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[C2H2405] Summary of cost-effectiveness evaluation of brivaracetam (Briviact®)

1. Indications

Partial onset seizures of epilepsy with or without secondary generalization

2. Price of the drug

Brivaracetam for myelodysplastic syndrome with anemia has been reimbursed since August 2024 at JPY 373.30 for 25 mg and JPY 609.30 for 50 mg (as of February 2026). The price was calculated based on a similar efficacy comparison method, and the product was designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost–effectiveness evaluation

This product has been used to treat partial-onset seizures in epilepsy. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below:

Population	Partial onset seizures of epilepsy. (a) Patients receiving monotherapy (b) Patients receiving adjunctive therapy
Comparator	(a)(b) Levetiracetam

4. Evaluation of additional benefits

To evaluate additional effectiveness, a systematic review (SR) conducted by the manufacturer for population (a) identified no randomized controlled trials (RCTs) that directly compared brivaracetam and levetiracetam. No SR was conducted for

non-RCTs. As a result, for population (a), it was determined that no trials of sufficient quality existed for evaluation; thus, no additional benefits could be drawn. For population (b), seven studies examined the additional benefit of combination therapy with brivaracetam, although no RCTs directly comparing brivaracetam + drug therapy and levetiracetam + drug therapy were identified. Furthermore, the manufacturer conducted a frequentist network meta-analysis (NMA) after performing literature selection and outcome extraction based on prior studies and applying continuity correction to data with zero events. The manufacturer concluded that additional benefits were demonstrated based on point estimates of the complete seizure freedom rate and the treatment discontinuation rate due to adverse events. The academic group conducted an independent SR and determined that there were no RCTs or appropriate non-RCTs to evaluate the additional effectiveness for the population (a). The academic group determined that for population (b), additional benefit was demonstrated for "treatment discontinuation due to adverse events," while clear evidence demonstrating additional benefit for "seizure suppression" was lacking.

5. Results of cost-effectiveness analysis

The manufacturer conducted a cost-effectiveness analysis of the population (b) by constructing a Markov model to evaluate the cost-effectiveness of brivaracetam + drug therapy. The academic group identified several methodological issues in the analysis performed by the manufacturer and conducted a reanalysis. First, they conducted a reanalysis assuming that treatment effects on seizure suppression were null (OR=1.000). Second, the manufacturer estimated a higher treatment continuation rate for brivaracetam + drug therapy by directly comparing data obtained from RCTs and observational studies. In the academic group assessment, the treatment continuation rate for brivaracetam + drug therapy was estimated by multiplying the treatment discontinuation rate of levetiracetam + drug therapy by the treatment effect on "treatment discontinuation due to adverse events." Third, while the manufacturer modeled the "post-treatment" state as equivalent to "death," the academic group judged this approach to be inappropriate and applied the costs and quality of life (QOL) values for "non-responders." Fourth, the academic group conducted a reanalysis using QOL values obtained directly from patients in clinical trials (trials N01252, N01253, and N01254). The ECCEE accepted the following results:

Population	Comparator	Additional benefit	ICER (JPY/QALY)
(a) Patients receiving monotherapy	Levetiracetam	Impossible to analyze	Impossible to analyze
(b) Patients receiving adjunctive therapy	Levetiracetam	Proven	48,163,534