PP112 Reimbursement Decisions for Medical Services in Austria: An Analysis of Influencing Factors for the Hospital Individual Services Catalogue

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Introduction. This study aims to (i) describe the (evidence-based) reimbursement process of hospital individual services, (ii) evaluate the accordance between evidence-based recommendations and reimbursement decision of individual services and (iii) elaborate potential aspects that play a role in the decision-making process in Austria.
Methods. The reimbursement process is described based on selected relevant sources such as official documents. Evidence-based recommendations and subsequent reimbursement decisions for the annual maintenance of the hospital individual service catalogue in Austria between 2008 and 2020 were analyzed using a mixed methods approach, encompassing descriptive statistics and a focus group with Austrian decisionmakers.
Results. One hundred and eighteen evidence-based recommendations were analyzed. There were 93 (78.8%) negative and 25 (21.2%) positive evidence-based recommendations. In total, 107 out of 118 evidence-based recommendations (90.1%) did not lead to a deviating reimbursement decision. We identified six aspects that may have played a role in the decision-making process for the annual maintenance of the hospital individual service catalogue, with clinical evidence being the most notable. Further aspects included quality assurance/organizational aspects (i.e., structural quality assurance), costs (if comparable to already existing medical services, not: cost-effectiveness), procedural aspects (e.g., if certain criteria for adoption have not been met formally through the proposals), "other countries" (i.e., taking into account how other countries decided) and situational aspects (such as the COVID-19 pandemic).
Conclusions. There is good accordance between evidence-based recommendations and reimbursement decisions regarding hospital individual services in Austria. Beyond clinical evidence, organizational aspects seem to be considered often with regard to quality assurance but costs do not appear to play a major role. The Austrian system has mechanisms in place that can restrict widespread adoption of novel hospital individual services with uncertain clinical benefits. Future studies could investigate how well these mechanisms work and how they compare to other health systems in Europe.

PP113 Reimbursement Of Oncology Therapies With Limited Clinical Evidence In The Netherlands

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Introduction. The number of novel therapies that achieve registration in oncology based on limited clinical evidence like non-randomized studies (NRS) is increasing. Dutch health authorities determine the therapeutic value of medicines evaluated in randomized controlled trials based on formal criteria for minimal relative efficacy or clinical treatment guidelines. However, there are no criteria to determine the therapeutic benefit of treatments assessed in NRS, which impacts reimbursement and patient access. Additionally, clinicians in the Netherlands see potential clinical benefit in off-label use but are currently unable to prescribe these because of absent clinical evidence.
This review aims to identify and summarize initiatives to improve patient access to oncology therapies with limited or no clinical evidence in the Netherlands.
Methods. Relevant public reimbursement documents for the Netherlands were identified through a pragmatic literature review.
Results. The main initiatives to improve access for therapies with limited clinical evidence are outside regular reimbursement pathways.
The Drug Rediscovery Protocol (DRUP, initiated 2016) and drug access protocol (DAP, initiated 2021) are two initiatives to improve access in solid tumor oncology. DRUP collects real-world data and provides access for targeted therapies in patients with targetable mutations in off-label indications. At least 25 therapies have been included to date.
DAP uses the same data framework to reimburse on-label solid tumor therapies through a managed entry agreement based on response. The first participating therapies are cemiplimab (NRS, failed ZiN reimbursement), entrectinib and larotrectinib (both NRS, tumor-agnostic).
Finally, Dutch clinical experts proposed criteria for therapeutic value of therapies studied NRS in oncology.
Conclusions. Patient access to both off-label and on-label oncology therapies is addressed in DRUP and DAP. New criteria for the therapeutic value of therapies studied in NRS may decrease the relevance of DAP, although these criteria would not address the need for comparative evidence for cost-effectiveness analysis.

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