

Preserving Survival Time (RPSFT) model were used as secondary analyses. The Inverse Probability of Censoring Weights (IPCW) method and the Cox model using treatment as a time-dependent covariate were used as sensitivity analyses. **RESULTS:** Overall, 71% of patients randomized to dexamethasone crossed over to bortezomib. The primary analysis led to a hazard ratio of 0.59 (95%CI: [0.32,0.86]) for bortezomib versus dexamethasone, compared to 0.77 (95%CI: [0.61,0.97]) using the ITT approach. The results of the secondary analyses were consistent with the primary analysis. The IPCW provided results, which were very sensitive to the choice of the time interval. Lastly, the Cox model with treatment as a time-dependent variable resulted in a counter-intuitive higher hazard ratio than the ITT analysis, consistent with results from simulation studies indicating this approach is biased. **CONCLUSIONS:** Adjusting for crossover led to a decrease of the hazard ratio from 0.77 to 0.59, and resulted in wider confidence intervals than the ITT analysis. Additional analyses are required to assess the performance of the IPCW method compared to the IPE algorithm and the RPSFT model under different scenarios.

#### Cancer – Cost Studies

##### PCN24

#### BUDGET IMPACT MODEL FOR RARE CANCER TREATMENT: CASE IN POINT CUTANEOUS T-CELL LYMPHOMA

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**OBJECTIVES:** Develop budget impact model to forecast total cost of treatment for cutaneous T-cell lymphoma (CTCL) for US public and private payer. **METHODS:** The clinical efficacy and safety data were obtained from the published pivotal study results. Costs of adverse events were estimated based on claims database analysis, AHRQ's HCUP and CMS Medicare 2009 databases. Drug cost was estimated based on 2011 AWP price. Epidemiology data were obtained from NCI-SEER and CDC databases. A budget impact model was implemented over a period of five years, based on a stable population and on different penetration and substitution rates of newly approved therapy. Model was developed in excel based format. Blinded Model design and outputs were tested with payers and KOLs. **RESULTS:** For rare cancers such as CTCL, the budget impact of treatment with targeted cancer therapies is in the range of \$460,000-\$530,000 per 1 million covered lives. The per patient per member (PPPM) budget impact of this treatment is 46-53 cents. Medical cost offsets were estimated but were insignificant compared to total cost of treatment. US payers rated PPPM output as the one of the most important relevant outputs of model. **CONCLUSIONS:** This budget impact model shows that new treatments for rare forms of cancer are likely to have minimal budget impact on payers. PPPM based outputs are more relevant to payers, than per patient treatment costs. However, an emerging concern is the total budget impact of all therapies indicated for ultra-orphan disorders, which might be an important consideration for future models.

##### PCN25

#### BUDGET IMPACT ANALYSIS OF SWITCHING TO DIGITAL MAMMOGRAPHY IN A BREAST CANCER POPULATION-BASED SCREENING PROGRAM

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**OBJECTIVES:** Digital mammography is costlier than screen film mammography but presents benefits at the technological and logistic level. The aim of this study was to analyze the budget impact and the health benefits of the introduction of digital mammography in a population-based breast cancer screening program. **METHODS:** A discrete-event simulation model was implemented including the processes under a breast cancer screening program and the natural history of breast cancer. The screening events included: invitation (biennial) of the target population (women aged 50-69 years), participation, screening test, confirmatory tests after a positive mammography result, cancer diagnosis and treatment. Natural history of breast cancer included the following health states: no cancer, pre-clinical (non symptomatic) cancer, clinical (or symptomatic) cancer and death. Digital and analogical mammography had the same sensitivity, but different specificities were applied according to type of mammography and also initial or successive screening. Results were collected during a 20-year screening scenario. **RESULTS:** A total of 90,575 women were screened under both techniques during the simulated 20 years. This population resulted in more than 262,500 screening mammograms. The recall rate was 5.9% under digital mammography and 6.4% under analogical mammography, while the numbers of confirmatory tests needed were 23,728 and 32,697, respectively. The cancer detection rate was 0.7% for both techniques. Digital mammography saved 1.909.167 euros in additional tests, while it was 1.026.807 euros more expensive in screening mammograms and presented similar costs of treatments. **CONCLUSIONS:** Results suggest that, although population-based breast cancer screening with digital mammography is costlier in terms of screening mammographies, it saves money in terms of additional tests needed. The health benefits are similar to those of conventional analogical mammography, but it reduces the number of additional tests needed, which represent a clear benefit to participating women.

##### PCN26

#### LONG-TERM FISCAL IMPLICATIONS OF MEPACT IN THE TREATMENT OF HIGH-GRADE NON-METASTATIC OSTEOSARCOMA: A BUDGET IMPACT MODEL AND A LIFETIME TAX PERSPECTIVE

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**OBJECTIVES:** The addition of MEPACT as an add-on treatment to adjuvant chemotherapy in the treatment of high-grade non-metastatic osteosarcoma after macroscopically complete surgical resection has been shown to significantly increase overall survival of young patients. This study assessed the costs (drug and administration) and the long-term financial impact on the UK (UK) government of introducing MEPACT. **METHODS:** Based on the cost of MEPACT and using survival rates derived from a clinical trial, we projected the net budgetary impact of MEPACT compared to no MEPACT. Further, we modelled the net tax contribution to the state of a surviving patient over a lifetime by subtracting direct government transfers that are made to the individual (child benefit, education etc) from the individual's gross tax contribution based on average anticipated earnings. **RESULTS:** Using UK incidence rates of osteosarcoma the model estimated approximately 54 newly diagnosed non-metastatic cases per year. Assuming that 38 doses of MEPACT (calculated from trial data) are added to the treatment regimen of 50% of patients at a cost of £91,189, the expected 1-year cost would be UK £3,972k compared with £1,450k had all patients been treated without MEPACT. Administration costs accounted for 3% of total costs. The lifetime discounted value of net taxes from a 14 year old patient treated with MEPACT is £79,000. The breakeven age, defined as the point at which the net tax contribution becomes greater than zero, is approximately 41 years. **CONCLUSIONS:** The additional budget impact due to MEPACT is mainly due to the cost of the drug. From the tax calculations, we conclude that investment in MEPACT does not negatively impact the long run fiscal budget of the UK government. Conversely, by taking a broader government perspective over an average lifetime, a surviving patient returns a positive net value to the State.

##### PCN27

#### BUDGET IMPACT ANALYSIS FOR CHRONIC MIELOID LEUKEMIA THERAPY IN BULGARIA

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**OBJECTIVES:** To evaluate the budget impact of nilotinib for newly diagnosed patients with chronic myeloid leukemia (CML) for the health care system in Bulgaria. **METHODS:** Current standard of therapy (imatinib) is compared with the newly authorized for sale nilotinib and dasatinib used as a first line therapy. Cost of yearly pharmacotherapy and adverse drug reactions management have been calculated for 3 years for different proportions of newly diagnosed patients with CML in chronic phase. The exchange rate is 1 BGN = 0.51 EUR. **RESULTS:** Clinical studies shows significant benefits from nilotinib but the question remains if it is worth the cost of therapy. Calculation of the yearly pharmacotherapy cost per 100 patients arranges the medicines in monetary value order as follows: 5,398,092 BGN for imatinib, 6,564,681 BGN for nilotinib, and 8,365,872 BGN for dasatinib. Weighted cost by the probability of appearing of the ADR is 733.26 BGN for imatinib, 509.75 for nilotinib, and 1,010.29 BGN for dasatinib. The relative share of patients treated with nilotinib in first line is 12% for the first year, 32% for the second, and 38% for the third year. The introduction of nilotinib will change the budget for all patients with CML to 6,895,316 in comparison with 6,725,246 BGN before the introduction, to 7,177,671 BGN in the second year, and to 7,262,378 BGN in the third year. Thus the over all increase for the observed 3 years will be within 179,044 BGN. **CONCLUSIONS:** The introduction of nilotinib as first line therapy for patients with newly diagnosed CML will lead to relatively small increase in the health care budget in Bulgaria compared to the clinical benefit in terms of achievement of deeper response, improvement of overall survival and less disease progression.

##### PCN28

#### CAPECITABINE FOR THE TREATMENT OF BREAST CANCER IN PRIVATE HEALTH SYSTEM IN BRAZIL: COST ANALYSIS BASED ON REAL WORLD DATA

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**OBJECTIVES:** Capecitabine (C) is approved in Brazil for the treatment of breast cancer (BC), 2nd or subsequent lines. In the private sector, it's not often used, due to the fact that health insurance plans (HI) do not offer coverage for oral (PO) chemotherapy (CHEMO), only for intravenous (IV). Our aim was to determine if the use of C could spare costs if adopted by HI. **METHODS:** We searched Evidencias Database for BC patients eligible for the use of C, in the year of 2008. This database has information from over 2 million of users of 14 HI. We identified the IV CHEMO actually used and the costs paid. Then, based on the data of each individual patient and in the length of use of CHEMO, we calculated the associated costs in a scenario where C replaced the IV CHEMO used. Also, we performed some sensitivity analysis based on different percentages of substitutions of IV by PO chemo. We considered only the prices of drugs. **RESULTS:** We found 518 BC patients eligible for C use. These patients received 3581 cycles of chemotherapy (Paclitaxel, Docetaxel, Gemcitabine, Vinorelbine, Doxorubicin). The total cost for these treatments were US\$ 5 364 000. If C replaced 100% of the IV CHEMO, the total cost would drop to US\$2,078,000, 62% smaller than the IV alternative. In a simulation, where 60% of the patients would use the IV option and 40% would use C, the total cost would also be smaller: US\$4,050,000, 25% smaller than when IV route is used exclusively. **CONCLUSIONS:** The adoption of C by HI in Brazil is cost-saving for BC patients.

##### PCN29

#### BUDGETARY IMPACT OF ADOPTION OF ERLOTINIB FOR LUNG CANCER IN THE PRIVATE HEALTH INSURANCE MARKET IN BRAZIL: A REAL WORLD DATA ANALYSIS