国立保健医療科学院　保健医療経済評価研究センター
Center for Outcomes Research and Economic Evaluation for Health (C2H), National Institute of Public Health (NIPH) | URL: http://c2h.niph.go.jp

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[C2H2002] Summary of cost-effectiveness evaluation of cabozantinib (cabometyx®)

1. Indications

・Unresectable or metastatic renal cell carcinoma (RCC)

・Hepatocellular carcinoma (HCC) in patients who have previously been treated by chemotherapy.

2. Price of the drug

Cabozantinib has been reimbursed since May 2020 at JPY 8007.6 for 20mg and JPY 22,333.00 for 60mg (as of June 2022). The price is calculated using a similar efficacy comparison method (I), with a usefulness premium (II) of 10%. This product is designated as an H1 cost–effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for metastatic RCC or HCC. Hereafter, the scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described.

Population	[RCC] Patients with unresectable or metastatic renal cell carcinoma who receiving (A) First-line therapy (intermediate or high risk by IMDC classification) (B) Second-line or subsequent therapy (after the treatment by anti-VGFR inhibitor) [HCC] Second-line or subsequent therapy

Comparator	[RCC] (A) Sunitinib (B) Everolimus and Axitinib [HCC] Regorafenib

4. Evaluation of additional benefits

[RCC] As a results of systematic review, randomized CABOSUN trial for population (a) and randomized METEOR trial for population (b) was detected. METEOR trial compared cabozantinib with everolimus. In the CABOSUN trial, cabozantinib significantly extended PFS. Based on it, the academic group concluded that cabozantib has an additional benefit compared with sunitinib. In the METEOR trial, superiority of cabozantinib to everolimus was shown. On the other hand, to evaluate additional benefit to axitinib, indirect comparison was used. As a result, the manufacturer and the academic group concluded cabozantinib has an additional benefit compared with axtinib. For indirect comparison, the manufacturer perform network meta-analysis using METEOR trial, RECORD-1 trial, TARGET trial and AXIS trial. However the academic group it is not appropriate to include TARGET trial because crossover is permitted. Instead, the academic group assumed everolimus has the same effectiveness with axitinib.

The third session of the ECCEE concluded that the results of the academic group are more appropriate.

[HCC] As a result of systematic review, CELESTIAL trial which compares cabozantinib with placebo was detected. In addition to CELESTIAL trial, RESORCE trial which compared regorafenib with placebo was used for indirect comparison. As a result, the manufacturer concluded cabozantinib has no additional benefit to regorafenib. The academic group agreed with the manufacturer’s conclusion.

5. Results of the cost–effectiveness analysis

The manufacturer performed cost-effectiveness analysis for RCC using partition survival model. Cost-minimization analysis was applied to the HCC population. The manufactures’ analysis is basically acceptable and the drug price was renewed by the academic group.

Population	Comparator	ICER (JPY/QALY)
RCC (a) first line	Sunitinib	6,074,752
RCC (b) second line	Everolimus	5,064,156
	Axitinib	6,268,535
HCC	Regorafenib	Cost-saving