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[C2H2402] Summary of cost-effectiveness evaluation of capivasertib (Truqap®)

1. Indications

Hormone receptor-positive, HER2-negative unresectable or recurrent breast cancer with one or more PIK3CA/AKT1/PTEN-alteration

2. Price of the drug

Capivasertib (Truqap ®) has been reimbursed from May 2024 at JPY 11116.2 for 160 mg, and JPY 13493.2 for 200 mg (as of November 2025). The price was calculated based on a similar efficacy comparison method (I) and this product was designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for the treatment of adult patients with hormone receptor-positive, HER2-negative unresectable or recurrent breast cancer with one or more PIK3CA/AKT1/PTEN-alteration. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

Population	Hormone receptor-positive, HER2-negative unresectable or recurrent breast cancer with one or more PIK3CA/AKT1/PTEN-alteration
Comparator	Fulvestrant plus a CDK4/6 inhibitor with the lowest price

4. Evaluation of additional benefits

As no randomised controlled trials (RCTs) have directly compared capivasertib

with comparators, the manufacturer conducted a network meta-analysis (NMA). For progression-free survival (PFS), the NMA using 10 trials estimated a hazard ratio (HR) of 0.53 (95% confidence interval [CI]: 0.33-0.85) for capivasertib plus fulvestrant versus fulvestrant plus abemaciclib, demonstrating statistically significant PFS prolongation. For overall survival (OS), the NMA using 5 trials estimated an HR of 0.78 (95% CI: 0.43-1.43) versus fulvestrant plus palbociclib, showing no statistically significant difference. The manufacturer concluded that capivasertib had additional benefits.

The academic group conducted a systematic review and identified four trials: CAPItello-291, postMONARCH, PACE, and MAINTAIN. For the base-case analysis, academic group excluded PACE and MAINTAIN, which evaluated CDK4/6 inhibitor continuation, and performed an indirect comparison using postMONARCH, which assessed the switch strategy. The analysis yielded an HR of 0.53 (95% CI: 0.33-0.86) for PFS, demonstrating a statistically significant improvement. As OS data were immature in postMONARCH, the academic group did not use OS to determine additional benefits. The academic group concluded that capivasertib plus fulvestrant demonstrated additional benefits compared to fulvestrant plus abemaciclib. In the scenario analysis, additional benefits were also demonstrated for exemestane plus everolimus.

5. Results of the cost-effectiveness analysis

In the cost-effectiveness analysis, the manufacturer employed a partitioned survival model comprising three health states—progression-free, post-progression, and death. In the academic group analysis, given that the postMONARCH trial demonstrated a statistically significant improvement in PFS for fulvestrant plus abemaciclib compared with fulvestrant monotherapy, a corresponding benefit in OS was inferred. To address uncertainty surrounding OS estimations, the academic group conducted sensitivity analyses in which the OS hazard ratio for fulvestrant plus abemaciclib versus fulvestrant was varied between 0.85 and 1.02, supplementing the base-case analysis that assumed a hazard ratio of 0.95.

Furthermore, in addition to the aforementioned OS estimations, the academic group applied the most recent drug prices and excluded the cost of genetic testing from the analysis. The ECCEE subsequently endorsed the results.

[Population	Comparator	ICER (JPY/QALY)
Hormone receptor-positive, HER2-negative unresectable or recurrent breast cancer with one or more PIK3CA/AKT1/PTEN-alteration	Fulvestrant plus a CDK4/6 inhibitor with the lowest price	13,994,792