the ATAG speculated that in the specified analysis framework, the treatment efficacy would move in the direction of being smaller than that observed in the clinical trials.

5. Results of the cost-effectiveness analysis

For the cost-effectiveness analysis, the manufacturer used a Markov model consisting of nine health states that considered the Alzheimer's disease severity, care setting, and death. In the model, the proportion of patients receiving lecanemab decreased at a constant rate over time, but the effect of reducing the severity of disease as a group was extrapolated directly, regardless of the proportion of patients receiving lecanemab. Therefore, even if the administration rate decreased, the difference in efficacy increased. In addition, while the efficacy after a patient moved to moderate disease was assumed to be equivalent to that of patients with mild disease, in the company’s model, the administration of lecanemab was discontinued once the patient moved to moderate disease. In addition, the company’s model set the mortality rates by severity on the basis of observational studies and assumed that patients in the lecanemab group with a prolonged duration of mild cognitive impairment or mild Alzheimer's disease would have prolonged

survival. The academic group conducted a reanalysis using a newly constructed model.

In the manufacturer's method for estimating the QALYs of family caregivers, the absolute utility values of the caregivers were used rather than the decrement in their quality of life. However, this approach effectively includes QALYs for both the patient and the caregiver. Therefore, in the academic analysis, the QALY gain was calculated based on the decrement in the caregiver's quality of life, rather than their absolute utility value.

In addition to the above estimates of the effectiveness of lecanemab, issues were raised regarding the settings of utility weights for patients and caregivers and the method of estimating costs. The results are shown below.

[Public healthcare payer’s perspective]

| Population | Comparator | ICER (JPY/QALY) |
|---|---|---|
| (a) Mild cognitive impairment due to Alzheimer’s disease | Non-pharmacological intervention | 16,840,769 |
| (b) Mild dementia due to Alzheimer’s disease | Donepezil + non-pharmacological intervention | 18,426,082 |

[Public healthcare and long-term care payer’s perspectives]

| Population | Comparator | ICER (JPY/QALY) |
|---|---|---|
| (a) Mild cognitive impairment due to Alzheimer’s disease | Non-pharmacological intervention | 15,388,842 |
| (b) Mild dementia due to Alzheimer’s disease | Donepezil + non-pharmacological intervention | 16,703,239 |

[Drug Price Corresponding to an ICER of JPY 5,000,0000 per QALY]

The drug price corresponding to an ICER of JPY 5,000,0000 per QALY is as follows. The listed price of Leqembi 200 mg is JPY 45,777 (A) and that of the 500 mg is JPY 114,443.

| Population | Perspective | The drug price for 200 mg (JPY)(B) | The drug price for 500 mg (JPY) | 1-{(B)÷(A)} |
|---|---|---|---|---|
| (a) Mild cognitive impairment due to | Public healthcare payer | 13,567 | 33,917 | 70.4% |

| | | | | |
|---|---|---|---|---|
| Alzheimer’s disease | Public healthcare and long-term care payer | 16,329 | 40,822 | 64.3% |
| (b) Mild dementia due to Alzheimer’s disease | Public healthcare payer | 11,663 | 29,158 | 74.5% |
| | Public healthcare and long-term care payer | 14,404 | 36,010 | 68.5% |