

Another Hurdle in Anticancer New Drug Listing in Korea – Setting the Reimbursement Scope

Sungju Kim, Eileen J. Shin, Jinhwan Chung (Lee & Ko, Seoul, Korea)

* sungju.kim@leeko.com



BACKGROUND

Since the adoption of the positive listing system (PLS) as a measure for optimizing drug expenses, new drug listing in Korea requires the applicable reimbursement criteria are first determined, and thereafter, that cost-effectiveness is proven within such criteria^{1,2}. Reimbursement criteria are determined within the scope of the regulatory approval, and for high-cost treatments, the reimbursement criteria are often narrower than regulatory approval, based on overseas Health Technology Assessment results, guidelines and etc. Anticancer drugs and non-anticancer drugs are categorized separately when the reimbursement criteria are established through expert advisory meetings.

OBJECTIVE

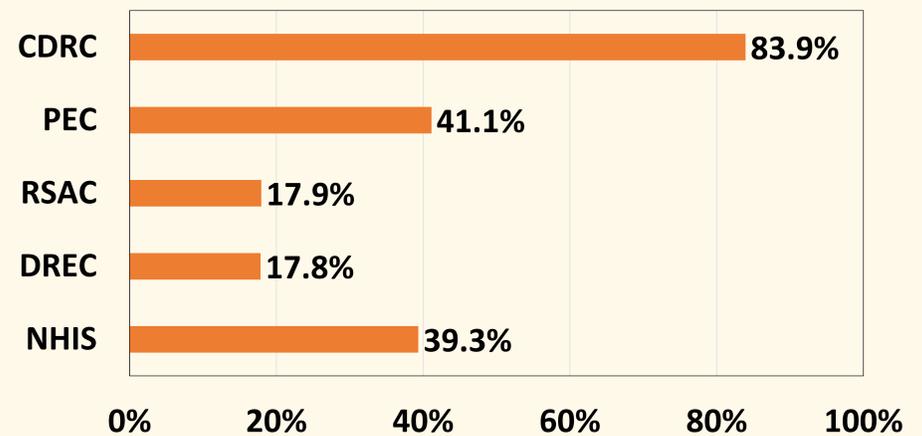
Since the introduction of the PLS in 2007, reimburseability of a new drug has been evaluated on the target patient group after establishing the reimbursement scope. However, there have been increasing concerns for decreased patient accessibility for innovative anticancer drugs due to the frequent failure in setting the reimbursement scope. This study analyzes the scope approval status for anticancer drugs.

METHODS

We conducted a survey pharmaceutical companies to assess the need for improvement in determining the reimbursement scope for anticancer drugs by the Cancer Disease Review Committee (CDRC)¹. The reimbursement scope approval rate was analyzed based on Health Insurance Review and Assessment Service's publicly disclosed CDRC results from January 2022 to June 2023³. The approval rate was determined based on drugs which were assigned reimbursement scope among all products submitted for review, and any duplicate drugs were treated as individual, and for multiple indications, reimbursement scope was deemed approved if any indication was assigned a scope.

RESULTS

A total of 56 respondents participated in the survey, and 83.9% responded that improvements are necessary in the CDRC decision making process [Figure 1]. 32 drugs were included in the analysis of the reimbursement scope approval rate, and the approval rate during the analyzed period was 41%. Among these, 31% (=10/32) drugs underwent duplicate reviews, and 25% (=8/32) had multiple indications <Table 1>. The time from regulatory approval to submission for the 1st CDRC review took a median of 183 days (range: 41-5,489), and the median time from reimbursement scope approval to listing was 337 days (range: 199-402).



CDRC: cancer disease review committee; PEC: pharmacoeconomic evaluation committee; RSAC: risk-sharing agreement committee; DREC: drug reimbursement evaluation committee; NHIS: national health insurance service.

Figure 1. Survey results pertaining to the need for improving the P&R evaluation process for anticancer drugs (N=56).

There have been criticisms from the pharmaceutical industry that the CDRC excessively focuses on price and financial impact when establishing the reimbursement criteria. Critics have pointed out that, since there is a separate committee responsible for evaluating cost-effectiveness and financial impact after the setting of the reimbursement criteria, CDRC should instead focus on determining the Reimbursement Criteria corresponding to clinical evidence¹.

Table 1. Reimbursement criteria approval rate and time to CDRC submission

	N	Criteria approval rate	Time to CDRC Submission from Regulatory Approval – Median (range), unit: days
Including repeat review products	32	13 (41%)	229 (41 - 5,439)
Initial review products	22	8 (36%)	183 (41 - 5,439)

In the case of multi-indication products, the product was deemed as having obtained reimbursement criteria if reimbursement criteria has been set for only one indication. As such, had the reimbursement criteria approval rate been reviewed on an indication-by-indication basis, the approval rate would be lower.

CONCLUSIONS

PLS is a system that selectively lists new drugs which prove cost-effectiveness. In order to assess cost-effectiveness, it is necessary to determine the target patient population, however, evaluations are frequently stalled due to the failure to set reimbursement scope. To improve patient accessibility, there is a need for standardizing the evaluation criteria for better predictability and increased approval rate.

References

- Kim S et al. An Industry Survey on Unmet Needs in South Korea's New Drug Listing System. *Ther Innov Regul Sci*. 2023 Jul;57(4):759-768.
- Kim S et al. Trends in the pricing and reimbursement of new anticancer drugs in South Korea: an analysis of listed anticancer drugs during the past three years. *Expert Rev Pharmacoecon Outcomes Res*. 2021 Jun;21(3):479-488.
- [HIRA website] <https://www.hira.or.kr/main.do>