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Title: REIMBURSEMENT OF FOODS FOR SPECIAL MEDICAL PURPOSES

PRODUCTS FOR PHENYLKETONURIA IN POLAND: A BUDGET IMPACT

**ANALYSIS** 

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**OBJECTIVES:** The aim of the analysis was to estimate the budget impact of including new foods for special medical purposes (FSMP) for phenylketonutria (PKU) on the reimbursement list in Poland. Patients with phenylketonuria must adhere to phenylalanine-restricted diet in order to prevent neurological impairment.

METHODS: In 2008 the reimbursement list in Poland included several FSMP; however, most of them were relatively old (basic portfolio). On the other hand, there were a lot of new PKU products not yet reimbursed (milupa pku2 prima, milupa pku2 secunda, milupa pku2 shake, milupa pku3 advanta, milupa pku3 shake, milupa pku3 tablets, Minaphlex, Lophlex, Easiphen, XP\_Maxamum). This analysis was performed from the public payer's perspective (National Health Fund). A 5-year time horizon was adopted (2009-2013). The prognosis was based on the assumption that the PKU products sales in Poland will increase at the same rate as in the past few years. The market shares of specific PKU products were estimated based on data obtained from other European countries (scenario 1) and a questionnaire survey (scenario 2). The base scenario, assuming no changes on the reimbursement list, was also defined. Total and incremental costs were calculated. Incremental costs were defined as the difference between scenario 1 (or scenario 2) and the base scenario.

**RESULTS:** In the base scenario the total cost related to reimbursement of PKU products would amount to 23.95 million PLN in 2009 and 25.82 million PLN in 2013. In scenario 1, the expenditure for PKU products would increase by 0.3 million PLN in 2009 and 1.4 million PLN in 2013. In scenario 2 the expenditure would increase by 0.9 million PLN in 2009 and 2.9 million PLN in 2013.

**CONCLUSION:** This analysis showed that reimbursement of new PKU products would be associated with an incremental cost of about 3 million PLN.