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DISEASE PREVALENCE AND HEALTHCARE RESOURCES CONSUMPTION IN PATIENTS WITH BASAL CELL CARCINOMA IN ITALIAN LHUS

Degli Esposti L[1], Sangiorgi D[1], Buda S[1], Crovato E[1], Cerra C[2]

[1]*CliCon S.r.l., Ravenna, Italy,* [2]*Pavia LHU, Pavia, Italy*

OBJECTIVES: The aim of this study was to assess basal cell carcinoma (BCC) prevalence in real practice, and to calculate the related healthcare resources consumption. **METHODS:** An observational retrospective cohort analysis based on administrative databases of three Italian Local Health Units was conducted. Beneficiaries who have been hospitalised for BCC (ICD-9 code 173) or with a histological diagnosis (ICD-O M8090/3-8093/3) from January 1st, 2009 to December 31st, 2013 - index date - were included. Patients were characterised back to Jan 2009, and followed up till the end of the observation period (Dec 2013) to assess healthcare resource consumption. **RESULTS:** According to preliminary findings on around 550'000 beneficiaries, BCC prevalence through discharge diagnosis was around 6 cases every 10.000 patients/year; considering also pathological anatomy database, 10 cases of BCC every 10.000 patients/year were reported. Advanced patients (aBCC) were reported to be around 4%, most of them defined according to the following criteria: two surgical excisions on the same side and at least one subsequent procedure (surgery, radiotherapy, photodynamic therapy or imiquimod), 0,3% of enrolled patients had metastasis.During follow-up, ambulatory surgery was performed in 63.5% of advanced patients, around 1.6% underwent radiotherapy and 38.1% of them had at least one hospital admission; imiquimod was prescribed in 11.1% of patients. Yearly aBCC patients resource expenditure was around 404€ for hospitalisations - index costs excluded - 32€ for ambulatory care and 77€ for drugs (anti-inflammatories, antibiotics and topic drugs; 16€ for imiquimod). **CONCLUSIONS:** As BCC patients are reported to have a low recurrence of hospitalisations, discharge-based analysis would underestimate real prevalence. With pathological anatomy database, this study estimated 0.4 advanced BCC cases/10'000 beneficiaries/year. Healthcare consumption in this sub-population was driven by hospitalisations and ambulatory costs due to surgical excision

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ASSESSMENT OF BURDEN AND ECONOMIC IMPACT OF THE VANDETANIB RESTRICTED DISTRIBUTION PROGRAM IN CANADA

Frise S[1], Bergamasco A[2], Kozmenko M[1], Salvo F[3], Moride Y[4]

[1]*AstraZeneca Canada, Mississauga, ON, Canada,* [2]*YolaRx Consultants, Paris, France,* [3]*INSERM Unité 657, Bordeaux, France,* [4]*Faculty of Pharmacy, Université de Montréal, Montreal, QC, Canada*

OBJECTIVES: Vandetanib, approved in 2012 in Canada, is indicated for the treatment of advanced medullary thyroid cancer. QTc-prolongation or torsade de pointes is considered in the risk management plan as an identified risk. To minimize this risk a restricted distribution program (RDP) has been implemented. Although shown effective, there are limited data on its associated burden to patients, health care professionals and the healthcare system. The objectives of the present study are to evaluate qualitatively and quantitatively the burden associated with the different components of the vandetanib RDP and, to determine the economic impact of the program for the healthcare system. **METHODS:** A mixed method evaluation has been used. Burden was determined by comparing prescribing and monitoring practices under the RDP with those that would have been observed in the absence of the RDP. Data on healthcare usage were collected through interviews conducted in convenient samples of HCPs (prescribers, pharmacists and nurses) either exposed to the RDP or not yet certified for the vandetanib RDP (i.e., unexposed) but familiar with the treatment of medullary thyroid cancer. A mapping of patient journeys, with and without the RDP, was developed to identify major components of the program. An economic evaluation, considering the perspective of the third party payers completed this analysis. Avoidable costs corresponded to those associated with activities deemed redundant with routine oncology care. **RESULTS:** Major components of the vandetanib RDP have been identified as well as areas of redundancies with standard oncology care. For each component, the qualitative burden for HCPs and ultimately patients was determined along with its associated costs considering the third party payers perspective. **CONCLUSIONS:** Risk minimisation measures should avoid duplication of efforts and loss of economic resources. Evaluation of burden, key to optimize the effectiveness of risk management plans, should be conducted systematically.

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COMPARATIVE ANALYSIS OF EXPENDITURE OF DRUGS FOR MALIGNANCY

Sabo A[1], Tomic Z[1], Sklenarova Z[1], Paut Kusturica M[2], Milijasevic B[2]

[1]*Faculty of medicine, Novi Sad, Serbia and Montenegro,* [2]*Faculty of Medicine, Novi Sad, Serbia and Montenegro*

OBJECTIVES: Consumption and expenditure of drugs for malignancy varies between countries. One of the main reason is the high price of this innovative drugs. Developed countries have more resources for the treatment of malignant diseases and better access to expensive drugs than countries with midle income. **METHODS:** We compared the data on expenditure and consumption of innovative anticancer drugs in middle income country Serbia (13,020 USD), and high income country with different GDP: Slovakia (26,497USD) and Norway (64,406 USD) during the year 2012. Consumption data were expressed in grams of active ingredient per million in one year, expenditure in EU. **RESULTS:** In Norway 144 drugs for malignancy is on market, while in Serbia only 92 drugs are available for ttreatemnt of malignancy. In Norway in year 2012 440 million eur was spent for drugs for malignancy, or about 80 million euros per million inhabitans. Slovakia had more than half lower consumption of anticancer medicines, 190 million euros, or about 37 million euros per million inhabitants. In Serbia only 73 million euros was spent for anticancer drugs, or about 10 million euros per million ihabitants, which is much less compared to the other two countries. Data on consumption 10 most expensive oncology drugs, show that the least of these drugs are consumed in Serbia when comparing to Norway and Slovakia. Among them, the most frequently used drug in Serbia is trastuzumab(treatment of metastatic breast cancer). For this indication is also marketed lapatinib, which has the highest consumption among the most expensive drugs in Norway and Slovakia. **CONCLUSIONS:** Countries with lower GDP have less availability of anticancer medicines in amount and in quantity. Countries with lower GDP must control the usage of drugs for malignancy treatemnt if they want to allocated their resurses for treatment of other diseases as well.

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PATIENT COUNT FORECASTS OF ADVANCED NON-SMALL CELL LUNG CANCER: RESULTS FROM THE UK, GERMANY, FRANCE, ITALY AND SPAIN (EU-5)

Kish JK[1], O'Day K[1], Manley-Daumont M[2], Campbell DJ[1], Penrod J[3]

[1]*Xcenda, Palm Harbor, FL, USA,* [2]*Bristol Myers Squibb, Paris, FL, USA,* [3]*Bristol Myers Squibb, New Brunswick, NJ, USA*

OBJECTIVES: Accurate estimates of the number of advanced (Stage IIIb and Stage IV) non-small cell lung cancer (ADV-NSCLC) patients are needed to estimate the potential clinical and economic outcomes of new targeted therapies for ADV-NSCLC. The objective of this study was to forecast counts of squamous/non-squamous cell patients eligible for first- through third-line treatment yearly from 2015-2019 in EU countries. **METHODS:** Segmented linear regression ("joinpoint") was used to forecast age- and gender-stratified lung cancer incidence rates from historical (year 2000+) population-based cancer registry data over the next five-years. Yearly incident case count totals by country were apportioned according to NSCLC morphology and stage at diagnosis. Early to advanced stage progression rates were estimated over a 10-year interval. Advanced patients receiving systemic treatment were further stratified by histology and line of treatment to obtain counts. A probabilistic sensitivity analysis (PSA) was used to estimate variability in the patient counts. **RESULTS:** By histology, the forecasted number of squamous and non-squamous ADV-NSCLC patients receiving first-line treatment in 2015 were: Germany =13,300 and 21,200; UK =8,400 and 21,300; France = 11,800 and 18,800; Italy = 7,600 and 20,500; Spain =7,100 and 11,400. Combined across both histologies, the numbers of patients receiving second- and third-line treatment in 2015 were: Germany =17,400 and 4,400; UK 15,500 and =4,000; France =15,500 and 4,000; Italy =14,600 and 3,800; Spain =9,400 and 2,400. The projected numbers of deaths due to ADV-NSCLC in 2015 were: Germany = 35,300; UK = 27,700; France = 30,800; Italy = 27,400; Spain = 19,500. **CONCLUSIONS:** These results represent the first published data to estimate the current and future number of patients eligible for targeted ADV-NSCLC therapies in the EU-5. Despite declining incidence trends, there remains a significant unmet clinical need for ADV-NSCLC treatments to reduce high mortality rates.

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THE CANCER DRUGS FUND AND PATIENT ACCES SCHEMES WITHIN THE UK: INCREASED ACCESS TO ONCOLOGY MEDICINES OR REDUCED VALUE FOR MONEY?

Maguire PT, Gibson E

Wickenstones, Goring Heath, UK

OBJECTIVES: Patient access schemes (PAS) give UK patients access to medicines not normally funded by the National Institute for Health and Care Excellence (NICE) and balance company profits and competitiveness with government interests to ensure availability of medicines at reasonable prices. In April 2011 the NHS payer funded Cancer Drugs Fund (CDF) was introduced in England to further improve access to life saving cancer medicines not approved by NICE. The objective of this study was to determine whether access to new, non-NICE funded oncology medicines continues to rely on the relatively cost effective PAS or increasingly depends on the more costly NHS payer funded CDF. **METHODS:** A search was undertaken for all NICE- or Scottish Medicines Consortium (SMC)-approved HTAs incorporating a PAS (PAS-HTAs) 4 years before and after introduction of the CDF. In addition, all medicines approved for use under the CDF were identified. **RESULTS:** Fifty five of 128 NICE- or SMC-approved PAS-HTAs between October 2007 and June 2015 were in oncology. Of these, 10 NICE and 4 SMC PAS-HTAs had been approved prior to, whereas 17 NICE and 24 SMC PAS-HTAs had been approved after introduction of the CDF, amounting to an almost 6-fold increase in SMC PAS-HTAs but a less than 2-fold increase in NICE PAS-HTAs over a similar period. However, 7 oncology medicines receiving HTA approval by the SMC but not NICE were included in the May 2015 CDF list of approved medicines. **CONCLUSIONS:** Since the introduction of the CDF, there has been a discrepancy between the number of PAS-HTAs in cancer treatments between NICE and the SMC. For selected medicines, the CDF appears not to have improved access to oncology products as part of PAS-HTAs but rather lead to increased costs to health service payers.

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IMPACT OF DRUG'S PRESENTATION ON PATIENTS' PERCEPTION OF TREATMENT'S RISKS & BENEFITS THROUGH NEW ORDINAL GEE MODELLING METHOD: RESULTS FROM IMI PROTECT WP6

Wiecek W[1], Karcher H[1], Amzal B[1], Beyer A[2], Hoekstra T[2], Fasolo B[3], Hillege JL[2]

[1]*LASER Analytica, London, UK,* [2]*University Medical Center Groningen, Groningen, The Netherlands,* [3]*London School of Economics and Political Science, London, UK*

OBJECTIVES: The mode by which patients receive information may impact their perception of drugs and consequently their compliance. This study aims to measure how different presentation factors (format - textual, tabular, graphical; order of presenting risks and benefits) and patient characteristics can impact perception of a drug's risks and benefits. **METHODS:** Data were collected via an online questionnaire presenting two drug options to patients in three therapeutic areas: atrial fibrillation, breast cancer, diabetes. Two questions were asked on the safety and the willingness to take the drug. A novel Generalized Estimating Equation method for correlated multinomial data proposed by Touloumis et al., 2013 was used to create an ordinal cumulative link model for the questions on perception. Factors controlled for were: presentation format, order of presentation of risks and benefits, comprehension of drug's effects by the subject, order of presentation of different formats, current mood, and demographic characteristics. **RESULTS:** Drug