Americans participants in the later stages of CKD may be associated with lack of health care access/socio-economic factors. The proportion of population suffering from hypertension and diabetes increased significantly from stage 1 to stage 5 along with marked racial disparities in the higher stages of CKD. Markers such as Vitamin D deficiency, Hypertension & serum creatinine levels can be better monitored by regular blood tests and prove to be effective early indicators in the progression of the disease.

URINARY/KIDNEY DISORDERS – Cost Studies

Abstracts

PUN6

FIVE-YEAR BUDGET IMPACT ANALYSIS OF ONCE-DAILY VERSUS TWICE-DAILY TACROLIMUS, IN PATIENTS UNDERGOING RENAL TRANSPLANT IN THE UNITED KINGDOM

Sudha M1, Lees L1, Warner J1

1Astellas Pharma Europe Ltd, Staines, Middlesex, UK, 2Abacus International, Brostent, Oxfordshire, UK

OBJECTIVES: Non-adherence to immunosuppressants increases risk of late acute rejection (AR) episodes, a known predictor of graft loss, which is associated with re-transplantation, dialysis and increased mortality. Once-daily immunosuppressant formulations demonstrate higher patient adherence than multiple daily doses and may lead to fewer AR episodes and graft losses. A model was constructed to estimate the five-year impact of potentially improved adherence in new renal transplant recipients receiving once- rather than twice-daily tacrolimus. METHODS: The increased potential for sufficient adherence with once-daily immunosuppressants, versus twice-daily, is reported as an odds ratio (OR) of 2.35 (published literature). Increased adherence is assumed to improve consistency in tacrolimus exposure, reducing AR each year post-transplant and may lead to fewer AR episodes and graft losses. Sufficient levels of expected adherence with once- and twice-daily tacrolimus are used to model five-year survival rates for: AR (insufficiently-adherent versus non-sufficiently-adherent patients); graft survival (no pre- or post-transplant rejection (AR) episodes, a known predictor of graft loss, re-transplantation. Results: Assuming 100 new renal transplant recipients annually, once-daily tacrolimus is associated with fewer AR episodes than twice-daily (8.4 and 10.5, respectively), due to improved adherence. Once-daily tacrolimus yields cumulative cost savings of £104,334, including savings in drug acquisition (£69,180); management of AR (£22,837); re-transplantation (£417); dialysis (£13,631). CONCLUSIONS: Use of once- rather than twice-daily tacrolimus reduces incidence of AR and could yield clinical improvements and cost savings over five-years.

PUK7

IMMUNOSUPPRESSANT THERAPY PATTERNS AND ITS COSTS IN POST KIDNEY TRANSPLANT PATIENTS IN THE NATIONAL TRANSPLANT PROGRAM IN BRAZIL

Tedesco-Silva Jr H1, Manfro RC2, Asano EI, Niza ME3, Carvalho P4, Dan S5, Donato BM6, Rahal E7, The KITJ7 STUDY GROUP P8

1Fundação Oswaldo Ramos - Hospital do Rio e Hipertensão, São Paulo, São Paulo, Brazil, 2Hospital de Clínicas de Porto Alegre, São Paulo, São Paulo, Brazil, 3Brazil-Myers Squibb, SA, São Paulo, São Paulo, Brazil, 4New BD Assessoria Empresarial LTDA, São Paulo, São Paulo, Brazil, 5Bristol-Myers Squibb Co, Wallingford, CT, USA

OBJECTIVES: Immunosuppressive drugs (IS) are used in combination/schemes to achieve optimal regimen of immunosuppression, increasing graft and recipient survival rates in post kidney transplant patients. The aim of this study is to determine immunosuppressant treatment patterns and associated costs in kidney transplant patients from the Brazilian National Transplant Program. METHODS: A review of the entire government administrative claim database (Outpatient Information System – SM DATASUS) was conducted from 2005 to 2008, to determine yearly expenses (in 2008 USD) with each IS combination. In order to assess the dynamics of the combinations used, a subset of this population, all patients from 7 hospitals who underwent kidney transplantation in 2004, was followed from January 2005 to December 2007 to estimate switching rates in IS combinations. RESULTS: A total of 4,678 patients were identified (1464 with IS combinations). The most frequently used IS combinations were: cyclosporine plus mycophenolate sodium (US$37,349,606 in 2008), and cyclosporine plus mycophenolate sodium (US$10,163,990 in 2008). A total of 540 patients were eligible for the sub-study. CONCLUSIONS: This study evaluated calcineurin inhibitors (CNI) switching rate and treatment adherence in terms of drug cost was 28% higher for DARB than EPO ($3163 vs. $4039, P < .001). Mean (SD) cumulative dose was 219,060 [226,830] Units for EPO and 818 [956] mcg for DARB, resulting in a dose ratio of 268:1 (Units: mcg DARB). The corresponding drug cost was 28% higher for DARB than EPO ($3163 vs. $4039, P < .001). From 2002 to 2009, a decreasing trend was observed in semi-annual mean weekly doses of ESAs (EPO: 17,053 to 13,674 Units (25% decrease); DARB: 63 to 51 mcg (20% decrease)). After adjusting for potential confounding factors, the DARB cost premium and the decreasing weekly ESA dosing trend over time remained significant. CONCLUSIONS: This study examined erythropoiesis-stimulating agents (ESAs), with >1 claim for CKD, and >1 ESA pharmacy claim were included. Patients diagnosed with cancer, receiving chemo-therapy or dialysis, or receiving both agents were excluded. Mean cumulative ESA dose was used to calculate drug cost (using 102009 wholesale acquisition cost) and dose ratio (Units EPO: mcg DARB). Average weighted weekly ESA dose was calculated during the treatment episode to assess ESA utilization trends over time. Multivariate analysis was also conducted. RESULTS: A total of 4,202 ESA-treated patients were identified (EPO: 1,111, DARB: 3,091). ESA patients were slightly older (60.1 vs 57.0, P < .001) with a higher Charlson Comorbidity Index (1.8 vs 1.4, P < .001). Mean (SD) cumulative dose was 219,060 [226,830] Units for EPO and 818 [956] mcg for DARB, resulting in a dose ratio of 268:1 (Units: mcg DARB). The corresponding drug cost was 28% higher for DARB than EPO ($3163 vs. $4039, P < .001). From 2002 to 2009, a decreasing trend was observed in semi-annual mean weekly doses of ESAs (EPO: 17,053 to 13,674 Units (25% decrease); DARB: 63 to 51 mcg (20% decrease)). After adjusting for potential confounding factors, the DARB cost premium and the decreasing weekly ESA dosing trend over time remained significant.

PUN9

SEVEN YEAR TRENDS OF PHARMACY BENEFIT ERYTHROPOIESIS-STIMULATING AGENT UTILIZATION AND COST CONSIDERATIONS OF CHRONIC PATIENT DISEASE NOT ON DIALYSIS: RESULTS FROM 2 LARGE CLAIMS DATABASES

Yekeman E1, Baileya RA2, Libertiya R2, Sernbort M2, McKenzie RS2, Lefabrav P2

1Analysis Group, Inc., Washington, DC, USA, 2Centocor Ortho Biotech Services, LLC, Horsham, PA, USA, 3Groupe d’analyse, Ltée, Montréal, QC, Canada

OBJECTIVES: This study compared ESA utilization patterns and associated costs as well as dosing trends over time in patients with chronic kidney disease (CKD) not on dialysis receiving epoetin alfa (EPO) or darbepoetin alfa (DARB) through a pharmacy benefit. METHODS: An analysis of pharmacy claims between July 2002 and March 2009 from the Ingenix IMPACT database was conducted. Patients ≥18 years, newly initiated on erythropoiesis-stimulating agents (ESAs), with ≥1 claim for CKD, and ≥1 ESA pharmacy claim were included. Patients diagnosed with cancer, receiving chemo-therapy or dialysis, or receiving both agents were excluded. Mean cumulative ESA dose was used to calculate drug cost (using 102009 wholesale acquisition cost) and dose ratio (Units EPO: mcg DARB). Average weighted weekly ESA dose was calculated during the treatment episode to assess ESA utilization trends over time. Multivariate analysis was also conducted. RESULTS: A total of 4,202 ESA-treated patients were identified (EPO: 1,111, DARB: 3,091). ESA patients were slightly older (60.1 vs 57.0, P < .001) with a higher Charlson Comorbidity Index (1.8 vs 1.4, P < .001). Mean (SD) cumulative dose was 219,060 [226,830] Units for EPO and 818 [956] mcg for DARB, resulting in a dose ratio of 268:1 (Units: mcg DARB). The corresponding drug cost was 28% higher for DARB than EPO ($3163 vs. $4039, P < .001). From 2002 to 2009, a decreasing trend was observed in semi-annual mean weekly doses of ESAs (EPO: 17,053 to 13,674 Units (25% decrease); DARB: 63 to 51 mcg (20% decrease)). After adjusting for potential confounding factors, the DARB cost premium and the decreasing weekly ESA dosing trend over time remained significant.

PUN10

IMPROVED RESOURCE UTILIZATION OUTCOMES ASSOCIATED WITH PREDIALYSIS USE OF PARACITOLAL FOR SECONDARY HYPERPARATHYROIDISM (SHPT)

Mara S1, Frye CB2, Khan SS2, Harshaw Q2, Audhya P4, Deering K5, Starz R1

1Abbott, Abbott Park, IL, USA, 2Tep-Q, Inc., Oak Brook, IL, USA

OBJECTIVES: The objective of this study is to evaluate hospitalizations, outpatient services and medication use in the first year of dialysis associated with pre-dialysis treatment with paricalcitol compared to no predialysis vitamin D receptor (VDR) activator use in chronic kidney disease (CKD) patients with SHPT. METHODS: A matched cohort analysis was conducted in 134 hemodialysis patients comparing utilization outcomes of predialysis use of paricalcitol compared to no VDR activator treatment, using the Medstat™ administrative claims database from 2000-2007. Patients were matched using propensity scoring for age, gender, Charlson co-morbidity Index, and pre-index total costs. Multivariate models adjusted for age, gender,
insurance, physician type, region, pre-dialysis co-morbidities, and pre-dialysis costs were used to evaluate the impact of pre-dialysis paricalcitol treatment on hospitalizations, outpatient services, and medication use in first year of dialysis. RESULTS: Multivariable analysis demonstrated predialysis paricalcitol use was associated with statistically significant reductions in all-cause hospitalizations (0.684–0.950), all-cause outpatient services (0.953, 95% CI: 0.933–0.973) and CKD-related hospitalizations (0.780, 95% CI: 0.635 – 0.958); CKD-related outpatient visits (0.962, 95% CI: 0.938–0.987); and CKD-related medications (0.922, 95% CI: 0.882–0.965). Over the first year of dialysis compared to no predialysis paricalcitol use, incremental cost-effectiveness ratio (ICER), defined as the ratio of additional costs to additional QALYs. Sensitivity analyses were conducted on model probabilities, cost estimates, utility values and the discount rate. RESULTS: At both moderate and severe symptom levels, tamsulosin was dominated by dutasteride, that is, more costly and less effective compared to dutasteride. Compared to dutasteride, combination therapy was more expensive but more effective with the ICERs of $197,625 for moderate symptoms and $241,032 for severe symptoms. However, considering a societal cost-effectiveness threshold of $150,000 per QALY, combination therapy was not cost-effective compared to dutasteride. In most sensitivity analyses, these results were not sensitive to changes in model parameters. CONCLUSIONS: This study showed that tamsulosin was more costly and less effective than dutasteride, and the ICERs for combination therapy compared to dutasteride were higher than the cost-effectiveness threshold. Therefore, combination therapy is not cost-effective relative to dutasteride for moderate-to-severe BPH patients.

**PUK13**

THE COST-EFFECTIVENESS OF EARLY SURGERY, ADDING BIOPY, AND WATCHFUL WAITING IN THE MANAGEMENT OF SMALL SOLID RENAL MASSES: EVIDENCE FROM A MARKOV MODEL


University of Utah, Salt lake city, UT, USA, ¹University of Pittsburgh, Pittsburgh, PA, USA.

OBJECTIVES: To compare the relative cost-effectiveness of three clinical strategies for managing T1a tumor (4 cm or smaller and limited to the kidney): early surgery upon detection of the tumor, adding percutaneous biopsy prior to surgery, and watchful waiting (WW) (monitor with computerized tomography every 6 months until the growth is greater than 2mm per year).

METHODS: A Markov decision tree was used to estimate the expected survival of patients with a QALY and incremental cost-effectiveness (ICER) for each strategy from a societal perspective, based on literature-derived estimates for the probabilities and costs of different outcomes. Multiple one-way and probabilistic sensitivity analysis were conducted to examine the robustness of the results. RESULTS: In the base case analysis, biopsy before surgery improved survival by 0.018 QALYs compared with immediate surgery, at an incremental cost of $55,244/QALY, while the ICER of WW relative to surgery was $11,712/QALY. In the base-case, percutaneous biopsy is more expensive and less effective than WW. The treatment decision was most sensitive to variation of the degree of tumor growth that triggers surgery, utility of living with a mass during WW, and the probability of diagnostic biopsy for benign tumors. Choice of WW versus surgery critically depends on patients’ preferences for tumor removal and the risk of recurrence post surgery. In probabilistic sensitivity analysis, surgery was the most favorable option (WW is less than $100/QALY) if patients are willing to pay $100,000/QALY for a one-year increase in life expectancy, while WW is favored as WTP increases beyond $100,000/QALY, and biopsy was favored over surgery when WTP is > $60,000. CONCLUSIONS: Although WW results in the highest life-time utility, the favorability of WW depends on patients’ preferences for living with a possibly malignant mass and natural history of watched masses during surveillance, which are poorly understood. Biopsy would be favored if its cost decreases and diagnostic certainty increases in the future.

**PUK14**

CHALLENGES IN ASSESSING COST-EFFECTIVENESS OF THERAPIES FOR DIALYSIS PATIENTS: A CASE STUDY OF SEVELAMER FOR THE TREATMENT OF HYPERPHOSPHATEMIA

Grune D., Mendez-Bout D., Avis P., Dunn E., Bernard L.

Cornerstone Research Group Inc., Burlington, ON, Canada, ²Humber River Regional Hospital, Weston, ON, Canada, ³Garveye Corporation, Cambridge, MA, USA

OBJECTIVES: Therapies that extend the lives of dialysis patients can not demonstrate incremental increases of dialysis costs if dialysis costs are included. This study aims to identify the cost-effectiveness if dialysis costs are included. The case study used resource use and survival data for DCOR patients and extrapolated using a Weibull regression model. The base case analysis used resource use and survival data for DCOR patients 265 years combined with Canadian unit costs and utility weights published in literature. Dialysis costs were excluded from the base case analysis, as dialysis use is unrelated to phosphate binder choice. Analyses were conducted for a 10-year time horizon using the Alberta Health Care System perspective, with costs and outcomes discounted at 5% per year. RESULTS: Compared with CBBs, sevelamer resulted in a gain of 1.02 LYS and 0.62 QALYs/patient (discounted) producing ratios of $20,847/LYS and $34,175/QALY. Over a lifetime horizon, the cost/LYS and cost/QALY were $23,804 and $39,022 respectively. Inclusion of dialysis costs resulted in ratios above $90,000/LYS and $150,000/QALY. CONCLUSIONS: The study highlights the challenges associated with assessing funding of therapies that extend life in dialysis patients and discusses the applicability of dialysis costs in such situations. It found that sevelamer offers good value for money compared to CBBs in the treatment of hyperphosphatemia in patients 65 years old receiving dialysis.

**PUK15**

COST-EFFECTIVENESS ANALYSIS OF THREE MONTHS TREATMENT WITH TESERODINE COMPARED TO GENERIC OXYBUTYNYL EXTENDED-RELEASE IN WOMEN WITH URINARY INCONTINENCE FROM A THIRD PARTY PAYER PERSPECTIVE

Blair DA¹, Kohn MJ¹, Ousterhout M²

UPMC Medical School, Shrewsbury, MA, USA, ¹Massachusetts College of Pharmacy and Health Sciences, Boston, MA, USA

OBJECTIVES: Six pharmacological agents are FDA-approved to treat urinary incontinence, a condition that has economic costs of $19 billion US dollars per year. This study compares the recently FDA-approved fesoterodine to generic oxybutynin extended-release (ER) to identify which agent is more cost-effective in the treatment of urinary incontinence for three months in women over age 60 from the third party payer perspective. METHODS: A search was conducted using the MEDLINE Database from 1980–2009 for the terms “oxybutynin,” “fesoterodine,” “randomized controlled trial,” and “urinary incontinence.” Five articles evaluating clinical improvement among a predominantly female population were identified for inclusion. For the purpose of this analysis, an effectively treated patient was defined as a patient demonstrating a decrease of 14 or more episodes per week of each of the following urge symptoms regarding the use of paricalcitol. Further studies are needed to confirm these results.

**PUK12**

ECONOMIC EVALUATION ON THE USE OF OXYBUTYNYL, TOLTERODINE, AND SOLIFENACIN IN PATIENTS WITH HYPERACTIVE BLADDER

De Lago Acosta A, Saizala O, Idrizo J¹, Zagar A, Alain A, Rico P¹

LaBioscience Mexico, DF, Mexico, ²Hospital Universitario de México Federico Gómez, Mexico, DF, Mexico, ³National Institute of Public Health, Cuernavaca, Morelos, Mexico, ⁴Guía Mark, Mexico, DF, Mexico, ⁵Guía Mark SA DE CV, Mexico, DF, Mexico

OBJECTIVES: Hyperactive Bladder (HB) is a common, debilitating condition with a considerable negative impact on quality of life. The cost-effectiveness (CE) of three medications was evaluated for the treatment of patients with Hyperactive Bladder from the Mexican Institute of Social Security (IMSS) perspective. METHODS: CE analysis from the perspective of the service provider (IMSS). Since it is a chronic disease with different stages, a Markov model with monthly cycles in a 12-month temporal horizon was developed. Only direct medical costs were used in the analysis. Direct medical costs were estimated on a sample of patient files in two IMSS medical units. Criteria for inclusion was patients with more than 6 months of treatment. The effectiveness measurement was taken from literature and was defined as the percentage of patients that did not present symptoms of incontinence. Unvaried and probabilistic sensitivity analyses were performed. RESULTS: The oxybutynin treatment reflected the lowest expected cost per patient treated for hyperactive bladder, US$45 (1 USD = 13.5MXN), followed by the solifenacin and tolterodine treatments, with a cost of US$80 and US$135, respectively. As for the effectiveness measurement, the percentage of patients that did not present incontinence within the temporal horizon of analysis was: with tolterodine 2.76%, with oxybutynin 7.11% and with solifenacin 7.46%. Therefore, cost-effectiveness ratios interpreted as the cost per percentage point of patients that did not present HB are: oxybutynin US$787, solifenacin US$1,310, and tolterodine US$441. The incremental cost effectiveness analysis indicates that tolterodine is a dominated alternative and that oxybutynin and solifenacin are positioned within the efficiency line. Nonetheless, when conducting the probabilistic analysis, it was found that with Solifenacin US$851 available, a solifenacin treatment would be more cost-effective for the institution. CONCLUSIONS: From an institutional perspective, solifenacin is a cost-effective alternative for treating patients with HB in the Mexican context.