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July 11th, 2023

[C2H2114] Summary of cost-effectiveness evaluation of enfortumab vedotin (PADCEV®)

1. Indication

Radically unresectable urothelial carcinoma that has progressed after cancer chemotherapy

2. Price of the drug

Enfortumab vedotin (EV) has been reimbursed for 30 mg since November 2021, and the drug was priced at JPY 99,593 as of February 2023. The price was calculated using a similar efficacy comparison method (I), with a 10% usefulness premium (II) and a price maintenance premium. This product was designated as the H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product has been indicated for treating radically unresectable urothelial carcinoma that has progressed after cancer chemotherapy. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below. The target population comprised adults with locally advanced or metastatic urothelial carcinoma who have had platinum-containing chemotherapy and an immune checkpoint inhibitor. Paclitaxel was selected as a comparator for the target population because it is less expensive.

Population	Adults with locally advanced or metastatic urothelial carcinoma who have had platinum-containing chemotherapy and an immune checkpoint inhibitor
Comparator	Select the less expensive paclitaxel and docetaxel

4. Evaluation of additional benefits

The results of EV-301, a phase III trial of enfortumab vedotin, showed that the median (95% confidence interval) overall survival (OS) in the EV group was 12.88 months (10.58–15.21), compared with 8.97 months (8.05–10.74) in the chemotherapy group, with a hazard ratio (HR) for death of 0.70 (0.56–0.89). Median (95% confidence interval) progression-free survival (PFS) was 5.55 months (5.32–5.82) in the EV group and 3.71 months (3.52–3.94) in the chemotherapy group, with

HR for progression or death of 0.62 (0.51–0.75). The HR in the EV-301 study was similar to that for paclitaxel obtained from the manufacturer's subgroup analysis of the EV-301 long-term follow-up data. The academic group concluded from the results of the EV-301 trial that EV has an additional benefit over paclitaxel because EV statistically significantly prolongs OS and PFS compared to chemotherapy.

5. Results of the cost-effectiveness analysis

The manufacturer performed a cost-effectiveness analysis using a partitioned survival analysis model. The academic group considered the methodology to estimate the OS and PFS for paclitaxel and the time horizon. Finally, the academic group accepted the manufacturer’s results. The ECCEE accepted the following result:

Population	Comparator	ICER (JPY/QALY)
Adults with locally advanced or metastatic urothelial carcinoma who have had platinum-containing chemotherapy and an immune checkpoint inhibitor	Paclitaxel	20,230,363