By comparison, only 7/88% (8%) of NICE-approved cancer appraisals have been subject to reimbursement after the fund is due to close in 2016. Nevertheless, the CDF does not categorize as a formal mechanism under which off-label medication can be provided for off-label use of cancer drugs, which NICE will not consider.

PCN257
APPLICATION OF THRESHOLD VALUE FOR COST-EFFECTIVENESS IN RECOMMENDATIONS ISSUED BY AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT IN POLAND FOR CANCER DRUG TECHNOLOGIES
Zagórski A, Manusawa W
Agency for Health Technology Assessment in Poland (AOTH), Warsaw, Poland
OBJECTIVES: To analyse HTA recommendations for cancer drug technologies issued by AOTH in Poland. HTA recommendations (RBP) are often off-label. An official threshold value for cost-effectiveness is respected. METHODS: The review of HTA recommendations concerning cancer technologies issued by AHTAPoI in the period from January 2012 to March 2014 was performed. The classification of HTA recommendations, with an approach labeling them as positive, positive with major with minor restriction and negative was conducted. Decisions and ICUR values from each recommendation were compared to the official threshold value for cost-effectiveness (in Poland defined as 3xGDP for each year) and each decision whether the ICUR value is either above or below the official threshold. Other aspects of recommendations, such as criteria for decision, type of RBP implemented and reasons for restrictions were also analysed. RESULTS: In the studied period AHTAPoI issued 42 recommendations for 35 different cancer drugs (due to the multiplicity, we limited our analysis to 4 drugs). After review, 32 recommendations with calculated ICUR (with Risk Sharing Scheme (RSS) if implemented) were included in the analysis. For 13 of these recommendations, ICUR values were below, and for 19 recommendations, ICUR values were above AHTAPoI’s threshold. For 7 of 11 positive recommendations ICUR values were calculated below threshold. On the other hand, for 5 of 7 positive recommendations with ICUR values that were positive with restrictions, all 7 restrictions were related to the unacceptable cost-effectiveness. The same analysis for the ICUR values without implementation of RSS was conducted to compare the results. CONCLUSIONS: The official threshold values set in AHTAPoI are respected in most of the cases of cancer drug recommendations. Nevertheless, the results indicate that the important criterion of decisions made by AHTAPoI. Clinical effectiveness, safety and specificity of end-of-life-ending medicines were also considered.

PCN258
PRICE CONTROL OF OUT-PATIENT CANCER DRUGS IN BULGARIA, 2010-2011: REFERENCE BASED PRICING AND PUBLIC TENDERS VersUS REFERENCE BASED PRICING ONLY
Djambazov SN1, Vekov TY, Petrov D2
1Cancer clinic Doc Dr Valentina Tsekova, Sofia, Bulgaria, 2Medical University Pleven, Pleven, Bulgaria, 3Bulgarian Medical Union, Sofia, Bulgaria
OBJECTIVES: To compare drug prices and public expenditure of out-patient cancer drugs between two consecutive periods: reference based pricing (RBP) and public tendering at MoH in 2010 and RBP only in a positive drug list (PDL) at the National Health Insurance Fund (NHIF) in 2011. METHODS: We compared the prices of the 40 products, which are used in outpatient setting. We used public documents like tender results from 2010 MoH tender and reimbursement list of NHIF in 2011. RESULTS: 70% of the products were with higher prices, 10% (n=6) with lower prices, and 10% (n=4) had lower prices in 2011. In 2010, 15% (n=6) had 50% lower prices than same products, prices in the PDL. For 10% of the products (n=4) in 2010, MoH tender prices were higher than RBP prices. For RBP drugs there were administered products, without generic competition, tendering is the ultimate solution. Tending should be used with caution, as it can drive some producers out of the market and create non-competitive environment with counter-productive results. Frequent changes of the laws and regulations, without budget impact analysis, is like gambling. Long-term national drug pricing policy is hardly needed and should be strictly followed.

PCN259
UNDERSTANDING CAREGIVER BURDEN IN COLORECTAL CANCER: WHAT ROLE DO PATIENT AND CARER FACTORS PLAY?
Manley MA1,2, O’Connell 3, Shalby J2
1National College of Ireland, Dublin, Ireland, National Cancer Registry Ireland, Cork, Ireland
OBJECTIVES: This study aimed to explore the key determinants of caregiver burden in colorectal cancer (CRC) carers. Specifically we analysed the effect of (i) patient health and care-related activities, and (ii) carer characteristics, as predictors of four distinct aspects of carer burden. METHODS: 495 CRC survivors (response rate = 39%) diagnosed 2007-2009 completed a questionnaire which collected information on sociodemographic characteristics, as well as disease and treatment-related factors. General health status was measured using the EORTC QLQ30.228 of these survivors indicated that they had informal carers who were then sent a questionnaire included in the consent letter. The questionnaire included covariates (e.g. sociodemographic factors, health status and costs as well as the Caregiver Reaction Assessment (CRA) scale. Hierarchical multiple regression analysis was used to assess the impact of patient factors, care-related activities and carer characteristics on four burden elements within the CRA (family support, concern about cancer, impact on work and health). RESULTS: 123 carers completed the caregiver questionnaire and were included in the analysis with their corresponding patients. Patient characteristics and disease-related factors were the strongest predictor of all four aspects of caregiver burden ranging from 20% to 40% of explained variance. Care-related activities also significantly predicted burden scores (explaining an additional 6% to 11% of variance), however carer characteristics only emerged as a significant predictor of the health burden scale (11% of explained variance). Key individual predictor variables of burden domains included patients’ general health status, presence of a stoma, and the time costs associated with care. CONCLUSIONS: These results highlight the need to recognise the role that various factors play in determining caregiver burden. Indeed, our findings highlight the potential for interventions to significantly reduce this, patient health and care-related activities have the most significant impact pointing to a need to deliver effective support to those most at risk of carer burden.

PCN260
INVESTIGATING THE USE OF PERSONALISED MEDICINE IN CANCER TRIALS – AN UPDATE
Hanly P., Wilson T
Carrick Medical Consulting Ltd., Cambridge, UK
OBJECTIVES: Personalised medicine continues to be a hot topic in health care evaluation of drug development. In therapy that targets the patient population is often heterogeneous. The results of an analysis previously presented at ISPOR showed that the proportion of cancer trials investigating personalised medicine rose 7-fold between 2000 and 2010. However, in 2011, this trend appeared to have continued. The objective of this study was to update the previous research to take account of the proportion of cancer trials which included personalised medicine between 2012 and 2013, inclusive, to assess whether this pattern has changed in more recent years. METHODS: Terms including ‘diagnostic’, ‘prognostic’ and ‘biomarker’ were used to search ClinicalTrials.gov for all interventional cancer trials which started between 2012 and 2013 and considered the use of personalised medicine. These trials were then compared to those of all interventional cancer trials listed on ClinicalTrials.gov starting in the same period. RESULTS: Of all cancer trials analysed between 2000 and 2013, inclusive, 3,664 of 25,203 (14.5%) considered personalized medicine. Of all trials conducted which included personalised medicine, 21% of these trials reached a plateau in personalisation in 2014. Therefore, this might suggest that cancer research is continuing to focus on traditional, non-personalised interventions.

PCN262
THE ROLE OF PRIOR BREAST CANCER DIAGNOSIS IN ARTICULATING EXPECTATIONS FOR RECONSTRUCTED BREAST APPEARANCE
Scotto L., Lawson R., Mason M., Kuykendall J., Holman D., Bremner A., Xia Z., Scott A.M.
Memorial Sloan Kettering Cancer Center, New York, NY, USA, 1Yeshiva University, Bronx, NY, USA, 2The New School for Social Research, New York, NY, USA
OBJECTIVES: Women who underwent mastectomy and whether due to a first-time breast cancer diagnosis or recurrence, are often presented with the option of breast reconstruction. Decisions whether to undergo reconstruction are informed by women’s surgery expectations, which develop based on many factors, including past knowledge and / or personal experience. The aim of this study was to examine the impact of prior breast cancer diagnosis on a women’s approach to expectation-identification of their reconstructed breast appearance. METHODS: This study was performed using cross-sectional approach and descriptive statistics. Expectation and appearance scores were administered in a clinical setting to breast cancer patients seeking immediate breast reconstruction. Responses were categorized into specific (likely, somewhat likely, neutral, somewhat unlikely, unlikely) expectations. The independent variable was defined as presence or primary diagnosis. Chi Square and one-way ANOVA were performed using SPSS 22. RESULTS: The study sample (n = 62, response rate, 66%) was characterized by a mean age of 49.6 ± 9.2 years, 82.3% married, 77.4% employed and 79.0% Caucasian. Twenty-three (37.1%) had a history of previous breast cancer diagnosis without mastectomy. Women who had previous breast cancer diagnosis were more likely to select a specific expectation in response to what their new breast would look like in the mirror clothed (ETA squared; 0.11, P=0.010) and unclothed (ETA squared; 0.09, P=0.017) one year after reconstruction. CONCLUSIONS: Expectancies guide perception, so that people tend to focus on events that are congruent with their expectations. In our study, women undergoing breast reconstruction were more likely to identify a specific expectation to attend the appearance of their reconstructed breast if they had been previously diagnosed with breast cancer. More research is needed to determine additional factors that may mediate the development of preoperative surgical expectations. Such information will aid in facilitating patient-physician communication.

PCN263
NICE RESTRICTIVENESS COMARED TO THE MARKET AUTHORIZATION IN ONCOLOGY AND NON-ONCOLOGY REVIEWS
Saka A, Westbrook L, Rubinstein E, Daniel K, Ho YS
Cancer Care Oncology, Inc., New York, NY, USA
OBJECTIVES: To determine how often NICE recommendations are more restrictive than market authorizations in oncology reviews compared to non-oncology reviews. METHODS: 161 NICE Technology Appraisal decisions from 2007-2013 were evaluated, 95 non-oncology and 66 oncology reviews. For each generic drug included in a review, the corresponding brand and market authorization was retrieved from the EMA or Mhra. NICE positive decisions were compared to the market authorizations for the corresponding decision that included language that restricted the population eligible for treatment or reimbursement for a given therapy was categorized as “recommend with restrictions.” NICE positive decisions that were not more restrictive than the market authorizations were categorized as “recommend.” Negative decisions were categorized as “do not recommend.” RESULTS: Oncology reviews were more likely to
To be issued a “do not recommend” decision due to the uncertainty in the OS: interim OS based on the improvements in the PFS and QoL. However, the significant gain in PFS was decreased. The HAS also granted crizotinib an improvement in actual benefit of III (QoL) items (e.g. chest pain, dyspnea, fatigue) were improved within the crizotinib treatment arms. Mend the use of crizotinib due to the uncertainties surrounding the OS: interim OS based on the improvements in the PFS and QoL. When treatment with crizotinib increased significantly the PFS (4.7 months) no significant improvement in OS was observed. Overall survival (OS) was a secondary endpoint. While treatment with crizotinib was considered in 40% of decisions, compared with those of three major HTA agencies: CADTH, NICE and PBAC. HTA reports and meeting transcripts were analysed and categorised by: data, therapy area, decision, rationale, and pricing decision. Resubmissions or those not assessed by the western HTA agencies were excluded. RESULTS: A total of 65 NHI reports were identified. Of these 26 reports decisions on oncology or cardiovascular drugs 2 were excluded (3 resubmissions, 9 not reviewed by the other agencies). Prior to 2GNHI, 4 out of 5 decisions were positive, or 80% approval rate, while after, only 4 out of 9 were positive, a 44% approval rate. Prior to 2GNHI, all NHI reimbursement decisions were made by CADTH, NICE, and PBAC. After 2GNHI only 69% or 66% matched. Clinical effectiveness and budget impact were most cited in reimbursement decisions. For example Zytiga, NICE appreciated the cost-effectiveness but stated budget impact was too high, issuing a negative recommendation, contrary to the other agencies. Interestingly, a ‘local’ product was recommended for limited reimbursement even though budget impact was high. CONCLUSIONS: Since implementation of Taiwan’s NHI reforms in January 2013, cardiovascular and oncology drug approvals decreased by 36% in Taiwan compared with western countries. 40%, placing an emphasis on budget impact. However, this analysis was constrained by its small sample size, and limited therapy areas.

PCN265

HEALTH TECHNOLOGY ASSESSMENTS IN ONCOLOGY: CRIZOTINIB CASE STUDY

Thurold M1, Kornfeld A1, Toussaint M1
1Creative Health, Paris, France

OBJECTIVES: Crizotinib (Xalkori®) was approved for the treatment of adults with non-small cell lung cancer (NSCLC). The objective of this study was to illustrate the diverse range of Health Technology Assessments (HTA) by categorising the reports of the National Institute for Health and Care Excellence (NICE), the Federal Joint Committee (G-BA) and French National Authority for Health (HAS). METHODS: Crizotinib’s pivotal trial (Study 1007) was analysed. NICE, G-BA and HAS undertook their assessments in different years, during which identified criteria and decision processes changed. RESULTS: Study 1007 was a randomised open-label trial comparing crizotinib with chemotherapy in patients with ALK+ advanced NSCLC and who had failed one chemotherapy regimen. The primary endpoint was progression-free survival (PFS) and overall survival (OS) was a secondary endpoint. While treatment with crizotinib increased significantly the PFS (4.7 months) no significant improvement in OS was observed versus chemotherapy group (OS interim analysis). Some quality of life (QoL) items (e.g. chest pain, dyspnea, fatigue) were improved within the crizotinib group. Even though no improvement in the OS was shown, the G-BA assessed the crizotinib benefit as considerable based on the improvement of QoL and morbidity decrease. The HAS also granted crizotinib an improvement in actual benefit of III based on the improvements in the PFS and QoL. However, the significant gain in PFS was not sufficient to get positive guidance from NICE. Indeed, NICE did not recommend the use of crizotinib due to the uncertainties surrounding the OS: interim OS for data and high rate of patients “cross-over” from standard therapy to crizotinib arm. CONCLUSIONS: Cross-over has become a real obstacle to appreciate oncology product value. While an additional benefit can be granted based on improvement in PFS plus morbidity and QoL results in Germany and France, products supported solely by an increased PFS and no change in OS may face access barriers in England.

PCN266

IMPACT OF HEALTH CARE REFORM ON DRUG REIMBURSEMENT DECISION-MAKING IN TAIWAN

Lai L1, Chou C1, Chien H2, Hsiao H2, Yen Eng A2
1Quintiles Consulting, Reading, UK, 2Quintiles Consulting, Hoofddorp, The Netherlands

OBJECTIVES: Taiwan is considered a challenging market to access, largely due to strict pricing and reimbursement policies. To assess the impact of health insurance reforms introduced in January 2013 (Second Generation National Health Insurance or 2GNHI), Taiwan reimbursement decisions and granted prices before and after the introduction were compared with major western countries. METHODS: Publications of Taiwan NHI from March 2011 to February 2014 were searched and reimbursement decisions identified. The largest therapy areas, oncology and cardiovascular, which accounted for 40% of decisions, were compared with those of three major HTA agencies: CADTH, NICE and PBAC. HTA reports and meeting transcripts were analysed and categorised by: data, therapy area, decision, rationale, and pricing decision. Resubmissions or those not assessed by the western HTA agencies were excluded. RESULTS: A total of 65 NHI reports were identified. Of these 26 reported decisions on oncology or cardiovascular drugs 2 were excluded (3 resubmissions, 9 not reviewed by the other agencies). Prior to 2GNHI, 4 out of 5 decisions were positive, or 80% approval rate, while after, only 4 out of 9 were positive, a 44% approval rate. Prior to 2GNHI, all NHI reimbursement decisions were made by CADTH, NICE, and PBAC. After 2GNHI only 69% or 66% matched. Clinical effectiveness and budget impact were most cited in reimbursement decisions. For example Zytiga, NICE appreciated the cost-effectiveness but stated budget impact was too high, issuing a negative recommendation, contrary to the other agencies. Interestingly, a ‘local’ product was recommended for limited reimbursement even though budget impact was high. CONCLUSIONS: Since implementation of Taiwan’s NHI reforms in January 2013, cardiovascular and oncology drug approvals decreased by 36% in Taiwan compared with western countries. 40%, placing an emphasis on budget impact. However, this analysis was constrained by its small sample size, and limited therapy areas.