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[C2H2205] Valbenazine (Dysval)

1. Purpose of use

Tardive dyskinesia

2. Price of the drug

Valbenazine has been reimbursed since May 2023, and its drug price is JPY 2331.2 for Dysval® capsule 40mg as of September 2023. The price is determined based on the Similar Efficacy Comparison Method with a 5% premium. The product is designated as an item for the Cost-effectiveness Evaluation with H2 classification.

3. Scope of Cost-effectiveness Evaluation

Valbenazine is used to improve the symptoms of tardive dyskinesia, primarily caused as side effects of antipsychotic drugs. The scope of Cost-effectiveness Evaluation determined at the first session of the Expert Committee of Cost–Effectiveness Evaluation (ECCEE) is described below.

In treating patients with tardive dyskinesia, reducing dose of and discontinuing drugs for underlying disease such as antipsychotic drugs is considered first whenever possible. Therefore, the target population is "Tardive dyskinesia patients whose symptoms are not sufficiently improved by reducing dose of and/or discontinuing drugs for underlying diseases". The comparator is "watchful waiting" since treatment options are limited for the target population.

Target population	Tardive dyskinesia patients whose symptoms are not sufficiently improved by reducing dose of and/or discontinuing drugs for underlying diseases
Comparator	Watchful waiting

4. Evaluation of additional benefits

The manufacturer conducted a systematic review of randomized controlled trials to evaluate additional benefits of Valbenazine. Using identified articles, the manufacturer performed a mixed-model meta-analysis comparing Valbenazine and placebo as a substitute for the comparator, with the outcomes changes from baseline in Abnormal Involuntary Movement Scale (AIMS) score, AIMS responder rates (defined as rate of improvement of 50% from baseline in AIMS score), and changes from baseline in Clinical Global Impression of Change - Tardive Dyskinesia (CGI-TD) score.

As a result, for the case of Valbenazine 40mg/day, the changes in AIMS score were larger (mean difference -2.10[95%CI: -2.83, -1.38]), AIMS responder rates were higher (risk ratio 2.50[95%CI: 1.39, 4.49]), and the changes in CGI-TD scores were larger (mean difference -0.53 [95% CI: -0.77, -0.29]) for Valbenazine group. Valbenazine also significantly improved those outcomes for the case of Valbenazine 80mg/day. Based on the results, the manufacturer concluded that Valbenazine 40mg/day had additional benefits.

The academic group considered the analysis by manufacturer was acceptable for Valbenazine 40mg/day. Since the meta-analysis for Valbenazine 80mg/day included a trial with different dosage of Valbenazine, the academic group performed a meta-analysis excluding that trial.

Based on these results, the academic group concluded that Valbenazine had additional benefits.

5. Results of the cost-effectiveness analysis

The manufacturer conducted cost-utility analysis using a microsimulation model, which had health states set based on responses from interventions, prescription of antipsychotic drugs, and recurrence of underlying diseases.

In the academic analysis, the response rate of Valbenazine was revised according to the results of clinical trials for Valbenazine.

The ECCEE accepted the following:

Population	Comparator	ICER (JPY/QALY)
Tardive dyskinesia patients whose symptoms are not sufficiently improved by reducing the amount of and discontinuing drugs for underlying diseases	Watchful waiting	6,719,339