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Mepact® (mifamurtide) is the first drug approved for treatment of high-grade resectable non-metastatic osteosarcoma in patients aged 2-30 in the last 20 years. It follows a randomised clinical trial showing a statistically-significant and clinicallyrelevant decrease in the risk of death without compromising safety. OBJECTIVES: This study assessed the cost-effectiveness and budget impact of mifamurtide added to the standard chemotherapy of cisplatin, doxorubicin and methotrexate with this same standard therapy (ST) without mifamurtide. METHODS: A Markov model was built to combine trial-based outcomes with Spanish resource use and unit cost of compared options. The analysis has been carried out from the perspective of the Spanish National Health Service, with a time horizon of up to 60 years in the base analysis. A probabilistic sensitivity analysis was carried out to assess the influence of the uncertainty of the variables introduced into the model. All the costs are expressed in euros for the year 2011 and, beyond the first year, both costs and effects (quality-adjusted survival) have been discounted with an annual rate of 3%, following local recommendations. **RESULTS:** The observed greater efficacy of mifamurtide in the trial translates into a gain of 3.03 (undiscounted) and 1.33 (discounted) QALYs and an additional cost of €102,000. The estimated budgetary impact of using mifamurtide in 10% to 100% of the potential population would cost €671,000 and €6.7 million respectively. **CONCLUSIONS:** The iCER of mifamurtide in Spain is in the low band ( $< \epsilon 100,000$ ) of the iCERs obtained by other orphan drugs and would have a limited, predictable and affordable cost in Spain.

## COST ANALYSIS IN THE TREATMENT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS IN RUSSIAN FEDERATION

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OBJECTIVES: To evaluate and compare costs of belimumab treatment plus standard of care (SoC) vs SoC alone in patients with systemic lupus erythematosus (SLE). METHODS: The cost analysis was conducted of the belimumab treatment plus SoC vs SoC alone for one year. Based on the results of clinical trials to assess safety and efficacy of belimumab (BLISS-52 and BLISS-76) the cost structure of treatment was determined. RESULTS: The costs were evaluated in the following groups: drug costs, costs of inpatient and outpatient visits, costs for correction of adverse events and costs for treating of SLE complications. The costs of inpatient visits comprised 91,830 RUB/ 1,976 EUR for SoC alone and 52,991 RUB/ 1,140 EUR for patients treated with belimumab plus SoC. The correction of adverse events came to  $\overline{7}$ ,763 RUB/ 167 EUR for SoC alone, while for belimumab plus SoC it was 7,846 RUB/ 169 EUR. The costs of treating SLE complications totaled 384,976 RUB/ 8,283 EUR and 370,229 RUB/ 7,966 EUR for SoC alone and belimumab plus SoC groups of patients, respectively. CONCLUSIONS: The costs of inpatient visits in belimumab treatment group were lower than those of the SoC group resulting from a reduction in the frequency of SLE flare. The costs for correction of adverse events were similar in both patients groups due to a good safety profile of belimumab. The level of costs for treating SLE complications was lower in belimumab as compared to that in SoC group as a consequence of lower frequency of cardiovascular, pulmonary, renal, and skin complications in the belimumab treatment group. A good safety profile and efficacy of belimumab, which had been demonstrated in clinical trials, led to a decrease in costs of inpatient visits and treatment of SLE complication in patients treated with belimumab.

# OPIOID PRESCRIBING AND THE IMPACT OF BRANDED GENERICS

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OBJECTIVES: Opioids are the mainstay of therapy for patients with moderate to severe pain. Mandatory generic substitution exists in South Africa, unless otherwise indicated by the prescriber or if the patient refuses. Few studies have been conducted in South Africa analysing the prescribing patterns and cost of opioid analgesics. METHODS: A retrospective, cross-sectional drug utilisation study was conducted on prescription data of a medical insurance scheme administrator in South Africa for 2011. The database contained 2 298 312 records for medicine, medical devices and procedures. **RESULTS:** A total of 97 491 analgesics were dispensed to 31 854 patients during the year. Within ATC category N02, opioids (N02A) accounted for 26.55% of analgesic prescriptions at a cost of R1 071 230.14. A total of 9 793 patients were prescribed 25 888 opioid analgesics. The average age of patients was 41.50 (SD=16.61) years. Female patients were slightly younger (average age: 40.69 (SD=17.05) years) than male patients (average age: 42.32 (SD=16.09) years). Nine different active ingredients and two combination products were prescribed. Tramadol, an atypical opioid, was the most often prescribed (68.11%), followed by pethidine (14.39%) and morphine (8.38%). The average cost per prescription was R41.38 (SD=R69.29). Fentanyl had the highest average cost per prescription (R454.43), and pethidine the lowest (R8.53). Overall, the average cost for an originator product was R56.25 and for a generic product R28.95. Tramadol accounted for 68.11% of prescriptions and 80.40% of cost. Tramadol had the most most branded generic equivalents on the market (7), yet only had 42.89% generic prescribing. Most prescriptions were issued by private hospitals (62.89%), followed by pharmacies (24.41%) and general medical practices (12.16%). Only 35.48% of the products were prescribed on a chronic basis. **CONCLUSIONS:** Tramadol dominated opioid prescribing. The study confirmed price differences for opioid analgesics between branded generics and originator products.

PILL BURDEN, HEALTH CARE RESOURCE UTILIZATION AND COSTS AMONG SUBPOPULATIONS OF IMMEDIATE RELEASE HYDROCODONE USERS

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OBJECTIVES: To assess pill burden, health care resource utilization (HRU), and costs among patients with long-term immediate release (IR) hydrocodone use. METHODS: We performed a retrospective analysis of health care claims from 2011-2012 Truven MarketScan® Commercial, Medicare supplemental, and Medicaid Multistate databases. Patients with IR hydrocodone prescription for ≥ 90 days during 6 month baseline period (July 2011- December 2011) with continuous enrollment during baseline and 12 month follow-up periods were selected. The final population was sub-categorized by prescribed coverage days (PCD) of IR hydrocodone during baseline into 90-119, 120-179, and  $\geq$ 180 days. Chi-square or ANOVA analyses were used to test pill burden, HRU and costs (standardized to 2013 US dollars) during baseline and follow-up periods across subpopulations. RESULTS: A total of 36,174 commercial, 32,699 Medicaid, and 8,873 Medicare IR hydrocodone users were selected. In the baseline period, subgroups with longer PCD had significantly more average hydrocodone pills per month yet fewer HRU and medical costs (all p<0.05). However, during the follow-up period, groups with longer PCD had greater increase in number of inpatient hospitalizations and other types of HRU (length of stay, outpatient hospital visits, office visits, and emergency room visits). The subgroup of patients with PCD <120 days had lower annual all-cause medical costs during follow-up compared with baseline (decreasing \$2,624, \$2,955, \$4,209 per patient per year in Medicaid, Medicare and commercial patients, respectively), while patients with longer PCD during baseline had increased costs (p<0.05). For example, Medicaid patients with 120-179 PCD had an increase of \$1,874 and those with  $\geq$  180 PCD had an increase of \$4,348. These trends were similar for all insurance types. CONCLUSIONS: Extended length of PCD, particularly after 120 days, corresponds with higher patient burden including elevated pill burden and rising HRU and costs in both commercial and public insurance patients with long-term IR hydrocodone use.

PREVALENCE-BASED MEASUREMENT OF THE ECONOMIC BURDEN OF RARE DISEASES: CASE REVIEW TO DETERMINE THE ANNUAL COST OF ACROMEGALY IN FRANCE

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OBJECTIVES: Although acromegaly is acknowledged as requiring resource-intensive treatment, its ultimate economic burden is unclear. As an extension of work presented at ISPOR 2013 International Conference (New Orleans, US), the objective of this research is to measure the annual economic burden of acromegaly in France using a case-review methodology with a prevalence-based sample of patients diagnosed with acromegaly. METHODS: A case-review method was used with a sample of 22 endocrinologists reviewing 88 patient cases (4 cases per physician) diagnosed with acromegaly. The patient case histories included: resource utilization including office visits and hospitalization, diagnostic procedures and labs, medications prescribed, medical procedures preformed, and an estimate of lost productivity. A micro-costing analysis was conducted to obtain costs in the prior 12 months for each patient case reviewed using published literature, medical fee schedules, and pharmaceutical cost databases to assign costs to treatments and medical procedures identified in the survey data. Annual costs were examined across a broad range of patients of different ages, gender and time from diagnosis. Two biomarkers were used to categorize acromegaly patients as Controlled vs. Uncontrolled: Insulin Growth Factor-1 (IGF-1) and Growth Hormone (GH). Several patient characteristics were used as control factors when comparing annual economic costs: age, sex, and time from diagnosis. Statistical tests and confidence intervals were calculated to determine the significance of patient characteristic effects on economic burden. **RESULTS:** Three patient subgroups were used to classify uncontrolled acromegaly patients: IGF-1, GH and both IGF-1 and GH. The annual per-patient economic burden of disease costs ranges from € 29,000 to € 79,400 across these groups. These cost ranges are benchmarked to other studies to provide context and validity. CONCLUSIONS: The total economic burden of acromegaly in France is significant. Understanding the factors impacting burden of illness will inform future improvements in treatment practice.

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RATES OF DIAGNOSED OPIOID ABUSE OR DEPENDENCE AND INCREMENTAL DIRECT HEALTH CARE COSTS AMONG PATIENTS WITH LONG-TERM USE OF IMMEDIATE RELEASE HYDROCODONE

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**OBJECTIVES:** To estimate rates of diagnosed abuse and incremental health care costs among long-term immediate release (IR) hydrocodone users. METHODS: We performed a retrospective analysis of health care claims from 2011-2012 Truven MarketScan® Commercial and Medicaid Multistate databases. Patients with IR hydrocodone prescription ≥ 90 days during 6 month baseline period (July 2011-December 2011) with continuous enrollment during baseline and 12 month follow up periods were selected. Opioid abuse was defined as a patient having at least one medical claim indicating opioid abuse/dependency (ICD-9-CM diagnosis codes: 304.0x, 304.7x, 305.5x, 965.00,965.02 or 965.09) during the study period. Rates of opioid abuse during baseline and follow up periods were estimated by plan type, along with total health care costs, standardized to 2013 US dollars. Generalized linear model regressions were used to estimate incremental costs in the post-index period. RESULTS: A total of 32,699 Medicaid and 36,174 commercial IR hydrocodone users were selected in the study. Rates of abuse were 96 and 36 per 10,000 patients,

respectively. Abusers had higher unadjusted annual total health care costs than

non-abusers during both baseline and follow up period (p<0.05). After controlling

for baseline characteristics of age, gender, Charlson Comorbidity Index, pill burden