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[C2H2103] Summary of cost-effectiveness evaluation of polatuzumab vedotin-piiq (POLIVY)

1. Indications

Patients with relapsed or refractory diffuse large B-cell lymphoma

2. Price of the drug

Polatuzumab vedotin-piiq has been reimbursed since May 2021 at JPY 298,825 for 30 mg and JPY 1,364,330 for 140 mg (as of January 2023). The price was calculated using a similar efficacy comparison method (I), with a usefulness premium (II) and a 5% premium to promote the development of new drugs and eliminate off-label use. This product was designated as the H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for treating patients with relapsed or refractory diffuse large B-cell lymphoma. The evaluation scope, which was agreed upon during the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE), is described below.

Population	Patients with relapsed or refractory diffuse large B-cell lymphoma receiving; (a) second-line therapy (b) third- or more line therapy
Comparator	The most cost-effective regimen in salvage chemotherapies, including rituximab.

4. Evaluation of additional benefits

The manufacturer identified salvage chemotherapy and a combination of bendamustine and rituximab (BR)—the comparator in the GO29365 study—as potential comparators. Assuming a comparable efficacy, they selected R-ICE as the comparator, as it is the least expensive option. The manufacturer conducted a systematic review and identified only the GO29365 study as a suitable source to

evaluate the additional benefits. This study was a randomized, multicenter, open-label trial that compared the efficacy and safety of polatuzumab vedotin combined with BR in patients with relapsed or refractory diffuse large B-cell lymphoma. The manufacturer reanalyzed the GO29365 study data for subpopulations (a) and (b) and claimed additional benefits for overall survival and progression-free survival (PFS).

The GO29365 study showed an imbalance between the polatuzumab vedotin and BR groups in terms of prognostic factors at baseline, potentially favoring the polatuzumab vedotin group. The academic group expressed concerns but agreed to use it for additional benefit evaluation.

5. Results of the cost-effectiveness analysis

The manufacturer performed a cost-effectiveness analysis using partitioned survival analysis. Although R-ICE was selected as the comparator chemotherapy, several clinical parameters were obtained from the GO29365 study.

After modifying the parameters of quality of life (QOL) values and drug prices, the academic group conducted a cost-effectiveness analysis for populations (a) and (b). The manufacturer used the QOL values converted from the SF-36 score to the EQ-5D, whereas the academic group applied the EQ-5D-3L as a preference-based measure. To consider age-related reductions in QOL values, the manufacturer applied different QOL values for PFS health status in patients aged over and under 70 years. However, the academic group determined that progressive disease (PD) status and detailed age should also be considered for an age-related reduction in QOL values. It used QOL values for each PFS and PD health status every 10 years. The ECCEE accepted the following results:

Population	ICER (JPY/QALY)
(a)Patients with relapsed or refractory diffuse large B-cell lymphoma receiving second-line therapy	3,316,899
(b)Patients with relapsed or refractory diffuse large B-cell lymphoma receiving third- or more line therapy	6,629,399