ACCESS TO INNOVATIVE ANTICANCER DRUGS IN THE OUTPATIENT SETTING IN LATVIA

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BACKGROUND

✓ Cost of cancer drugs increases rapidly and builds up to 10-20% of total direct costs for cancer treatment.

✓ The biggest financial impact on reimbursement budget comes from the inclusion of several high-cost innovative targeted drugs in the Positive list in adjuvant setting for common cancers such as lung, breast and colorectal cancer.

✓ Payers for healthcare in governmental institutions need to examine the efficacy of drugs as well as cost-effectiveness of innovative technologies.

✓ The trend towards greater patient demand and higher prices for innovative anticancer drugs present a significant challenge for regulatory authorities and payers in health care system.

OBJECTIVES

To review the clinical and pharmacoeconomic data on selected cancer drugs submitted for the inclusion in the positive list and to review the strategies used to raise patient access to new anti cancer agents.

METHODS

A retrospective analysis of clinical and pharmacoeconomic information submitted in year 2008 till 2010 by the holders of marketing authorization for decision making and strategies used by the Centre of Health Economics of Latvia to either support or refuse the reimbursement of innovative cancer drugs like Cetuximab for the treatment of head and neck cancer, Trastuzumab for the treatment of breast cancer and Bevacizumab fir the treatment of colorectal cancer.

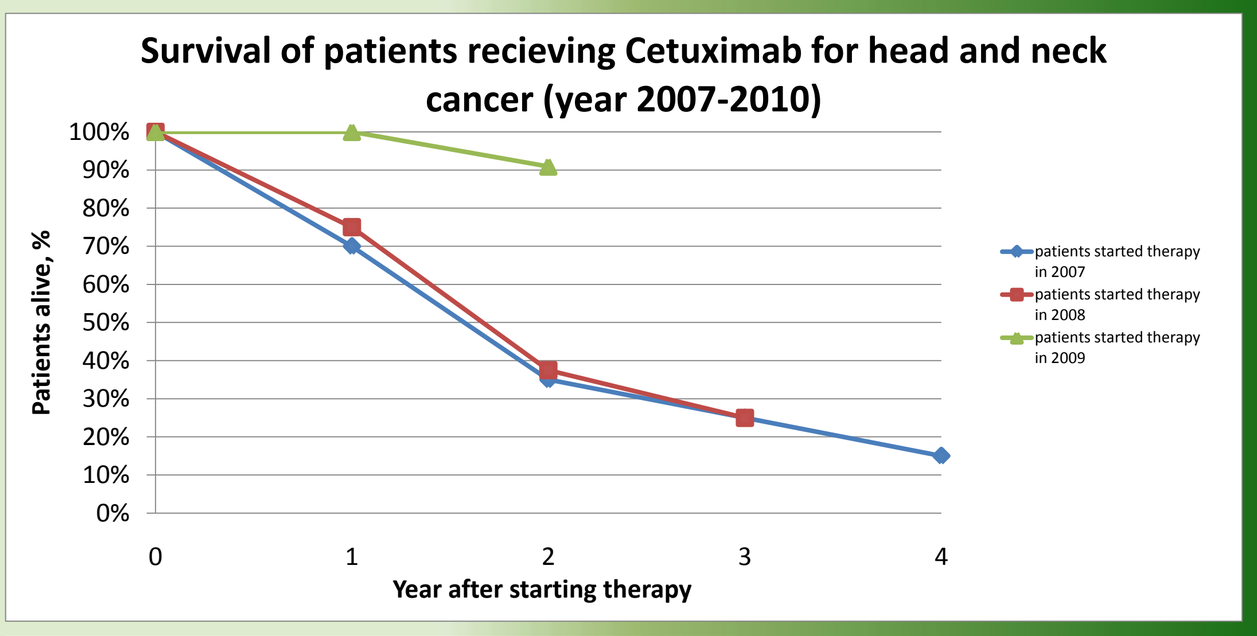
RESULTS

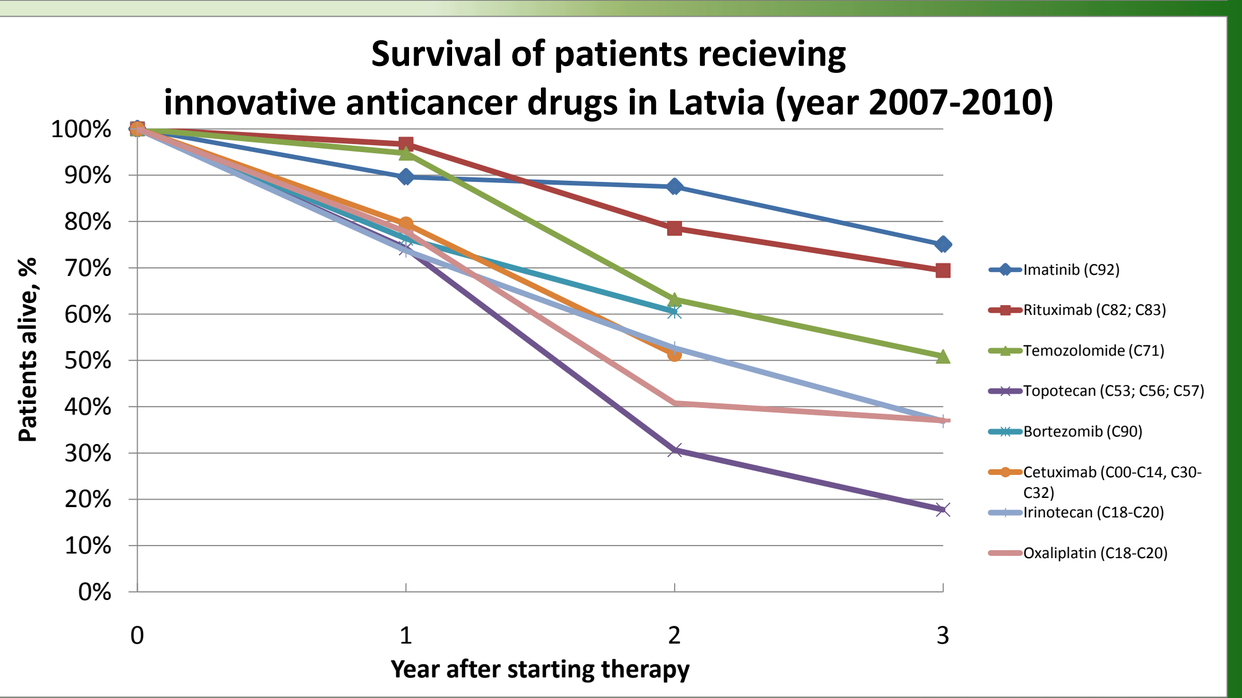
Monoclonal antibody **Cetuximab** was reimbursed in 2008 for the treatment of patients with head and neck squamous cell carcinomas in combination with irradiation. The incremental cost effectiveness ratio (ICER) per life year gained was 6 250 EUR.

A recombinant humanized monoclonal antibody **Trastuzumab** was included in the Positive list in 2010 for the treatment of patients with HER2 positive (IHC 3+), Grade II/III early breast cancer following surgery and within six weeks after adjuvant chemotherapy. ICER per life year gained was estimated within 19 500 and 35 100 EUR, depending on the model used for obtaining overall survival data.

Bevacizumab, a VEGF receptor inhibitor, was submitted for inclusion in the Positive list in 2010 for the treatment of patients with metastatic colorectal cancer in combination with fluoropyrimidine-based chemotherapy.

Because of cost-ineffectiveness (ICER per life year gained was more than 81 500 EUR) the appraisal was negative and inclusion of Bevacizumab was rejected.





LESSONS LEARNED

The decision about clinical and economic value of the new drugs was based on overall survival data from randomized, comparative phase III studies, as well as on pharmacoeconomic studies carried out by the holder of marketing authorization, the incremental cost-effectiveness ratio and price negotiations. The incremental costs have to be considered in context with gains in overall survival.

CONCLUSIONS

In the era of healthcare budget restrictions reimbursement with conditions does not solve the problem of patient access to new therapies because only a limited number of patients who meet the pre-set conditions will be able to receive therapy with the treatment.