during 2008. Appeals were evaluated according to literature sent and justifications. The budgetary impact was measured. **RESULTS:** A total of 960 chemotherapy bills from this HP were evaluated totaling US$1,277,181.12. There was at least one point of recommended coverage denial in 471 (49%) either of materials, drugs or the entire procedure, representing US$157,965.77. Denial was based on the best available evidence for each treatment. There were 100 appeals (US$47,889.11) following those denials, but 75% or US$35,939.53 was not reversed. We observed that contestations were more frequent for high cost drugs like Trastuzumab, Gemzar or Rituximab. The most frequent complaint was patient weight variation leading to the use of extra vials of these drugs, not previously approved. Interestingly, no such request was made for low-cost drugs. However, none of these variations resulted in dose increase larger than 5%, not justifying the waste of nearly all the drug in the vial. In none of these appeals was any literature sent. The appeals reversed were basically bureaucratic cases in which the coverage was denied based of incorrect form fillings or lack of any documentation. **CONCLUSIONS:** One in four denial appeals was reversed due to bureaucratic paper work. None of the other appeals was accompanied by supportive literature. Appeals are more frequent when high cost drugs are used in the chemotherapy.

PCN37

EXPECTED ECONOMIC BURDEN OF TREATING ADVANCED SOFT TISSUE SARCOMAS WITH TRABECTEDIN IN RUSSIA

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OBJECTIVES: To estimate annual expected economic burden (EEB) of treating advanced soft tissue sarcomas (STS) with trabectedin in Russia. **METHODS:** EEB of treating advanced STS with trabectedin was calculated in a model in comparison with EEB of bevacizumab for metastatic colorectal cancer (CRC) and sorafenib for advanced renal cancer (RC). All studied drugs are used for advanced cancer and have similar efficacy of expected increase of survival for several months. The model was based on the following assumptions: 1) trabectedin is given to patients with a new case of STS revealed at advanced stage and resistant to first-line therapy; 2) according to federal standards of care, bevacizumab is given to 80% of patients with a new case of metastatic CRC; and 3) sorafenib is given to all patients with a new case of metastatic RC. Number of new cases of advanced cancer was taken from the annual report about cancer morbidity and mortality in Russia. Dosing regimens of drugs were taken from clinical studies. Prices of bevacizumab and sorafenib were taken from RMBC database, price of trabectedin was proposed by the manufacturer. **RESULTS:** EEB of trabectedin was estimated to be 2.3 billion rubles (a. US$76.4 million) per year, EEB of bevacizumab for metastatic CRC was 16.0–21.3 billion rubles (a. 533.1–US$710.8 million), EEB of sorafenib for metastatic RC was 5.8 billion rubles (US$194.5 million) per year. **CONCLUSIONS:** EEB of trabectedin is less than of some other drugs for advanced cancer with comparable efficacy that have already been recommended for use in a health care system. Bevacizumab is included into federal standards of care, sorafenib is included into Essential Drug List, that means that these drugs should be available to patients. Therefore trabectedin looks affordable for the system.

PCN38

NUMBER NEEDED TO TREAT (NNT) TO AVOID ONE GASTROINTESTINAL STROMAL TUMOUR (GIST) RECURRENCE IN BRAZIL. COST COMPARISON AND BUDGET IMPACT ANALYSIS OF ADJUVANT TREATMENT WITH IMATINIB

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OBJECTIVES: To calculate the NNT to avoid a recurrence of GIST after resection, to compare the cost of adjuvant treatment with imatinib (IM) with the cost of recurrence, and to estimate a budget impact from the Brazilian Public Health Care System (SUS) perspective. **METHODS:** Available relative risk reduction at 1 year from the Z9001 clinical trial and historical rate of recurrence for no adjuvant treatment were applied to estimate absolute risk reduction and NNT. Adjuvant treatment effect was extrapolated to 3-year period as ongoing trials are investigating longer treatment duration (SSG XVIII). A 5-year time horizon was set for cost comparison and Budget Impact Analysis (BIA). Incremental Cost to Avoid Recurrence (ICAR) was defined as the difference between the cost of adjuvant treatment (IM, monitoring) and the cost of recurrence (IM, surgery, monitoring, best supportive care). ICAR was applied to adjuvant GIST incidence for BIA. Epidemiological data (incidence, proportion of resectables); health access, diagnosis and expected adjuvant treatment rates were obtained from literature. Resource utilization and cost data came from official guideline and administrative databases, literature and expert opinion. Costs are reported in 2007 Euros. A 5% discount rate was applied. Univariate sensitivity analysis was performed. **RESULTS:** The NNT to avoid a recurrence was estimated at 2.1 based on extrapolated GIST recurrence risk profile in Brazil. Cost of adjuvant treatment was €50,298 and the cost of a recurrence €61,998. Annual ICAR was €8,725. The annual impact on the Ministry of Health budget was 0.01%, which included impact on infrastructure (e.g. monitoring costs) of SUS. Results were sensitive to the recurrence rate and adjuvant treatment duration. **CONCLUSIONS:** Considering that imatinib is already reimbursed by SUS for metastatic/unresectable GIST, adjuvant therapy for primary GIST represents good value for money for the prevention of recurrence, and an annual budget impact of 0.01%.

PCN39

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF USING TEMSIROLIMUS COMPARED TO INTERFERON ALPHA IN METASTATIC RENAL CELL CARCINOMA

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OBJECTIVES: The purpose of the study was to evaluate the cost effectiveness and budget impact of temsirolimus compared to interferon alpha-2A (IFN) in any given population of metastatic renal cell carcinoma (mRCC). **METHODS:** Economic evaluations were performed from a US managed care perspective over a 30 months period. Cost of treatment was the summation of drug's cost, administration cost, premedication cost, and cost of associated adverse events. Outcomes measure for economic evaluations was progression free life months gained. Cost effectiveness was conducted using a Markov state-transition model in TreeAge®. Time dependent transition probabilities were calculated using multistate Kaplan Meier estimators based on clinical trial data. An Excel-based budget impact model was developed to compare two scenarios, one for the interferon scenario and one for the temsirolimus scenario. Inputs were obtained from SEER registry, clinical trial, and US census bureau. Sensitivity analyses were performed. **RESULTS:** The model yielded ICER $8944 per progression free life month gained. For a hypothetical managed care plan with 500,000 members, the Budget Impact model estimated 33 patients with mRCC. A 75% (n = 25) of mRCC was eligible to receive first line therapy. A 95% (n = 24) eligible patients would be treated with IFN. Assuming that temsirolimus was available to 12% of eligible patients the expected 30 months cost would be US $18215.7 per patient compared with $15,557.90 had all patients been treated with IFN alone. **CONCLUSIONS:** Temsirolimus was found not to be dominantly cost effective compare to interferon alpha-2A. This finding is indicative of two challenges: 1) temsirolimus needs to be available at a reduced cost; 2) its threshold for cost-effectiveness needs to be adjusted according to relative clinical efficacy. The budgetary impact of adding temsirolimus to health plan was estimated to be minimal. While its current availability allows new treatment options, temsirolimus may be too expensive to use in some managed care plans.

PCN40

COST OF MANAGING ADVERSE EVENTS IN THE TREATMENT OF FIRST LINE METASTASIC RENAL CELL CARCINOMA: BEVACIZUMAB + INTERFERON ALPHA-2A COMPARED WITH SUNITINIB IN SPAIN

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OBJECTIVES: To perform a cost analysis comparing the management of adverse events (AEs) and their associated cost in current clinical practice of bevacizumab (BEV) + interferon alpha-2a (IFN) versus sunitinib (SUN) in patients with metastatic renal cell carcinoma (mRCC) in Spain. **METHODS:** A decision analytic model was developed to compare the costs derived from the management of 40 grade 3/4 AEs in patients with mRCC, **using published data from published trials (BEV**+IFN: Escudier B. Lancet 2007;370:2103–11. SUN: Motzer RJ. N Engl J Med 2007;356:115–24**).** The analysis was performed from the Spanish public hospitals perspective. Estimation of resources used in managing AEs was made through an Expert Panel. Cost evaluation (€, 2009 values) included direct medical costs: **outpatient visits, diagnostic and** laboratory tests, hospitalization stays, surgeries, and medication. Unitary cost **data** were **collected from Spanish Data Base of Sanitary Costs 2009 and Catalogue of** Medicinal Products. **RESULTS:** Average cost of managing the grade 3/4 AEs per patient was €568 for BEV+IFN and €940 for SUN. The per patient cost savings of €372 when using BEV+IFN corresponds to a relative saving of 40% when compared to SUN. The main drivers for SUN costs were related to the management of laboratory abnormalities, anaemia, mucosal inflammation, decline in ejection fraction, diarrhea, thrombocytopenia, rash, epistaxis, and vomiting. In comparison, the main costs for BEV+IFN were associated to the management of gastrointestinal perforation, bleeding, proteinuria, venous thromboembolic event, anorexia and anaemia. **CONCLUSIONS:** The costs of managing side effects of SUN treatment are significantly greater than those for BEV+IFN in Spain. When selecting treatment options, the management costs of these side effects may be an important factor to consider for health care payers.

PCN41

COST-SAVINGS ASSOCIATED WITH BEVACIZUMAB PLUS CISPLATIN AND GEMCITABINE (BCG) COMPARED WITH CETUXIMAB PLUS VINORELBINE AND CISPLATIN (CVC) IN PATIENTS WITH ADVANCED OR RECURRENT NON-SMALL CELL LUNG CANCER (NSCLC) IN GERMANY

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OBJECTIVES: New treatment options for advanced NSCLC can offer improved survival over standard chemotherapy and should also offer value for money. Bevacizumab, a humanised monoclonal antibody (MAb) against VEGF, plus chemotherapy increases progression-free survival (PFS; median 6.8 months) in advanced NSCLC