Abstract

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Title of Thesis: **The budget impact and cost-effectiveness thresholds in the context of other criteria in reimbursement decision making of medicinal products**

KEY WORDS: cost-effectiveness analysis, Willingness to pay threshold, medicines, MCDA – multi-criteria decision analysis

OBJECTIVES: The aim of this study was to provide a structured overview of selected criteria that are / may be key to adopt new innovative technology in the reimbursement system, based on a retrospective analysis of selected decisions of the State Institute for Drug Control. It was investigated the relationship between the individual criteria (and scoring results) coming from the multi-criteria analysis and the value of ICER and BIA, for these medicinal products entering the reimbursed system.

METHODS: Retrospective analysis of selected legally closed, published and publicly available administrative proceedings of the State Institute for Drug Control in the period January 2020 – May 2021. A total of 20 administrative proceedings were selected for the final analysis, of which 12 medicinal products that were selected, entered the permanent reimbursement and the other 8 medicinal products reimbursed as so-called VILP1– i.e., entered the system as temporary reimbursed in the 1st period and at the same time all met the criteria of VILP (highly innovative medicinal product). Based on the theoretical part, a set of 9 criteria was selected, which was then used to evaluate individual products (interventions) in selected administrative proceedings. According to the information obtained from the analysis of administrative proceedings, a point score (coefficient) was given to each selected criterion. Each score coming from the individual criteria was sum up to obtain the final score characterizing the each evaluated intervention.

RESULTS: The highest possible total score that the medicinal product could achieve was 21. The results of the total score for the medicinal products evaluated as VILP did not differ so much (total score between 10 and 13), while for the 12 medicinal products that entered the permanent reimbursement system, there were higher deviations (total score between 7 and 13). However, it might be misleading to fully assess significance and relationship between the final publically available values of ICERs and BIAs, with other selected criteria, as these values (ICER, BIA) did not take into account non-public discounts, financial arrangements and other risk-sharing agreements) between the manufacturer and the health insurance company for the evaluated or compared intervention. This information was part of a trade secret.

CONCLUSION: Assessment/ Appraisal of added value for interventions through other criteria (in addition to the results of CEA, BIA), i.e., with via multi-criteria decision analysis (MCDA) can be a useful additional tool for reimbursement decision making process. This MCDA tool might be in particularly useful for interventions with the absence of robust clinical data to create cost-effectiveness analyses, resp. given the small target population treated (e.g., orphan drugs), and thus the high cost of the therapy itself, these interventions would not meet the standard willingness-to-pay threshold.

This retrospective study might support to set up a framework for the evaluation and subsequent interpretation of other criteria under which innovative drugs/ interventions could enter the reimbursed system in the Czech Republic. The objective of next research might be cultivation of methodology with regard to use of scoring system and its rules or the use of weights for individual criteria.