OBJECTIVES: Primary (first and subsequent cycles) prophylaxis with colony stimulating factors is recommended in the 2006 ASCO and EORTC clinical guidelines when the risk of febrile neutropenia (FN) is ≥20%. In clinical practice filgrastim has often been used for fewer than the recommended 11 days, which has been shown to compromise clinical outcomes. This study has evaluated, from an Italian perspective the cost-effectiveness of pegfilgrastim vs. filgrastim (11- or 6-days) primary prophylaxis in breast cancer patients receiving chemotherapy with ≥20% FN risk. METHODS: We constructed a decision-analytic model from a payer's perspective. Direct costs were taken from official price lists or literature data; they included: drugs, drug administration, FN-related hospitalizations and subsequent medical charges. FN risk (varied by days of filgrastim), FN case-fatality, relative dose intensity (RDI) of chemotherapy, its impact on survival, and utility scores were based on a comprehensive literature review and expert panel validation. Breast cancer mortality and all-cause deaths were obtained from official statistics. Model robustness was tested using multi-way sensitivity analyses. RESULTS: Pegfilgrastim appeared to be more effective and less expensive than 11- and 6-day filgrastim. The average cost, risk of FN (%), life expectancy and quality-adjusted life year (QALY) per person for pegfilgrastim, 11-day filgrastim, and 6-day filgrastim were €3316, 7%, 16.47 years, and 15.32 QALY; €5240, 12.5%, 16.41 years, and 15.27 QALY and €3630, 17.5%, 16.35 years, and 15.22 QALY, respectively. The results were sensitive to the relative costs of drugs and FN risk. Age and cancer stage had minimal impact. CONCLUSIONS: These preliminary data confirm that primary prophylaxis with pegfilgrastim may improve health outcomes and suggest that, in Italy, it could be cost-saving when compared with filgrastim (also for less than 11 days). A larger application of the sensitivity analyses will be necessary to further validate the model.

PCN18

A SENSITIVITY ANALYSIS OF THE COST PER QUALITY ADJUSTED LIFE YEAR (QALY) OF TRASTUZUMAB IN THE TREATMENT OF EARLY BREAST CANCER (EBC)

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OBJECTIVES: To evaluate the sensitivity of the cost per QALY of trastuzumab for the treatment of EBC using one-way and probabilistic sensitivity analysis (PSA). METHODS: A 5-state Markov model with annual transition cycles was constructed to estimate the long-term health outcomes of EBC patients based on results from the HERA clinical trial. Population-based utilities were used for the health states in the model. NHS resource use and costs were estimated from a consensus panel of experts and published unit costs respectively. Costs and benefits were discounted at 3.5% per annum. Using the base case Markov model, key assumptions and model parameters were varied through plausible ranges identified in the literature to evaluate the stability of the base case cost per QALY. Key assumptions modified in the sensitivity analysis included: 1) proportion of patients receiving trastuzumab in the metastatic setting in both the Adjuvant trastuzumab and No adjuvant trastuzumab arms when they develop metastatic disease; 2) baseline patient age; 3) the duration of the treatment effect of trastuzumab; 4) the baseline risk of disease progression. Five thousand iterations were applied in the PSA with beta pert and beta distributions applied to the ranges of each parameter. RESULTS: The estimated base case cost per QALY for adjuvant trastuzumab was low at £2387. Trastuzumab remained cost effective in all evaluated scenarios with the cost per QALY always falling below the cost effectiveness threshold of £30,000. The parameters with the largest impact upon the cost per QALY were the re-treatment rate in the metastatic setting and the duration of the treatment effect. 100% of all iterations were below £30,000 per QALY in the PSA. CONCLUSION: The cost per QALY of trastuzumab for the treatment of EBC has been demonstrated to be robust and remain below commonly accepted thresholds despite wide variations in model assumptions.

PCN19

COST-EFFECTIVENESS OF CETUXIMAB IN COMBINATION WITH RADIOTHERAPY VERSUS RADIOTHERAPY ALONE IN THE TREATMENT OF LOCALLY ADVANCED HEAD AND NECK CANCER IN SPAIN

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Definitive radiotherapy is the current standard of care for patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN) who are contraindicated and/or not able to tolerate the severe acute and late toxicities associated with concomitant chemoradiotherapy. Erbitux (cetuximab) in combination with radiotherapy has been shown to significantly improve patient outcomes when compared to radiotherapy alone without aggravating the side effects of radiotherapy. OBJECTIVE: To estimate the cost-effectiveness of Erbitux in combination with radiotherapy (ERT) compared to radiotherapy alone (RT), for the treatment of locally advanced head and neck cancer in patients for whom chemoradiotherapy is inappropriate or intolerable in Spain. METHODS: A decision-analytic model was used to estimate the clinical and economic consequences of locally advanced SCCHN. Model parameters and health resources use were derived from an international phase III clinical trial. Costs were obtained from local data and validated by local clinical experts. Effectiveness was measured as progression-free survival (PFS) and QALYs gained and extrapolated beyond trial follow-up. Costs and outcomes were discounted at an annual rate of 3%. RESULTS: ERT was associated with an incremental effectiveness of 1.17 years free of disease progression and 0.97 QALYs, and with additional cost per patient of about €8777 resulting in incremental cost-effectiveness ratios of €7532 per progression-free life years and €9091 per QALY gained. The probabilistic sensitivity analysis showed that the probability of ERT being cost-effective at the accepted cost-effectiveness threshold in Spain of €30,000 per QALY is over 99%. CONCLUSIONS: Cetuximab added to radiotherapy is a cost-effective option compared to radiotherapy alone, with better outcomes at a reasonable additional cost. Its clinical and pharmacoeconomic profile makes Cetuximab + radiotherapy the optimal treatment for a significant proportion of patients with locally advanced SSCHN who are unable to tolerate or are contra-indicated to Chemo-Radiotherapy.

PCN20

COST-EFFECTIVENESS ANALYSIS OF LETROZOLE COMPARED TO TAMOXIFEN FOR TREATMENT OF EARLY BREAST CANCER IN THE HUNGARIAN HEALTH CARE SETTING

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OBJECTIVE: A comprehensive decision model has been developed and adopted to the Hungarian health care settings to evaluate the cost-effectiveness of letrozole as adjuvant therapy for breast cancer compared to tamoxifen. METHODS: The analy-

sis uses a cohort Markov model to estimate lifetime costs and QALYs to extrapolate observed clinical trial results (the BIG 1-98 trial). The model was designed to describe all the relevant states during the disease course and to capture the incidence and costs of all the relevant adverse events the letrozole and tamoxifen patient groups: endometrial cancer; bone fractures; myocardial infarction; venous thromboembolic events; and hypercholesterolaemia. Cost items were obtained from official data sources and were attached to estimate the resource use by patients spending a year in each of the health states included in the model, as well as to resources used to treat the mentioned AEs. The utility parameters associated with the model's breast cancer states are based on a primary utility study, that used the standard gamble approach to estimate utility values for breast-cancer related health states. **RESULTS:** Letrozole treatment for breast cancer in the early adjuvant setting resulted an additional 388 (discounted) years of disease free survival are gained, with 250 life years, and 277 quality adjusted life years (QALYs). The incremental cost per life year was HUF 6,060,371, and the incremental cost per QALY was HUF 5,462,685. The lower cost per QALY than cost per life year gained indicates that the difference in the utility gained as result of fewer patients experiencing a distant recurrence outweighs the gain in life years due to the survival impact of distant recurrence. **CONCLUSION:** Our cost utility analyses showed that letrozole was cost-effective as a treatment for postmenopausal oestrogen receptor positive women following diagnosis with early breast cancer in Hungary.

RETROSPECTIVE COMPARATIVE PHARMACOECONOMIC ANALYSIS OF VARIOUS TREATMENT SCHEMES IN PATIENTS WITH ADVANCED HODGKIN'S DISEASE

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OBJECTIVE: To compare cost and effectiveness of various schemes of treatment patients with advanced Hodgkin's disease and to determine more cost-effective schemes in Russia. **METHODS:** In order to determine quantity of drugs and cost of different treatment schemes we used data from individual medical documentation (history of disease) in Hematological Scientific Center and data from price-lists of pharmaceutical distributors in Moscow. In order to determine effectiveness we analyzed data from clinical trials. We chose data from clinical trials, which is possible to compare. It was data from clinical trial, which guided German Hodgkin Study Group (GHSG). In this trial scientists estimated 3 years Freedom from Treatment Failure (FFTF) of 4 schemes: COPP/ABVD, BEACOPP-baseline, BEACOPP-escalated and BEACOPP-14. In the end, we calculated and analyzed cost-effectiveness rates (CER) of different schemes. **RESULTS:** Effectiveness of investigating schemes (3 year FFTF) was 70% for COPP/ABVD, 79% for BEACOPP-baseline, 89% for BEACOPP-escalated and 90% for BEACOPP-14. Cost of treatment by these schemes was 138,600 rubles (€3960), 125,500 rubles (€3586), 537,900 rubles (€15,370), and 503,900 rubles (€14,400) (35 rubles = 1 Euro) for COPP/ABVD, BEACOPP-baseline, BEACOPP-escalated and BEACOPP-14, respectively. CER for these schemes was 1979, 1588, 6043, and 5598 rubles per percent or 57, 45, 173, and 160 euros per percent, for COPP/ABVD, BEACOPP-baseline, BEACOPP-escalated and BEACOPP-14, respectively. BEACOPP-baseline had minimal CER but BEACOPP-escalated and BEACOPP-14 were more effective and more expensive. BEACOPP-14 was less expensive and more effective than BEACOPP-escalated. Thus, BEACOPP-baseline and BEACOPP-14 are more cost-effective

than COPP/ABVD and BEACOPP-escalated, respectively. **CONCLUSIONS:** We compared cost and effectiveness of 4 therapy schemes of advanced Hodgkin's disease and determined more cost-effective schemes (BEACOPP-baseline and BEACOPP-14). In order to choose between BEACOPP-baseline and BEACOPP-14 we have to know budget, which payer has, or price, which payer is able to pay for treatment.

COST-EFFECTIVENESS (CE) OF THE PREVENTION OF ORAL MUCOSITIS (OM) WITH KEPIVANCE® (PALIFERMIN) IN PATIENTS UNDERGOING MYELOABLATIVE THERAPY WITH AUTOLOGOUS STEM CELL TRANSPLANTATION (ASCT) IN SPAIN

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OBJECTIVE: OM is a frequent, serious, and one of the most debilitating side effect among patients who undergo myelosuppressive therapy and hematologic stem cell transplants. Palifermin is the first and only mucosal growth factor indicated to decrease the incidence, duration and severity of OM in patients with haematological malignancies receiving myeloablative therapy associated with a high incidence of severe mucositis and requiring ASCT. Assess palifermin CE in the prevention of OM in patients requiring ASCT in Spain. **METHODS:** CE was assessed based on a palifermin phase 3 clinical trial (1) comparing palifermin with best supportive care (BSC), local mean hospital costs (1051,50€ per-diem) (2) and assuming palifermin ex-manufacturer price of 4.700€/treatment. A sensitivity analysis applying a correction factor of 15% to hospital cost since severity of OM is associated with an increase utilization of health care resources. (3) Effectiveness measured in terms of number days reduction with OM and decrease of grades 3/4 OM incidence. **RESULTS:** Compared to BSC, palifermin effectively decreased the duration of severe (WHO grade 3 or 4) OM from 9 to 3 days (p < 0.001) (1), and was associated with a lower incidence of severe OM (98% vs 63%; p < 0.001) (1), and reduced post-transplant inpatient stay by 1.9 days (from 17,2 to 15,3; p = 0,008) (4). The CE model shows an incremental cost-effectiveness ratio (ICER) of using palifermin over BSC of 7.720,43€ per episode of grade 3/4 OM avoided and an ICER of 450,36€ per day of grade 3/4 OM avoided. Adjusting for severity of OM, the ICER are €825,60 per episode of grade 3/4 OM avoided and €48,16 per day of grade 3/4 OM avoided. **CONCLUSIONS:** Palifermin is a cost-effective therapy for ASCT patients. When taking into account the impact of OM severity OM on health care resources, palifermin could be a cost-neutral intervention. [1] Spielberger R, et al. N Engl 2004 Dec 16;351:2590–8 2 Spain MOH (MSC 2002) 3 Sonis, et al. Journal Clinical Oncology. 2001;19:2201–2205 4 Emmanouilides C, et al. Blood 2003;102(11): Abstract #883.

ADDING RITUXIMAB TO STANDARD CHEMOTHERAPY IS COST NEUTRAL AND CLINICALLY SUPERIOR IN ADVANCED STAGE NON-HODGKIN'S LYMPHOMA (NHL)

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OBJECTIVES: To identify cost and cost effectiveness of R-MCP (rituximab, mitoxantrone, chlorambucil, prednisolone) vs. MCP in NHL-patients from the perspective of a third party payer in Germany (statutory sickness fund). **METHODS:** Resource utilization data on 329 patients were collected in parallel to a RCT