PRESS RELEASE

Health-Apps on prescription?

Health insurance providers lack consistent criteria to decide on the benefits and reimbursement of health apps

Austrian Institute for Health Technology Assessment (AIHTA) publishes guidance on evidence-based evaluation of health apps

Vienna, December 2020: Health insurance funds lack clear, coordinated criteria according to which they can assess the benefits of health apps and thus assume costs. The Austrian Institute for Health Technology Assessment (AIHTA) has therefore published a guidance for orientation based on a critical analysis of six existing concepts and eleven apps. The analysis shows that a proof of effectiveness is demanded differently in different countries. In only a few cases, clear requirements are set for such studies that could prove a health benefit of the apps.

Health apps are on everyone's smartphones: there are already several hundred thousand different ones. The spectrum of services ranges from passive monitoring of bodily functions (e.g. blood sugar, heart rate measurement) to reminder apps for taking medication (e.g. antidepressants) to diagnostic tools for skin changes (e.g. melanoma). Depending on the potential risk associated with the use of the app, clinical studies may (e.g. melanoma diagnostics) or may not be required (e.g. pedometers) for approval. The proof of their benefit for reimbursement decisions by the health insurance funds, on the other hand, is currently regulated inconsistently in the best case or not at all in the worst case. The health insurance funds lack a sound basis on which to decide whether to cover the costs of the utilization of apps. Developers also do not know exactly what requirements their apps are required to fulfil for this purpose. AIHTA has now come up with an initial guidance for orientation to remedy this situation.

Six methodoogy papers from internationally renowned institutes served as the basis for the analysis of AIHTA, in which approaches were proposed to support the decision-making of health insurance funds. In addition, eleven apps were identified for which national health insurance funds in Germany, the Netherlands or Belgium are already reimbursing the fees. "Here, digital progress has clearly overtaken the health system in Europe", summarises Priv. Dr. Claudia Wild, Director of AIHTA, the results of the analysis. "Neither nationally nor internationally are there any coordinated and standardised criteria for how the benefits of a health app are to be assessed and to be proven. This means that no evidence-based coverage of fees for utilization by the health insurance funds is possible". While the efficacy of drugs or devices has to be proven for approval and strict protocols for the design and the course of (clinical) studies have to be followed, such a strict requirement for health apps is currently completely missing. "The Medical Devices Regulation, which will apply to the European market in 2021, does improve the situation somewhat, but it also provides only initial guidance on the evaluation of apps," emphasises Dr. Wild. With the analysis of the proposals (frameworks) of other health technology assessment organisations in Belgium, Germany, England, France and the Netherlands, AIHTA now shows a possible way (out) for Austria.

In fact, of the six frameworks examined, the AIHTA team found only one case where health apps were classified according to risk classes. Just as few cases included aspects of artificial intelligence, the basis of many health apps and being applied ever more often. Suggestions on how to design studies for a proof of benefit of apps were only available in four of the six frameworks. "All in all, we

found an extremely heterogeneous picture," Dr. Wild summarizes. "However, the British National Institute for Health and Care Excellence "NICE" provided a ray of hope, both by suggesting study designs and by clearly calling for a classification according to risk classes for health apps. It therefore also served as a role model for our recommendations."

In these recommendations to Austrian health insurance providers and decision makers, AIHTA favours the combination of several frameworks and recommends a stepped approach. In a first step, the CE marking required for medical devices should be reviewed and the health apps should be classified according to risk classes. Subsequently, according to the AIHTA recommendation, the NICE framework should be used as a guideline with regard to risk classes and the corresponding evidence requirements, and at the same time any existing evidence of effectiveness should be searched for and documented. The final evaluation should then consider health technology assessment aspects and be based on expectations regarding effectiveness and consequences. In view of the novelty of such an evaluation process, AIHTA recommends starting with a pilot phase that allows for later adaptation.

Overall, AIHTA points to an acute need for catching up in the healthcare system due to the rapid spread of digital health applications. The focus on verifiable evidence and health technology assessment criteria in remedying this deficiency would ensure an objective and thus fair approach for all parties involved - the health system, patients and developers. Current efforts at national level are already pointing in this direction.

Original publication:
Jeindl R, Wild C. (2020): Framework for reimbursement decisions of digital health technologies (mHealth) and its (retrospective) application on selected examples. HTA-Projektbericht 134. Vienna: HTA Austria – Austrian Institute for Health Technology Assessment GmbH. https://eprints.aihta.at/1279

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