vs. $130,800, p = 0.046, age 45–49: $75,700 vs. $104,600, p = 0.001; age 50–54: $78,100 vs. $91,400, p = 0.059) than women ≥55 years (age 55–59: $87,500 vs. $91,600, p = 0.61; age 60–64: $78,300 vs. $83,100, p = 0.48). CONCLUSIONS: Among adult women with commercial insurance, RS receipt was associated with less use of adjuvant chemotherapy practice settings respectively. Oncologist ranking of product attributes concerning Midwest-23%/South-32%/West-16%; 53% and 47% were from hospital and private-practices reported.

The survey assessed for survey participation to be geographically representative. The survey assessed performance could present a significant barrier to uptake or increases risk of non-payment, to incentivize patients. These methods should be piloted by healthcare systems to ensure practical application brings benefits, without high service burden. PCN166 THE EVOLVING GLOBAL ROLE OF NONTRADITIONAL PAYERS AND REINSURANCE IN THE REIMBURSEMENT OF HIGH COST THERAPIES

Roughan D, Spouge DR, Kristjapon J, Doyle JJ, Faulkner K

INTRODUCTION: Manufacturers are developing an increasing number of high cost therapies for rare and orphan diseases. These medications are typically purchased by employers self-funded health plans and small group first-dollar coverage, which represent approximately 60% of the privately insured population. Stop-loss carriers (SLCs) play a role in reimbursing employers when costs exceed a pre-determined “threshold” or “attachment” amounts. In these cases, SLCs determine whether coverage is applicable or not (reimbursement) met by examining FDA labeling, first-dollar insurer plan policies, and site of care covered by the insurer. The objective of this study was to examine the time to reimbursement for high cost therapies across different countries. We assessed the global role of health care reinsurance as an alternate funding model for high cost treatments, including opportunities for manufacturers to partner with reinsurance to expand the market for innovative therapies. METHODS: We conducted a literature search, scanned secondary resources and conducted informal interviews with healthcare reinsurance executives and other internal experts to identify key trends in reinsurance, including case studies and funding mechanisms. RESULTS: In the US, reimbursement is prevalent in the context of state-sponsored insurance, which is typically purchased by the public sector. Reimbursement processes are still a major barrier to access for patients, and the variability in payment practices across different countries significantly impacts drug affordability. SLCs have been suggested as a potential solution to address this issue. The time to reimbursement varies depending on the country, with the highest time to reimbursement being observed in the US. CONCLUSIONS: SLCs play a crucial role in the reimbursement process for high cost therapies, and their impact is particularly significant in countries with limited public health insurance coverage. Further research is needed to better understand the factors influencing the time to reimbursement and to develop strategies to improve access to these medications.
OBJECTIVES: The aims are to quantify the expected impacts of different cancers throughout the lifetime and to determine median rate by which individuals would lose quality-adjusted life years (QALYs) related to cancer. The study is prospective and takes into account the QALYs (quality-adjusted life year) as the common unit, to aid in prioritizing policy decisions. METHODS: 646,727 patients with pathologically confirmed cancer registered in the Taiwan Cancer Registry during 1998-2009 were used to estimate lifetime health-related quality-of-life (HRQoL). RESULTS: Liver and lung cancer were found to be the highest expected lifetime health impacts in males and females, and expected lifetime losses of 0.97 and 0.41 QALYs could be averted, respectively. While the priority changes for prevention based on expected health impacts were slightly different for females based on standardized mortality rates, those of males involve a broader spectrum, including oral, colorectal, esophageal and stomach cancer. CONCLUSIONS: The integration of incidence rate with loss-of-QALY could be used to represent the expected losses that could be averted by prevention, which may be useful in prioritizing strategies for cancer control.

PCN172 QUALITY OF EVIDENCE SUPPORTING INCLUSION OF PHARMACOGENOMIC BIOMARKERS IN PRODUCT LABELS OF FDA APPROVED ONCOCLOGY THERAPIES in the USA Gupta J, Kapoor A, Mazumder D Ohio State University, Columbus, USA

OBJECTIVES: Pharmacogenomic biomarkers aid in predicting drug response and adverse drug reactions. Drug label provides information about these biomarkers; however, it is unclear if the quality of evidence regarding biomarker use is clear. We investigated the FDA-approved drug labels for the availability and quality of evidence supporting the biomarkers use in conjunction with targeted therapies in different cancer therapeutics. METHODS: We searched the US FDA website to identify the US FDA approved drug labels. Further, we provide information on the pharmacogenomic biomarkers of the targeted cancer therapies. The Evaluation of Genomic Application in Practice and Prevention Working Group's guideline was used to assess the clinical validity and utility of the referred clinical studies. The available evidence was graded as convincing, adequate, or incomplete. We also assessed the completeness of studies and recommendation in the label. RESULTS: Fifty-three drug biomarker combinations were identified, encompassing 42 unique drugs and 23 unique biomarkers. Combinations were most frequently identified in breast cancer (26%), chronic myeloid leukemia (15%), and colorectal cancer (11%). Half of the supporting evidence in drug labels (51%) were not graded with convincing validity (i.e., the ability to predict the phenotype of interest) and more than half (60%) were incomplete pertaining to utility (i.e., the ability to improve measurable clinical outcomes). Complete information of the referenced clinical studies was included in only 11% labels, whereas 62% labels provided partial information. The treatment recommendations about clinical decision were based on the drug's mechanism of action in 75% of the labels and on drug-biomarker association in 21% of drug labels. Also, the biomarker’s prediction of improved drug response and contraindications was provided in 77% and 25% labels, respectively. CONCLUSIONS: Majority of the labels lacked convincing validity and utility regarding biomarker use. As biomarkers may enhance clinical care, it has become extremely important for inclusion and rational use of pharmacogenomic information in drug labels, for optimized decision-making.

PCN173 CARBOHYDRATE INTAKE AND BREAST CANCER RISK IN AFRICAN AMERICAN AND EUROPEAN AMERICAN WOMEN IN THE WOMEN'S CIRCLE OF HEALTH STUDY Johnson N.M., Bandera E.1

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OBJECTIVES: The overall incidence of breast cancer is lower in African American (AA) women in comparison to European American (EA) women; however AA women are more likely to die of the disease. National data has reported that compared to EA women, AA women have a poorer diet quality and are also among the highest consumers of added sugar. This analysis aims to explore the association of carbohydrate intake and breast cancer risk among AA and EA women. METHODS: We evaluated the association in a case-control study including cases (breast cancer positive) and controls (cancer negative). Food consumption was collected using a Food Frequency Questionnaire. Multivariable logistic regression controlling for relevant breast cancer risk factors was used to calculate Odds Ratios (OR) and 95% Confidence Intervals (CI). RESULTS: Our sample size was 3148. Overall, EA women had consumed larger amounts of total carbohydrates (highest quartile) had a significantly decreased risk of breast cancer compared to those who consumed lower amounts of total carbohydrates (lowest quartile) OR=0.60; 95% CI: 0.43-0.83. In stratified analysis, there was a 30% decrease in breast cancer risk among EA women for total carbohydrates (OR=0.46; 95% CI: 0.30-0.78) and added sugars (OR=0.56; 95% CI: 0.35-0.89). Additionally in EA women with ER+ tumors, there was a 28% decrease in risk of breast cancer for those who consumed higher amounts of total carbohydrates. For AA women, we found no evidence of an association for total carbohydrates, glycemic load or added sugars. CONCLUSIONS: This study suggested an inverse association between carbohydrate consumption and breast cancer risk in AA women, particularly in those with ER+ tumors. However, we could not establish and association between carbohydrate consumption and breast cancer risk in AA women. Moreover, the specific types of carbohydrates and food sources need be studied for both EA and AA women to better understand the association.

PCN174 THE ROLE OF IMMUNE CHECKPOINT INHIBITORS AS ADJUVANTS: FUTURE CHALLENGES FOR PRICING AND REIMBURSEMENT Wieffer HM, McIndoeck J, Petropoulos A, Saldan M

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OBJECTIVES: Adjuvant therapy is additional treatment administered after the primary treatment (usually surgery) to lower the risk of recurrence. The mechanism of action of the recently developed immune checkpoint inhibitors suggests they have potential as adjuvant therapies; by their action in enhancing the anti-tumor immune response, residual tumor cells may be eliminated. In this study, we identified potential challenges to pricing and reimbursement (P&R) assessment of these drugs as adjuvant given the likely high cost of these innovative agents. METHODS: We examined the field of immune checkpoint inhibitors as adjuvant therapy, and identified recent trials of immune checkpoint inhibitors as adjuvant therapies. We then searched the website of the UK health technology assessment agency, NICE, for appraisals of adjuvant cancer therapies, identified the number of submissions and the outcomes of the agency’s meetings, and identified key challenges. RESULTS: We identified nine trials with an immune checkpoint inhibitor used as adjuvant therapy, only one of which was Phase 3. Six NICE appraisals of pharmacological agents used as adjuvants were identified, all of which had also been assessed by FPA and the SMC. Particular areas of concern in evaluations were the extrapolation of disease-free survival to overall survival, and the balance between safety and benefit in disease prevention. Restrictions were imposed in several decisions on the duration of adjuvant treatment and the risk status of patients, dependent on the available clinical evidence. So far, adjuvant therapies have rarely tested acceptable cost-effectiveness thresholds. CONCLUSIONS: Development of immune checkpoint inhibitors as adjuvant therapies is at an early stage. Consideration of the economic and clinical case for these drugs will be needed to ensure successful P&R. Experience with the evaluation of high-cost therapies in this context is limited, so engagement will be needed with other manufacturers and agencies to define the required evidence and willingness to pay.

PCN175 PREDICTORS OF A POSITIVE CANCER DRUG FUND DECISION Taks A, Liden D, Ho Y

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OBJECTIVES: Since 2011, the United Kingdom has set aside £200 million per year through the Cancer Drug Fund (CDF) to pay for oncology treatments not reviewed or approved by NICE. The CDF scores drugs on progression-free survival (PFS), overall survival (OS), quality of life (QoL), safety, unmet need, and strength of evidence (SE). The scores determine if the drug will be included on the CDF priority list. This analysis attempts to determine the weight each score has on the reimbursement decision. METHODS: All available CDF decision summaries post April 2013 were analyzed. Scores for PFS, OS, QoL, safety, unmet need and SE were extracted from each decision summary. The CDF decision was classified as positive (recommended) or negative (do not recommend). Deferred decisions or drugs not scored were excluded. A probit model was used to estimate the probability of a positive decision based on the scores. RESULTS: Drugs filling an unmet need, or drugs with the similar/improved toxicity predicted a positive reimbursement decision perfectly. Drugs with significantly worse toxicity predicted a negative decision perfectly. Securing a positive PFS/PFS increment has the largest impact on predicted positive probability. CONCLUSIONS: Of all the evaluated variables (including SE) were excluded from the model. Of the remaining variables in the model (PFS, OS, and QoL), only OS was significant. An increase in OS was related to a higher probability of getting a positive reimbursement decision (ie, if OS was less than 0.99, the probability of a positive decision was 41%, but the probability of a positive decision increases to 99% for 6-7 months OS). CONCLUSIONS: Unmet need and similar/improved toxicity are perfect predictors of a positive CDF decision. If a drug increases OS by 6-7 months there is a 99% probability of a positive decision.

PCN176 BARBECUEQ ONCOLOGY MARKET ACCESS & HOW BBQ,PULLED PORK IS SIMILAR TO EUROPEAN P&R NEGOTIATIONS Swilling N, Atler J.

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OBJECTIVES: In this study, we look at the market access delays caused by lengthy pricing and reimbursement negotiations in the EU5. In addition, we look at the results of those pricing negotiations compared to the US, and the outcome with regards to access for specific subpopulations. METHODS: We examined over 20 oncology NMEs with EMA approval over the last three years and looked at the date of initial price publication in each market, HTA agency outcomes (where available), and price level at launch to compare the length of the price negotiation and price levels across EU markets as well as with the United States. RESULTS: Coming to a negotiated agreement for reimbursement in France, Italy, and Spain typically takes over a year, but there is no recognizable trend by market. In addition, oncology pricing in the EU5 has been found to be significantly lower than the US. CONCLUSIONS: Unmet need and similar/improved toxicity for CDF drug are predictors of a positive CDF decision. If a drug improves OS by 6-7 months there is a 99% probability of a positive decision.

PCN177 PRICING & REIMBURSEMENT IN THE ENDOCRINE SYSTEM Jaksa A., Liden D., Ho Y., Wieffer H.M., McKendrick J., Petropoulos A., Saltman D.

PCN178 Efficacy of olaparib for advanced ovarian cancer in the phase III PRIMA trial: a randomised, double-blind, placebo-controlled trial feels, Smith & Nephew, UK

OBJECTIVES: The PRIMA trial is a randomised, double-blind, placebo-controlled phase III trial which has shown the efficacy of olaparib in the treatment of patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. METHODS: The trial enrolled 1127 patients between 2009 and 2012 at 367 sites in 26 countries. From September 2012, patients entered the maintenance phase of the trial. Patients who had progressed in the first-line platinum-based chemotherapy were randomised to receive olaparib or placebo. The primary endpoint was progression-free survival (PFS). RESULTS: Of 1127 patients enrolled, 1090 were evaluable for efficacy. Median PFS was significantly longer in the olaparib group compared with placebo (9.2 months vs 4.3 months, HR: 0.29, 95% CI: 0.22 to 0.38). CONCLUSIONS: Olaparib significantly prolongs progression-free survival compared to placebo in patients with advanced ovarian cancer who have progressed on first-line chemotherapy.