Conclusions. At a societal WTP of THB 160,000 per QALY gained (USD 5,197 per QALY gained), dolutegravir for HIV patients resistant to first- and second-line ARTs in Thailand was found to be not cost-effective.

PP14 Budget Impact Of Sapropterin Dihydrochloride For Phenylketonuria

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Introduction. The National Committee for Health Technology Incorporation (CONITEC) evaluates health technologies to recommend their inclusion or exclusion within the Brazilian Public Health System (SUS), and uses the budget impact assessment to estimate costs to the system. The Ministry of Health (MS) guideline recommends treatment of phenylketonuria (PKU) with restricted phenylalanine diet and phenylalanine-free amino acid formula (PFAAf) supplementation. CONITEC evaluated the inclusion of sapropterin dihydrochloride for PKU in the SUS.

Methods. The population eligible for treatment was evaluated by the number of patients receiving PFAAf between 2014 and 2017 registered in the SUS. Patients were stratified by age/weight and a simple linear regression was performed to estimate the future population. The costs of treatment and testing the responsiveness of sapropterin dihydrochloride were estimated according to the recommended dosage guideline of the MS, leaflet and public purchasing prices. A univariate deterministic sensitivity analysis was performed to evaluate different prices, responsiveness test methods and variations in the reduction of formula use.

Results. The incorporation of sapropterin dihydrochloride would generate an incremental budget impact in the SUS of around BRL 79 million (USD 21.7 million) in 2019 and BRL 300 million (USD 82.1 million) in five years (2019-2023). The univariate sensitivity analysis estimated that the incremental budget impact could be between BRL 66 and BRL 103 million (USD 18 and USD 28 million) in the first year and between BRL 251 and BRL 388 million (USD 69 and USD 106 million) in five years. Sensitivity analysis showed that the price of sapropterin dihydrochloride was the most sensitive variable in the model.

Conclusions. The incorporation of sapropterin dihydrochloride in the SUS represents a significant budgetary impact and covers a small number of patients. Sapropterin dihydrochloride was recommended by CONITEC for the treatment of women with PKU, with a positive drug responsiveness test, and who are in the preconception period or in the gestational period.

PP20 Challenges In The Health Technology Assessment Of New/Emergent Non-Pharmacological Technologies

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Introduction. The methodological guides for the assessment of new/emerging non-pharmacological technologies differ from the traditional health technology assessment (HTA) guidelines developed by the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS). The aim of this study is to identify the special features and challenges of carrying out HTA on new/emergent non-pharmacological technologies.

Methods. The application of traditional and new/emergent HTA guidelines is compared along the consecutive evaluation phases in four practical cases carried out at the Agency for Health Quality and Assessment of Catalonia (AQuAS) in 2017-2018.

Results. Main learning and outstanding challenges: (i) Instead of following a defined protocol, the evaluations are carried out from a preliminary short report which generates a lack of justification and delimitation of its scope. (ii) References' identification and data extraction are often limited due to lack of studies, and sometimes require the use of grey literature or other sources less informative, for example, trial registries. It can be challenging to exclude references related to other indications. (iii) The assessment of resource use and costs of running the technology is complicated due to the lack of public prices information and specific impacts of use. (iv) The evidence considered during the assessment usually does not meet high quality requirements (risk of bias) because of indirect evidence, lack of comparator or no having clearly defined outcomes, among others. (v) It's difficult to draw conclusions and, consequently, recommendations due to abovementioned aspects and especially for the usual evidence gap that faces this type of technology in early stages of diffusion and/or in a competition situation of manufacturer companies.

Conclusions. The most recent innovation in non-pharmacological technologies merits a differentiated assessment approach. However, there is need to reconsider the methodology applied in order to overcome the challenges and limitations identified.

PP21 High Risk Class Medical Devices Evaluation In Germany: Another Arzneimittelmarkt-Neuordnungsgesetz?

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Introduction. In 2011 the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) evaluation process for new drugs was implemented in Germany. Since then, the evidence requirements follow high standards and results impact reimbursement price negotiations. More recently, in 2016, a legal norm (§137h SGBV) to evaluate new treatment and diagnostic methods (MDs) of high risk classes by the Federal Joint Committee (G-BA) was introduced. The requirements, involved stakeholders, timing and results for both processes are outlined and compared.

Methods. Methodological guidelines from G-BA and Institute for Quality and Efficiency in Health Care (IQWiG), consultations and evaluations for MDs according to §137h and for drugs according to AMNOG were reviewed and compared. Published assessment results were analyzed according the decision criteria and impact on price negotiations with Statutory Health Insurance.

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