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[C2H2307] Summary of cost-effectiveness evaluation of epcoritamab (EPKINLY)

1. Indications

For the treatment of relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma, high-grade B-cell lymphoma, and primary mediastinal large B-cell lymphoma) or relapsed or refractory follicular lymphoma

2. Price of the drug

Since November 2023, Epcoritamab has been reimbursed at JPY 137,724 for 4 mg and JPY 1,595,363 for 48 mg (as of April 2025). The price was calculated using a similar efficacy-comparison method (I), with a usefulness premium (II) and a 10% premium to promote the development of new drugs and eliminate off-label use. This product was designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for treating patients with relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma, high-grade B-cell lymphoma, and primary mediastinal large B-cell lymphoma) or relapsed or refractory follicular 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 large B-cell lymphoma (diffuse large B-cell lymphoma, high-grade B-cell lymphoma, and primary mediastinal large B-cell lymphoma) or relapsed or refractory follicular lymphoma
Comparator	The least expensive regimen in salvage chemotherapies

4. Evaluation of additional benefits

The manufacturer primarily based its arguments on the results of a matching-adjusted indirect comparison (MAIC) using individual patient data from the EPCORE NHL-1 trial and aggregate data from the SCHOLAR-1 trial. The manufacturer argued the additional benefits of epcoritamab based on the MAIC analysis, which indicated

that epcoritamab had a statistically significant effect on the overall survival (OS) relative to salvage chemotherapy. The Academic Technology Assessment Group (ATAG) accepted the manufacturer's arguments of the additional benefits based on these results while acknowledging several methodological challenges, including the high uncertainty associated with unanchored MAIC, biases inherent in single-arm trial designs, and strong assumptions regarding effect modifiers and prognostic factors.

5. Results of cost-effectiveness analysis

The manufacturer employed a "partitioned survival analysis" model, which comprises three health states: progression-free survival (PFS), post-progression survival, and death. The R-ICE regimen was selected as the least-expensive salvage chemotherapy regimen for comparison. The manufacturer's model assumed that patients who maintained PFS for three years would achieve long-term remission, and that patients in long-term remission would have utility values equivalent to those of the general population. The ATAG determined that these assumptions might not accurately reflect clinical reality and thus modified the analysis by setting the utility value for long-term remission equal to that of the PFS state and adopting a mixture-cure model for survival curve extrapolation. The ECCEE accepted the following results:

Population	ICER (JPY/QALY)
Patients with relapsed or refractory large B-cell lymphoma (diffuse large B-cell lymphoma, high-grade B-cell lymphoma, and primary mediastinal large B-cell lymphoma) or relapsed or refractory follicular lymphoma	10,058,394