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[C2H2101] Summary of cost-effective analysis evaluation of galcanezumab (Emgality®)

1. Indication

Prevention of migraine attacks

2. Price of the drug

Galcanezumab has been reimbursed since April 2021 at JPY 44.943 for Emgality® Subcutaneous Injection Autoinjectors and at JPY 44,811 for Emgality® Subcutaneous Injection Syringes as of December 2022. The prices were determined based on the Cost Calculation Method. The products were designated as items for Cost-effectiveness Evaluation with H1 classification.

3. Scope of Cost-effectiveness Evaluation

The scope of Cost-effectiveness Evaluation determined in the first session of the Expert Committee on Cost–Effectiveness Evaluation (ECCEE) is described. The target populations were as follows: (a) episodic migraine patients who had failed /not tolerated one or two migraine preventive drugs, (b) chronic migraine patients who had failed /not tolerated one or two migraine preventive drugs, (c) episodic migraine patients who had failed/not tolerated three migraine preventive drugs, and (d) chronic migraine patients who had failed/not tolerated three migraine preventive drugs.

There were no significant differences in the 3 migraine preventive drugs in terms of efficacy. Therefore, as lomerizine is the most frequently used first-line treatment, the comparator for target populations (a) and (b) is a drug with a lower cost between propranolol and valproic acid (propranolol was chosen as a comparator in the cost-effectiveness analysis). The comparator for the target populations (c) and (d) is “Best Supportive Care” as treatment options for these populations are limited.

Target populations	(a) Episodic migraine patients that have failed/not tolerated 1 or 2 migraine preventive drugs (b) Chronic migraine patients that have failed/not tolerated 1 or 2 migraine preventive drugs (c) Episodic migraine patients that have failed/not tolerated 3 migraine preventive drugs (d) Chronic migraine patients that have failed/not tolerated 3 migraine preventive drugs
Comparators	Populations(a)(b)：Drug with a lower cost between propranolol and valproic acid (propranolol) Populations (c)(d): Best Supportive Care

4. Evaluation of additional benefits

The manufacturer used integrated patient data from five randomized controlled trials (CGAG, CGAH, CGAW, CGAI, and CGAN) to evaluate the additional benefits of galcanezumab based on the number of monthly migraine headache days (MHD). For populations (a) and (b), indirect comparison between galcanezumab and propranolol showed that the galcanezumab group had significantly fewer MHDs, respectively. For populations (c) and (d), the results of the meta-analysis comparing galcanezumab and placebo, which was a substitute for the Best Supportive Care, showed that the galcanezumab group had significantly fewer MHDs, respectively.

Based on the aforementioned results, the manufacturer concluded that galcanezumab had additional benefits to both propranolol and Best Supportive Care.

The academic group accepted the manufacturer’s conclusion.

5. Results of the cost-effectiveness analysis

The manufacturer performed a cost-effectiveness analysis using a Semi-Markov model. The utility values used in the model were generated by mapping the scores of the Migraine Specific Questionnaire to those of EQ-5D-3L. The mapping algorithm was created using the U.K. tariff, which may underestimate the utility values for Japanese patients. While the academic group considered that utility values measured in clinical trials should be used, it used the mapped values adjusted for the difference in the EQ-5D-3L tariffs between the U.K. and Japan under an order from the ECCEE. In addition, the frequency of hospitalization and

the drug price were changed in the academic analysis.
The ECCEE accepted the following:

Population	Comparator	ICER (JPY/QALY)
(a) Episodic migraine patients that have failed/not tolerated 1 or 2 migraine preventive drugs	Propranolol	11,060,803
(b) Chronic migraine patients that have failed/not tolerated 1 or 2 migraine preventive drugs	Propranolol	5,371,334
(c) Episodic migraine patients that have failed/not tolerated 3 migraine preventive drugs	Best Supportive Care	5,741,268
(d) Chronic migraine patients that have failed/not tolerated 3 migraine preventive drugs	Best Supportive Care	3,459,856