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COST-EFFECTIVENESS ANALYSIS OF FIRST-LINE TREATMENT FOR METASTATIC RENAL CELL CARCINOMA IN COLOMBIA

Nuñez SM¹, Godoy JI², Cardona AF³, Otero JM³, <u>Lujan M</u>⁴, Lopera D⁵, Carranza H⁶, Spath A7, Gis PR1

¹Pfizer Colombia, Bogota, Cundinamarca, Colombia, ²Hospital Militar Central, Bogota, *First Colombia, Bogota, Cunainamarca, Colombia, *Hospital Militar Central, Bogota, Cundinamarca, Colombia, *Gundinamarca, Colombia, *Gundinamarca S.L.U, Madrid, Spain

OBJECTIVES: Renal cell carcinoma (RCC) is the most common renal tumor and accounts for 2 to 3% of all adult malignancies. Up to 30% of patients with renal-cell carcinoma present with metastatic disease. The aim of the study was to assess the cost-effectiveness of first-line medications for patients with metastatic RCC from the payer's perspective. METHODS: A Markov model was developed using 6-week cycles for evaluating the cost-effectiveness of four mRCC first-line therapies: Interferon-α (3 million units (MU)/day 3 times-per-week for first week; 6MU/day 3 timesper-week for second week, 9MU/day 3 times per-week third week onward), sunitinib (50mg/day 4 weeks ON + 2 weeks OFF), sorafenib (400mg/twice-a-day) and bevacizumab plus Interferon α (10mg/kg/bi-weekly + 9MU 3 times-per-week every 3 weeks). The model had a 10-year time horizon. The four model stages were: No progression, progression, best supportive care and death. Effectiveness data were obtained through a systematic review, resource utilization were collected from a Colombian Delphi Panel, and costs included were retrieved from Colombian tariff manual (SOAT). Effectiveness was measured by progression-free life years (PFLY) and life-years gained (LYG). Costs and outcomes were discounted with a 3% annual rate. Univariate sensitivity analysis was developed. RESULTS: Sunitinib showed higher overall mean costs per patient (US\$ 5,215.48) compared to interferon; while comparing against sorafenib and bevacizumab + interferon sunitinib costs per patient revealed to be lower in US\$12,946.01 and US\$ 102,780.16 respectively. Sunitinib had the higher effectiveness RESULTS: 1.35 PFLY, 2.9 LYG and 1.87 QALY. Incremental cost-effectiveness analysis shows sunitinib is cost-saving compared to sorafenib and to the combination of bevacizumab + interferon, and compared to monotherapy with interferon the incremental cost-effectiveness ratio (ICER) per LYG for sunitinib was US\$12,099, per PFLY was US\$8,381 and per QALY was US\$14,901. CONCLUSIONS: This analysis indicates that sunitinib represents the most cost-effective option for first-line mRCC treatment in Colombia.

ADDITION OF BIVALENT OR QUADRIVALENT HPV VACCINES TO CERVICAL CANCER SCREENING, IN COLOMBIA. A COST- EFFECTIVENESS ANALYSIS

 $\frac{Aponte}{J^1}, Eslava-Schmalbach J^1, Gamboa O^2, Fajardo L^1$ 1 Universidad Nacional de Colombia, Bogotá, Colombia, 2 IECAS, Bogotá, Colombia

OBJECTIVES: To compare the costs and the effectiveness of three strategies against Cervical Cancer (CC): (i) Screening for CC; (ii) Bivalent vaccine (BV) for HPV 16/18 along with screening and (iii) Quadrivalent Vaccine (QV) for HPV 6/11/16/18 along with screening. METHODS: A Markov model was designed to simulate natural history of disease in women, since 12 -vaccination-until 85 years old. Transition probabilities were selected or adjusted to correspond to HPV distribution profile among Colombian women. A systematic review was performed to obtain efficacy of vaccines and screening. Societal perspective was used. The costs analysis included medical and non-medical such as transport, patient/ companion time and care at home. Effectiveness was measured in number of life years saved (LYS). Since QV protects against HPV 6/11 which caused Genital Warts, the impact of this additional effect is measured in the saved money by the reduction in treatment of GW cases. RESULTS: BV was found to be the most costly and also the most effective strategy, followed by QV and finally screening alone. QV resulted to have an incremental cost- effectiveness ratio of US 2232 per LYS; BV compared with QV had an incremental cost-effectiveness ratio of US 7335. Per 100.000 women vaccinated with QV, 8252 LYS are gained over screening alone. For BV only 348 LYS were gained over QV. According to sensibility analysis, results were not affected by vaccines effectiveness but changes in current price of them could modify cost-effectiveness profile. With a 12% price reduction, BV dominate over quadrivalent vaccine. CONCLUSIONS: Both vaccines resulted to be similar in costs an also in effectiveness for Colombian context. HPV vaccination is far more effective but also far more expensive than screening. HPV vaccination is recommended in Colombia but price considerations should be taken into account.

THE COST EFFECTIVENESS OF CETUXIMAB PLUS BEST SUPPORTIVE CARE (BSC) VERSUS BSC ALONE IN LAST LINE FOR KRAS WILD TYPE METASTATIC COLORECTAL CANCER PATIENT POPULATION

Chaugule S, Hay J

University of Southern California, Los Angeles, CA, USA

OBJECTIVES: Cetuximab, a chimeric monoclonal antibody, improved the overall survival and progression free survival of chemorefractory metastatic colorectal cancer (mCRC) KRAS wild (unmutated) type patients in the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) CO.17 study. The objective of our study was to conduct the cost-effectiveness analysis of cetuximab plus best supportive care versus best supportive care alone in KRAS wild type mCRC patients. METHODS: A Markov cohort simulation model was used to simulate therapy costs and effectiveness from the US societal perspective. All estimates of costs and effectiveness were obtained from the literature. The cost-effectiveness ratio was reported as incremental cost per quality-adjusted life-year (QALY) gained. A life time horizon was used. Base case costs and QALYs were discounted at an annual rate of 3%. All costs were adjusted to 2011 US dollars. One-way and probabilistic sensitivity analyses were used to determine the robustness of the model's results using @Risk. The model was developed using Microsoft Excel. RESULTS: The incremental cost with cetuximab compared with best supportive care alone was \$93,934 and the mean gains in quality adjusted survival were 0.30 QALYS. This resulted in base case ICER of \$313,113 per QALY gained. The results were highly sensitive to the cost of cetuximab and health state utility values. CONCLUSIONS: The incremental cost effectiveness ratio of \$313,113 per QALY gained for cetuximab plus BSC compared with BSC alone suggests that cetuximab is not cost effective in KRAS wild type patients with metastatic colorectal cancer even with a willingness-to-pay cut-off threshold of \$120-\$150,000 per QALY gained.

COST-EFFECTIVENESS ANALYSIS OF HYPOMETHYLANT THERAPY (DECITABINE/ AZACITIDINE) COMPARED TO TRANSFUSION THERAPY IN MYELODYSPLASTIC SYNDROME IN COLOMBIA

 $\frac{\text{Cantor E}^1}{\text{Imederi Hospital, Bogota, Cundinamarca, Colombia, }^2 Janssen Cilag Colombia, Bogota, D.C.$

OBJECTIVES: To describe outcomes and economic impact of hypomethylating therapy (Decitabine/Azacitidine) compared to transfusion therapy in adult patients with Myelodysplastic syndrome (MDS) non-candidates to transplant. METHODS: Was building a Markov Model simulating the disease with 6 stages; Myelodysplastic syndrome in treatment, Complete + Partial + Hematologic Response (C+P+HR), transfusion independent, transfusion dependent, Myeloid Leukemia and Death. Every medication was compared with each control group in two different simulations because the characteristics of every control group were different. We were interested in finding the incremental values in outcomes and costs of each treatment. Our case base was an adult patient with MDS non-candidate to transplant. The Temporal Horizon was 1 year, perspective of insurer and mortality avoided progression free disease (PFD) and survival as outcomes. The statistics inputs of the model for the transitions were the Kapplan-Meier curves of Kantarjian H and Fenaux P papers. Were used direct costs from a private hospital in Bogota, Colombia and government prices according regulation laws. RESULTS: The simulation project incremental effectiveness for both hypometilants compared with transfusion therapy. In terms of C+P+HR was 40% for Decitabine and 28% for Azacitidine, in PFD was 73% for Decitabine and 76% for Azacitidine and survival was 50% for Decitabine and 37% for Azacitidine. Compared with transfusion therapy Decitabine was a cost-saving alternative (better results with lower costs) vs. cost-effectiveness for Azacitidine (better results with higher costs). CONCLUSIONS: In Colombia the hypomethylant therapy with Decitabine is a costsaving alternative compared with transfusion therapy.

ECONOMIC EVALUATION OF ABIRATERONE ACETATE AS TREATMENT FOR METASTATIC CASTRATION RESISTANT PROSTATE CANCER AFTER FAILURE OF DOCETAXEL IN SWEDEN

Persson U1, Nilsson S2, Hjortsberg C3, Prûtz C3

¹The Swedish Institute for Health Economics, Lund, Sweden, ²Department of Oncology-Pathology, Stockholm, Sweden, ³Janssen-Cilag AB, Sollentuna, Sweden

OBJECTIVES: Abiraterone acetate (AA), a selective androgen biosynthesis inhibitor, blocks the action of CYP17, thereby inhibiting adrenal and intratumoral androgen synthesis. In a preplanned interim analysis of the Phase 3 trial COU-AA-301, AA plus prednisone (P) showed a significant overall survival (OS) benefit of 3.9 months vs placebo plus P (de Bono, NEJM 2011). A preplanned and updated analysis showed that the improvement in median OS increased from 3.9 months to 4.6 months (HR = 0.74) (Scher, ASCO 2011). The purpose of this study was to evaluate the cost-effectiveness of AA compared to cabazitaxel. METHODS: A survival-based decision analysis model was developed incorporating 3 health states: progressionfree survival, post-progression survival, and OS (indirect comparison). Assuming mitoxantrone (M) + P versus P equivalence, a cost-effectiveness model was populated with data from two placebo-controlled randomized clinical trials in which: (1) AA was an add-on to P (de Bono, NEJM 2011), and 2) cabazitaxel or M was an add-on to P (de Bono, Lancet 2010) in patients with metastatic castrate-resistant prostate cancer post-docetaxel. Resource utilization and costs reflected Swedish treatment conditions within a broad societal perspective. Drug costs per 3-week-model-cycle were \$3180 (€2300) and \$6730 (€4860) for AA and cabazitaxel, respectively. RESULTS: Total costs per patient were \$103,100 (€74,400) and \$104,600 (€75,500) for AA and cabazitaxel, respectively. Quality-adjusted life years (QALYs) were 0.94 and 0.83 for AA and cabazitaxel, respectively. **CONCLUSIONS:** The results show that AA treatment is superior to cabazitaxel in cost per QALY gained. AA appears to provide an OS benefit, compared to cabazitaxel, with a highly manageable and benign safety profile. Adverse events affect both costs associated with taking a given drug as well as health-related quality-of-life of patients receiving treatment.

COST EFFECTIVENESS OF ZOLEDRONIC ACID (ZOL) IN POSTMENOPAUSAL WOMEN WITH EARLY BREAST CANCER RECEIVING ADJUVANT LETROZOLE FROM GERMAN AND ITALIAN PERSPECTIVES

<u>Xue M</u>¹, Fishman P², Botteman M¹

Pharmerit International, Bethesda, MD, USA, ²Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

OBJECTIVES: In the ZO-FAST trial, postmenopausal women with early breast cancer (pmBCa) and a bone mineral density (BMD) T-score ≥-2 and receiving adjuvant Letrozole (2.5 mg/day) were randomized to either immediate ZOL (4 mg/6 months) treatment ("Upfront ZOL") or to the same therapy but only when BMD T-score

decreased to <-2 or fracture occurrence ("Delayed ZOL"). After 60 months, Upfront ZOL increased both BMD and disease-free survival (P<.05) relative to Delayed ZOL. The present analysis assessed the cost effectiveness of Upfront vs. Delayed ZOL in this population, from German (DE) and Italian (IT) payer perspectives. METHODS: A Markov state-transition model was constructed to estimate the lifetime costs and QALY for hypothetical cohorts of pmBCa women receiving Letrozole with Upfront or Delayed ZOL. Consistent with ZO-FAST, at baseline, patients were 57 years old and BCa-recurrence free. Patients could progress over time to "Local Recurrence", "Contralateral Tumor", "Distant Recurrence", or Death. Annual transition probabilities were derived from ZO-FAST, supplemented with literature estimates. Direct costs and utilities were literature-based. All results were discounted using countryspecific rates. RESULTS: In IT, Upfront ZOL treatment was associated with 15.01 OALYs and €21 998, Delayed ZOL was associated with 13.98 OALYs and €19 458. Thus, Upfront ZOL cost €2 453/QALY. In DE, Upfront ZOL treatment resulted in 15.44 QALYs and €24 032. Delayed ZOL was associated with 14.37 QALYs and €23 081. Therefore, Upfront ZOL cost €888/QALY. In both countries, the results were very insensitive to changes in individual model input values. Compared to Delayed ZOL, Upfront ZOL treatment cost ≤€20 000/QALY in >95% of 1000 probabilistic sensitivity analysis model runs in both IT and DE. CONCLUSIONS: This analysis suggests that treatment with Upfront ZOL may reduce recurrence and increase QALY and is highly cost effective relative to a Delayed ZOL strategy from an IT and DE health care perspective.

COST-EFFECTIVENESS OF HER-2-POSITIVE METASTATIC-BREAST-CANCER TREATMENT IN POST-HERCEPTIN PROGRESSION IN COLOMBIA

Chicaiza L¹, Garcia-Molina M¹, Gamboa O², Castañeda C¹, Urrego J¹, Moreno M¹ ¹Universidad Nacional de Colombia, Bogotá, Colombia, ²IECAS, Bogotá, Colombia

OBJECTIVES: Breast Cancer (BC) is the first cause of death among women, and it progresses to metastatic breast cancer (MBC) in half of the cases. HER-2 overexpression is a marker of the worst prognosis and the target of guided therapies. The aim of this study is to assess the cost-effectiveness of therapies against BC with overexpressed HER-2 in Colombia. METHODS: A cost-effectiveness study of MBC treatment in HER-2-positive patients progressing to Trastuzumab was conducted, with a 5-year horizon. Lapatinib + Capecitabine was compared to Herceptin + chemotherapy (Capecitabine, Vinorelbine or a Taxane). The effectiveness rates of those therapies were identified based on published primary studies. In the absence of head-to-head comparisons, Weibull functions for each chemotherapy were estimated from the survival curves and were multiplied by their hazard ratios. The perspective was that of the third payer including all direct medical costs based on Standard National Tariffs. Finally, a Markov model was developed, incremental cost-effectiveness ratios, (ICER), sensitivity analysis, and acceptability curve were estimated. The discount rate used was 3%. RESULTS: Lapatinib + Capecitabine (L+C) is the most effective and less expensive alternative. Hence, it overcomes the alternatives. The cost-effectiveness ratio of such strategy is Col\$49 725 045 per year of life gained. CONCLUSIONS: The strategy with lapatinib is cost-effective in the treatment of MBC after progression to Herceptin.

COST-EFFECTIVENESS ANALYSIS OF AROMATASE INHIBITORS AND TAMOXIFEN AS AN ADJUVANT THERAPY IN POSTMENOPAUSAL WOMEN WITH EARLY-STAGE HORMONE RECEPTOR POSITIVE BREAST CANCER

Sura SD, Sansgiry SS

University of Houston, Houston, TX, USA

OBJECTIVES: The objective of this study was to estimate the cost-effectiveness of Aromatase Inhibitors (AIs) (anastrozole, letrozole and exemastane) and tamoxifen as adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. METHODS: A Markov model comprising of five health states (on treatment, local recurrence, distant cancer, die due to breast cancer and die due to other causes) was developed to estimate the incremental cost per quality adjusted life-year (QALY) gained for anastrozole, letrozole, exemestane and tamoxifen. The analysis was carried out from a third party payer perspective. Transition probabilities were estimated based on randomized clinical trials. Drug costs, health utilities, and direct and indirect costs were obtained from published literature. The time horizon used was 25 years for the hypothetical cohort of 1000 postmenopausal women with hormone receptor positive breast cancer. Costs and QALY were discounted by 5% annually. Sensitivity analyses were performed by varying the values of key parameters, QALY and costs. RESULTS: Under base case assumptions, more OALYs per patient would be gained with letrozole (4.6) than with anastrozole (3.6). exemestane (3.6) and tamoxifen (3.3). The cost of gaining one QALY with letrozole was \$42,307 compared with exemestane (\$71,081), tamoxifen (\$76,826) and anastrozole (\$ 78,114). The estimated ICER of letrozole, exemestane and anastrozole compared with tamoxifen was -\$47,560, \$9,828 and \$93,513 respectively. These results were robust to the two-way sensitivity analyses performed. CONCLUSIONS: In our analysis, letrozole was the cost-effective treatment compared to anastrozole, exemestane and tamoxifen for the primary adjuvant treatment postmenopausal women with hormone receptor positive early-stage breast cancer. Instead of comparing only monotherapy for cost-effectiveness, future research should consider combination therapy while allowing switching between drugs.

COST EFFECTIVENESS ANALYSIS BASED ON PROGRESSION FREE SURVIVAL (PFS) OF PAZOPANIB VERSUS SUNITINIB FOR THE TREATMENT OF ADVANCED RENAL CELL CARCINOMA (ARCC) IN THE MEXICAN CONTEXT

Anaya P¹, Delea TE², Pichardo P¹, Diaz JR³

GlaxoSmithKline, Mexico City, D.F., Mexico, ²Policy Analysis Inc. (PAI), Brookline, MA, USA, ³GlaxoSmithKline, London, London, UK

OBJECTIVES: To develop a cost-effectiveness analysis based on PFS of pazopanib versus sunitinib in the treatment of aRCC in the Mexican context. METHODS: First an adjusted indirect comparison was calculated between pazopanib versus interferon (IFN) and pazopanib versus sunitinib. The hazard ratio (HR) of pazopanib versus BSC was obtained from the IRC subanalysis based on scan dates for patients who progressed; same for sunitinib versus IFN. The HR of IFN versus BSC was obtained from the MRCRCC study. A Markov model comparing pazopanib versus sunitinib was designed with a two years time horizon and with a 5% discount in costs and effectiveness. The costs of drugs and adverse events (AE) grades III and IV were included for both alternatives. We did a probabilistic sensitivity analysis (PFS) with 1,000 simulations. Exchange rate: 1USD = 13.6MXN. RESULTS: The adjusted indirect comparison yield a HR for pazopanib versus IFN of 0.545(95% CI, 0.341-0.871) and for pazopanib vs. sunitinib of 1.012(95% CI, 0.613-1.670). The cost-effectiveness analysis showed a reduction in average cost per patient of \$8171 and a $reduction \, of \, 1.15 \, days \, PFS \, when \, using \, pazopanib \, compared \, to \, sunitinib; incrementary \, compared \, c$ tal cost-effectiveness ratio (ICER) of \$2,525,515 per PFS year (Mexican threshold is \$13,900). According to the PSA 0.7% cases were more effective at a higher cost, 47.4% cases were more effective at a lower cost and 51.9% cases were less effective at a lower cost compared with sunitinib. The AEs cost analysis showed that the cost of treating AEs of sunitinib was \$982(95% CI, \$788-\$1,112) and for pazopanib was \$137(95% CI, \$87-\$192). CONCLUSIONS: Based on PFS time pazopanib demonstrated to be an equivalent alternative to sunitinib in the treatment of aRCC. Sunitinib had an ICER considerably above the Mexican threshold. Pazopanib showed a different toxicity profile that was considerably less costly compared to sunitinib.

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COST EFFECTIVENESS ANALYSIS OF BUSULFAN + CYCLOPHOSPHAMIDE (BUCY2) AS CONDITIONING REGIMEN BEFORE ALLOGENEIC HUMAN STEAM CELL TRANSPLANTATION (HSCT): COMPARISON OF ORAL VERSUS IV BUSULFAN

 $\frac{T\acute{e}llez~Gir\acute{o}n~G^1, Salgado~JL^1, Soto~H^2}{^1Iteliness~S~A~de~CV, M\'exico~DF, Mexico, ^2Iteliness~Consulting, Mexico~City, Mexico~DF, Mexico, ^2OTE Mexico, ^2OT$ HSCT is used as the treatment of hematologic malignancies and BuCy2 is a conditioning regimen before HSCT but is associated to high rates of hepatic veno-occlusive disease (HVOD) mainly due to busulfan (oralBu) plasma concentration variability after oral administration. Intravenous busulfan (IVBu) shows constant plasma concentration allowing better targeting of plasma exposure and reducing occurrence of HVOD. OBJECTIVES: Develop an economic model based in Mexican Institute of Social Security (IMSS) resource payments to evaluate the cost-effectiveness of oralBu versus IVBu as conditioning regimen before HSCT in Mexico. METHODS: A two branch decision tree model in patients with 40 or 60 kg of weight was developed to evaluate the cost-effectiveness in Mexican pesos (MxP) of IVBu (0.8mg/Kg/6hrs) or OralBu (1mg/Kg/6hrs) combined with intravenous cyclophosphamide (60mg/kg/tid) as conditioning regimen before HSCT. The effectiveness measure was HVOD non-occurrence obtained from published clinical trials. Resource use and cost were obtained from an expert panel survey and IMSS published data. The model estimated non discounted cost per patient and incremental costeffectiveness ratios. Probabilistic sensitivity analysis was performed using Monte Carlo simulation second-order approach and deterministic analysis. RESULTS: HVOD non-occurrence was 84.88% in IVBu group and 51.34% in oralBu group. Cost per patient was lower with IVBu (\$148,712.19 - \$180,562.79 MxP) than OralBu (\$291,088.60 to \$293,296.88 MxP) showing that IVBu was the dominant alternative. Sensitivity analysis showed model robustness and confirm IVBu as dominant. CONCLUSIONS: IVBu is a cost-effective conditioning regimen in Mexico and should be considered by clinicians and decision makers as a favorable option before Allogeneic HSCT.

COST EFFECTIVENESS ANALYSIS OF NEW TREATMENTS FOR METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: DOES SEVERITY MATTER? Wilson LS¹, Zhong L¹, Pon V¹, Srinivas S², Frear M¹, Nguyen N¹, Gong C³, Kwon S¹,

Malmstrom R4, Loucks A1

¹University of California, San Francisco, San Francisco, CA, USA, ²Stanford University, Stanford, CA, USA, ³Veterans Affairs, San Francisco, CA, USA, ⁴Veterans Affairs, Martinez, CA, USA

OBJECTIVES: To evaluate cost-effectiveness of abiraterone and cabazitaxel compared to existing palliative chemotherapy, mitoxantrone and placebo for metastatic castration-resistant prostate cancer (mCRPC) patients; focusing on differences in baseline illness severity. METHODS: A decision tree comparing four treatment strategies in mCRPC patients over an 18-month-period was constructed from the societal perspective. Chance nodes included baseline pain as a severity indicator, grade III & IV neutropenia or cardiac events, and survival at 18 months. Probabilities and life expectancies were from two clinical trials (COU-AA1 and TROPIC2). Costs in 2010 US dollars included drugs (Redbook), physician visits, procedures, tests (CPT-codes) and hospitalizations (HCUP). Model cost inputs included drugs, chemotherapy administration, adverse events management, radiotherapy for pain palliation, and death. The short duration excluded need for discounting. Utilities for bone pain, neutropenia, cardiac events and radiation therapy were from published sources. Baseline severity was altered to reflect relatively ill populations. RESULTS: Cabazitaxel and abiraterone give the best effects and cabazitaxel is most costly. For mitoxantrone as compared with placebo, the incremental cost effectiveness ratio (ICER) was \$110K/QALYS and \$63K/LYS. For abiraterone versus mitoxantrone, the ICER was \$76K/QALYS and \$52K/LYS. Cabazitaxel has an ICER of \$925K/QALYS and \$378K/LYS compared to abiraterone. One-way and probabilistic sensitivity analyses show a robust model for most variables. This remained so across the majority of WTP thresholds shown in acceptability curves