conducted in health maintenance organizations were more likely to have a PSA-screening, compared to physician group settings. General practitioners were more likely to receive PSA-screening compared to other types of specialists. Interactions between race and insurance type were not significant. CONCLUSIONS: Hispanics and individuals insured by Medicaid are less likely to receive PSA-screening during an ambulatory care office-visit for a PHE. Efforts to improve access to cancer-screening services are warranted for these groups. It is necessary to consider the differential impact of PSA-screening policies on medically underserved populations.

PCN184
CANCER CARE COSTS TRENDS IN THE UNITED STATES: FINDINGS OF THE MEDICAL EXPENDITURE PANEL SURVEY 2008-2011
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OBJECTIVES: To estimate the annual financial burden of cancer care in the United States and to study the effects of cancer on total health care of the country.
METHODS: Direct medical cancer care costs for the years 2008-2011 were estimated using the household component of the Medical Expenditure Panel Survey (MEPS). The resulting costs are generated from patient charges that have been adjusted by a utilization and expenditures for the US civilian non-institutionalized population. The likelihood of having a cancer diagnosis by age, race and insurance status and other variables were also assessed. RESULTS: Aggregate cost of cancer in the US increased from $183 billion in 2008 to $236 billion in 2011. While total out-of-pocket (OOP) costs per case decreased from $1,419.43 in 2008 to $1,254.77 in 2011, total cost per case increased from $10,461.66 to $12,583.69 over 2008 to 2011. The OOP and total medical care expenditures per case in 2008 were $1,560.54 and $1510.69 respectively in 2011 prices using Urban Medical Consumer Price Index. OOP per case declined at an annual rate of 7.3% while the total direct cost increased at an annual rate of 4.5%. Whites, females and 65-64 year olds were more likely to have a cancer diagnosis and most cancer care costs were covered by private insurers. Geographical location was not associated with cancer diagnosis although the southern US had a higher concentration on impact-insurance ratios. As age increases the excess lifetime risk of cancer decreases. The excess lifetime risk of cancer was $1,000 (43-178) for persons aged 50-54 and $2,000 (931-3871) for persons aged 55-85. The number of coronary angiograms increased from one to five over 12-month period, the total risk of cancer increased to 17 (8-33) and 23 (12-43) per 10,000 respectively. As the number of coronary angiograms increased from one to five over 12-month period, the total risk of cancer increased to 17 (8-33) and 23 (12-43) per 10,000, thereby potentially confounding the clinical benefit of the active therapy. Of the 19 positive recommendations which had an RCT design and assessed OS as an endpoint, progression-free survival (PFS) was significant with or without additional clinically or statistically significant secondary endpoints. CONCLUSIONS: This study highlights that positive pCODR recommendations may be made in the absence of a clear OS benefit, provided strong PFS and or additional endpoint data exist.

PCN190
INSIGHTS INTO THE PAN-CANADIAN ONCOLOGY DRUG REVIEW RECOMMENDATIONS - THREE YEARS AFTER ITS INCEPTION
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BACKGROUND: In 2010, the permanent national oncology-specific drug review process, pan-Canadian Oncology Drug Review (pCODR), was established to assess the clinical evidence and cost-effectiveness of new cancer drugs and provide recommendations to the provinces (except Quebec) and territories to guide their drug funding decisions. OBJECTIVES: This study sought to identify characteristics and decision patterns of the pCODR recommendations. METHODS: Twenty-eight recommendations, covering 33 requested populations, publicly accessible at www.pcodr.ca were reviewed since pCODRs operation: 13 July 2011 - 9 December 2013. Additional information was obtained from the www.reimbursementdecisions.com database. RESULTS: Of the twenty-four positive recommendations for coverage, three were rejected due to less than the required population size (less than the one requested). Four population funding requests received positive recommendations for the requested population without conditions. In seventeen cases, positive recommendations for the requested population were conditional on important cost-effectiveness ratios. Nine negative recommendations were made due to: a) limitations in evidence from phase two trials; b) modest progression-free survival, lack of statistically significant overall survival, lack of quality of life data and poor cost-effectiveness, and c) unclear clinical benefit and an unacceptable cost-effectiveness model. Many economic reviews by pCODR included re-analyses of the cost-effectiveness ratios which in some cases had substantial impact on cost-effectiveness. The most common changes from the submitted analyses where limiting product benefit post-progression, time horizon reductions, or changes to post-progression mortality risk. CONCLUSIONS: Most submissions resulted in a positive funding recommendation. The positive conditional pCODR recommendations supported a continued provisional drug product listing agreement in the absence of evidence from head-to-head confirmatory trials of the active therapy compared to the comparator. The economic re-analyses of the post-progression survival benefit indicates a need for manufacturers to provide comprehensive consideration of uncertainty surrounding such benefits in the submitted cost-effectiveness analysis.

PCN191
LESSONS FOR ADAPTIVE LICENSING: ANALYSIS OF CONDITIONALLY APPROVEDEMA COMPOUNDS, THEIR REIMBURSEMENT STATUS AND REGULATORY DECISION PATTERNS
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OBJECTIVES: Understand how conditionally approved (CA) compounds in the EMA have performed in reimbursement assessment. Findings will inform current adaptive licensing initiatives. METHODS: CA EMA recommendations were analysed to identify CA compounds from 2006–2013. HTA reports from national reimbursement authorities of the UK (NICE, SMPC), France (HAS), Germany (G-BA) and Italy (AIFA) were also analysed to understand reimbursement status of these products. RESULTS: 20 CA compounds were identified. 11 with current CA status, 7 fully approved and 2 withdrawn. Approval was based upon strength of clinical data from FI/FIII studies. In France, 86% of CA indications were reimbursed, most with an ASMV R. In Italy, 62% of CA indications were reimbursed. Risk sharing agreements (RSA) were used in at least 38% of approvals. In Germany, approximately 50% of CA products licensed after AMNOG were reimbursed. In the UK, only 6 CA products received a positive NICE recommendation, 5 under RSAs to fulfil the cost-effectiveness criteria. CA is granted on limited clinical evidence. Countries using a therapeutic-benefit assessment (e.g. France) reimbursed more CA compounds than cost-effectiveness (CI) driven countries (e.g. UK). RSA is a key tool to win reimbursement in cost-effectiveness countries where high ICR thresholds impede reimbursement (Bosutinib) or do not exist (Pixatanone). Positive reimbursement decisions were driven by robust clinical data in orphan or small indications with limited therapies. Strategies employed by companies to overcome payer concerns include: 1) Initial restriction of compound approval to small high unmet need subpopulations; 2) Provision of financial risk sharing arrangements; 3) On-going evidence development plans. CONCLUSIONS: Reimbursement outcomes for CA compounds are variable across the EU. This is due to differences in national approaches to reimbursement, the design of evidence, and the implementation of these uncertainties, agreed mechanisms for continual evidence development and RSA implementations should be incorporated into on-going adaptive licensing initiatives.

PCN192
CORRELATION OF HTA DECISION OUTCOMES IN FRANCE AND GERMANY
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OBJECTIVES: The objective of this study is to compare the HTA decisions of oncology products in France and Germany and provide insight into the most important asset values that characterize a positive appraisal in these markets. METHODS: We analysed the G-BA and the HA3 assessments of 11 oncology products published during the period 2008–2013. RESULTS: We found that the correlation of HTA decisions in France and Germany was statistically significant. The most important asset values that characterize a positive appraisal in these markets were: 1) robust clinical data (Pixatanone). Positive reimbursement decisions were driven by robust clinical data in orphan or small indications with limited therapies. Strategies employed by companies to overcome payer concerns include: 1) Initial restriction of compound approval to small high unmet need subpopulations; 2) Provision of financial risk sharing arrangements; 3) On-going evidence development plans. CONCLUSIONS: Reimbursement outcomes for CA compounds are variable across the EU. This is due to differences in national approaches to reimbursement, the design of evidence, and the implementation of these uncertainties, agreed mechanisms for continual evidence development and RSA implementations should be incorporated into on-going adaptive licensing initiatives.