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PRICE ANALYSIS OF MULTIPLE SCLEROSIS DISEASE-MODIFYING THERAPIES MARKETED IN THE US

Bin Sawad A[1], Seoane-Vazquez E[1], Rodriguez-Monguio R[2]
[1]MCPHS University, Boston, MA, USA, [2]School of Public Health and Health Sciences, UMASS, Amherst, MA, USA

OBJECTIVES: To assess the trends in average wholesaler prices at market entry for multiple sclerosis (MS) disease-modifying therapies (DMTs) approved by the US Food and Drug Administration (FDA) in the period 1987-2014. **METHODS:** DMTs regulatory information was derived from the FDA website. Average wholesaler prices (AWP) per unit at market entry data were derived from the RedBook (Truven Health Analytics, Inc.). The AWP history was collected from year of approval to October 2014. The daily defined dosage (DDD) for adult patients was obtained from FDA approved labels. AWP per DDD and the AWP per year were computed. Descriptive statistics and Wilcoxon tests were performed. Statistical significance level was set at 0.05. **RESULTS:** The National Multiple Sclerosis Society listed 11 FDA approved DMTs (5 new drug applications [NDA] and 6 biological license applications [BLA]) as of October 2014. Two products were approved by the FDA using priority review. The FDA granted orphan designation to 5 DMTs. Only one DMT had generic competition in the study period. There was one DMT approved by US FDA in the 1980s, three in the 1990s and 2000s, respectively, and 4 in the period 2010-2014. The median AWP per DDD was $5.88 in the 1980s, $7.13 in the 1990s, $217.52 in the 2000s, and $274.76 in the period 2010–Oct 2014. Statistically significant differences were found in median AWP per DDD prices between NDAs and BLAs. The median AWP per DDD was not significantly different for FDA priority review drugs compared to standard review drugs, and for orphan compared to non-orphan drugs. **CONCLUSIONS:** The median AWP per DDD for DMTs at market entry increased substantially over time. No statistically significant differences were found in the median AWP per DDD between priority and standard review drugs, and between orphan and non-orphan drugs.

PND25

THE ECONOMIC BURDEN OF SPINAL MUSCULAR ATROPHY

Armstrong EP[1], Malone DC[2], Yeh W[3], Dahl GJ[4], Lee R[5], Sicignano N[6]
[1]Strategic Therapeutics. LLC, Oro Valley, AZ, USA, [2]University of Arizona, Tucson, AZ, USA, [3]Biogen Idec, Cambridge, MA, USA, [4]Naval Medical Center Portsmouth, Portsmouth, VA, USA, [5]Naval Medical Research Unit Dayton, Dayton, OH, USA, [6]Health ResearchTx, Trevose, PA, USA

OBJECTIVES: To evaluate the economic consequences of having spinal muscular atrophy (SMA). **METHODS:** This study was conducted using Department of Defense Military Healthcare System (MHS) data from 2003 to 2012. Eligible persons had a SMA diagnosis (ICD-9CM codes 335.0 or 335.1) on 1 inpatient or 3 outpatient claims before 18 years of age. Individuals had at least 6 months of data after first SMA diagnosis; or died within 6 months after first SMA diagnosis; or had at least 12 months of data before first SMA diagnosis. Subgroup analyses were conducted for early (≤1 years) and late diagnosis (>1 years). **RESULTS:** A total of 239 individuals met the inclusion criteria. The median total expenditure, while enrolled in the MHS, was $83,652 (25-75 percentile $29,620-$228,754) over a mean observation of 6.9±3.6 years, though rare outlier costs were as high as $4.4 million. The mean age (SD) at first observed SMA diagnosis was 7.5±6.4 years. The mean (SD) duration of observation following initial SMA diagnosis was 4.8±3.3 years with a median cost of $60,213 ($18,229-$192,559). For all patients, the primary cost driver was outpatient costs (median $53,152 ($23,902-$136,150)), followed by inpatient costs (median $11,258 ($0-$51,987)) and total prescription costs (median $3,167 ($943-$13,283)). The subgroup of patients with early diagnosis (n=45) had 4.3±2.9 years of observation with a median cost of $167,921 ($53,349-$678,412)). Approximately 17.8% of this subgroup died during the observation period, which highlights the devastating nature of early onset SMA. Patients with late diagnosis (n=194) had 7.5±3.4 years observation and median total costs of $70,380 ($28,196-$184,272). **CONCLUSIONS:** Individuals with SMA have a high degree of morbidity and mortality, particularly those diagnosed during infancy. SMA patients have significant medical expenditures and high utilization of health care services. There is significant economic burden caring for patients diagnosed with SMA. **DISCLAIMER:** Research derived from an IRB approved protocol at Naval Medical Center Portsmouth, VA. The views expressed in this abstract are those of the authors and do not necessarily reflect the official policy or position of the Department of the Army, Department of the Navy, Department of Defense or the United States Government. George J. Dahl and Rees Lee are members of the U.S. military. This work was prepared as part of their official duties. Title 17 U.S.C. 105 provides that 'Copyright protection under this title is not available for any work of the United States Government.' Title 17 U.S.C. 101 defines a United States Government work as a work prepared by a military service member or employee of the United States Government as part of that person's official duties.

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WITHDRAWN

PND27

OUT OF POCKET COST FOR PEDIATRIC EPILEPSY MANAGEMENT: RESULTS FROM MALAYSIAN POPULATION

Kashyap M, Bahari B
AIMST University, Semeling, Malaysia

OBJECTIVES: Epilepsy is common chronic disorder characterized by recurrent unprovoked seizures with incidence rate of 20 to 70 per 100 000 population per year. Approximately 150,000 children sustain a first-time unprovoked seizure every year, and of those, 30,000 develop epilepsy. To evaluate the economic burden of pediatric epileptic patients and cost of their epilepsy management from the patients' perspective. **METHODS:** This study adopted a prospective cross sectional design by interviewing the patient's parents from neurology clinic of Hospital Pulau Pinang, Malaysia. A retrospective data (for the past 12 months) was collected from patient's medical record for the laboratory test, investigations and treatment received. The collected data included information about the patient's resources utilization, lost productivity, and out of pocket expenditure. **RESULTS:** Majority of respondent was male which comprise of 64.2% whereby female was 35.8%. Mean (±SD) total annual cost from patient perspective was RM 1303.05 ± 2288.66 (USD 366.69±644.06) per patient. The highest item cost which contributes to the total annual cost was the loss of productivity which is RM 528.26 ± 786.22 (USD 148.66±221.25) followed by cost of caretaker RM 690.32 ± 1929.41 (USD 194.26±542.96) and meal/snack cost during clinic visit RM 44.97±56.87 (USD 12.66±16). The lowest contributor for annual cost from patient perspective was transportation cost with a mean of RM 39.51 ± 31.73 (USD 11.22±8.93). **CONCLUSIONS:** In conclusion, from patients' perspectives loss of productivity is the major contributor in economic burden to epilepsy management in pediatric. Type of seizure associated with neurological deficit and the response to the medication which affects the number of clinic visit, number of hospitalization and length of hospital admission influence lifetime cost of epilepsy bear by the patient depending on employment and monthly incomes as well as who is the caretaker and who bring the child to clinic visit and accompanied the child during hospital admission.

PND28

ANALYSIS OF MEDICAL COSTS OF RRMS RELAPSES

Nakamura Y
Milliman, Tokyo, Japan

OBJECTIVES: No recent study on the medical costs of multiple-sclerosis (MS) has employed real world data to analyze relapsing-remitting multiple sclerosis (RRMS) and primary progressive multiple sclerosis (PPMS). This paper analyzes the medical costs of RRMS to identify the causes of the high medical costs of MS. **METHODS:** We selected subjects from among active employees and their families who were covered by private health insurance from MedStat Commercial Data from 2005 to 2012. We developed logic to identify MS patients, MS relapses and RRMS patients and PPMS patients with claims data. The PPPM of RRMS patients was analyzed in cases where relapsing intervals were greater than the average interval length. **RESULTS:** The PPPM of RRMS patients was $4,964 PPPM. The frequency of RRMS relapses was 3.2 times during 5 years. The PPPM of RRMS patients was reduced by $958 PPPM when relapsing intervals were increased by 1.2 times compared to the usual RRMS relapsing intervals. The PPPM of RRMS patients was reduced by $1,139 PPPM when relapsing intervals were increased by 1.5 times compared to the usual RRMS relapsing intervals. **CONCLUSIONS:** The number of RRMS patients among MS patients was 87 %. The PPPM of relapses accounted for 83% of PPPM of RRMS. By restricting the frequency of relapses it is possible to reduce the PPPM of RRMS patients.

PND29

A RETROSPECTIVE ANALYSIS OF THE ECONOMIC BURDEN AMONG PATIENTS DIAGNOSED WITH CHRONIC MIGRAINE USING THE VETERANS HEALTH ADMINISTRATION MEDICAL DATA

Mao X[1], Shrestha S[2], Baser O[3], Wang L[2]
[1]University of Texas at Dallas and STATinMED Research, Plano, TX, USA, [2]STATinMED Research, Plano, TX, USA, [3]STATinMED Research, The University of Michigan, MEF University, Ann Arbor, MI, USA

OBJECTIVES: To evaluate the health care resource utilization and costs among patients diagnosed with chronic migraine (CM) in the Veterans Health Administration (VHA) medical dataset. **METHODS:** Patients diagnosed with CM were identified (International Classification of Diseases, 9th Revision, Clinical Modification diagnosis code 346.XX) using the VHA dataset from October 1, 2008 through September 30, 2010. The initial diagnosis date was designated as the index date. Patients without CM with the same age, gender and region (comparison cohort) were matched using a randomly chosen index date to minimize selection bias. Patients in both cohorts were at least age 18 years and had continuous medical and pharmacy benefits for 1 year before and after the index date. One-to-one propensity score matching (PSM) was used to compare health care costs and utilizations between the CM and the comparison cohorts, and was adjusted for baseline demographic and clinical characteristics. Pain scores were also included to investigate wellness after CM diagnosis. **RESULTS:** After risk-adjustment by PSM, 123,241 patients in each cohort were matched. Significantly more CM patients had inpatient admissions (6.44% vs. 1.75%, $p<0.0001$) and emergency room (ER; 14.42% vs. 5.50%, $p<0.0001$), outpatient office (68.80% vs. 42.15%, $p<0.0001$), outpatient (69.30% vs. 42.91%, $p<0.0001$) and pharmacy visits (70.84% vs. 41.43%, $p<0.0001$) compared to those without CM. Accordingly, CM patients also incurred higher costs for inpatient admissions and ER, office, outpatient and pharmacy visits compared to those without CM. Total costs incurred by CM patients were $4,776, almost triple that of

patients without CM ($1,756). There were more CM patients with accompanying pain at all levels (mild: 19.53% vs. 0.16%; moderate: 13.10% vs. 0.10%; severe: 16.20% vs. 0.12%; all p<0.0001). **CONCLUSIONS:** CM patients in the VHA population had substantial health care resource utilization, incurred higher costs and suffered worse pain compared to those without the disease.

PND30

HEALTH CARE RESOURCE UTILIZATIONS AND COSTS AMONG MIGRAINE PATIENTS IN THE U.S. MEDICAID POPULATION

Huang A[1], Shrestha S[1], Baser O[2], Yuce H[3], Wang L[1]
[1]*STATinMED Research, Plano, TX, USA,* [2]*STATinMED Research, The University of Michigan, MEF University, Ann Arbor, MI, USA,* [3]*City University of New York & STATinMED Research, New York, NY, USA*

OBJECTIVES: To examine the health care resource utilizations and costs among migraine patients in the U.S. Medicaid population. **METHODS:** Migraine patients were identified (International Classification of Disease, 9th Revision, Clinical Modification [ICD-9-CM] diagnosis code 346) using Medicaid data from January 01, 2009 through December 31, 2009. The first diagnosis date was designated as the index date, and patients were required to have at least a 1-year baseline (pre-index date) and 1-year follow-up (post-index date) period. A comparison cohort was created for patients without a migraine diagnosis during the study period, using 1:1 propensity score matching to control for age, region, gender and baseline Charlson Comorbidity Index score. The comparison cohort's index date was chosen at random to minimize selection bias. Patients in both cohorts were required to be age ≥18 years and have continuous medical and pharmacy benefits 1-year pre- and post-index date. Study outcomes (health care resource utilizations and costs) were compared between the migraine and comparison cohorts. **RESULTS:** After applying PSM, 380,751 patients were assigned to each cohort, and baseline characteristics were well-balanced. A higher percentage of patients with migraines had inpatient stays (21.53% vs. 11.00%, p<0.0001), other therapy (99.88% vs. 65.78%, p<0.001) and pharmacy visit claims (90.52% vs. 48.35%, p<0.0001), compared to those without a migraine diagnosis. The patients in the migraine cohort also incurred significantly higher other therapy ($4,111 vs. $2,312, p<0.0001) and pharmacy visit costs ($1,074 vs. $512, p<0.0001) than those in the comparison cohort. **CONCLUSIONS:** Migraine patients incurred significantly higher costs and had higher health care resource utilizations than those without migraines.

PND31

COST-EFFECTIVENESS ANALYSIS OF IPX066 IN ADVANCED PARKINSON'S DISEASE

Arnold RJ[1], Frasco MA[1], Layton A[1], Rustay NR[2], Chen S[2]
[1]*Quorum Consulting, San Francisco, CA, USA,* [2]*Impax Laboratories, Inc., Hayward, CA, USA*

OBJECTIVES: Parkinson's disease (PD) is a progressive disease associated with substantial economic and societal burden. Immediate-release (IR) carbidopa-levodopa (CD-LD) is the gold standard in treatment for advanced PD patients. However, effectiveness of IR CD-LD diminishes with long-term treatment and is associated with increased "off" time (re-emergence of PD symptoms) and the advent of motor complications. CD-LD plus entacapone (CL+E) has produced some clinical improvement over IR CD-LD alone. IPX066 is an extended-release oral formulation of CD-LD designed to address some of the limitations of IR CD-LD by rapidly attaining and maintaining therapeutic LD concentrations for a prolonged duration. The aim of the study was to evaluate the comparative cost-effectiveness of IPX066 against CL+E. **METHODS:** A Markov model was developed comparing IPX066 with branded and generic CL+E in the US market. Health states included ≤ 25% "off" time, > 25% "off" time, and dead. The model simulated a hypothetical patient's progression over a 5-year period through these health states, with a 6-month Markov cycle length. Outcomes evaluated were total direct costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICER). Dosing and efficacy data from a Phase 3 study comparing IPX066 and CL+E, average wholesale acquisition drug costs (RedBook), and published literature were utilized for this evaluation. Non-2014 costs were inflated to reflect the 2014 value using the medical component of the Consumer Price Index. The discount rate employed was 3%. **RESULTS:** IPX066 was dominant over both branded and generic CL+E therapies, with ICERs of (-$166,044) and (-$75,920), respectively. On average, patients who received IPX066 experienced a 5.1% increase in QALYs (2.90) compared with patients who did not receive IPX066 (2.76). IPX066 dominated the other two therapies throughout multiple sensitivity analyses, driven largely by improved effectiveness of IPX066. **CONCLUSIONS:** IPX066 is likely to be a cost-effective therapy in patients with advanced PD.

PND32

COST EFFECTIVENESS OF LEVODOPA/CARBIDOPA INTESTINAL GEL IN IRELAND

Baj R, Egan KM, McCarthy J
AbbVie Ltd., Dublin, Ireland

BACKGROUND: Parkinson's disease (PD) is an incurable, progressive neurological disease, with primary symptoms impacting movement, walking and posture; that eventually become severely disabling. Advanced PD (APD) has a significant impact on Quality of Life (QoL) for patients, their carer's/families. Levodopa/Carbidopa intestinal gel (LCIG) is indicated for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medications have not given satisfactory results. There are no published studies reporting the economic value of LCIG in treatment of patients with APD in Ireland. **OBJECTIVES:** Determine the cost-effectiveness of LCIG compared with Standard of care (SoC) for the treatment of APD patients in Ireland **METHODS:** A deterministic Markov model was used to evaluate LCIG vs. SoC in APD patients with severe motor fluctuations from an Irish health care perspective. The model simulated a cohort of 100 patients and redistributed them into disease-specific health states. Health states were defined by Hoehn & Yahr (H&Y) scale combined with amount of time in OFF-time. SoC comprised of standard oral therapy +/- sub-cutaneous apomorphine infusion and standard follow up visits. Clinical efficacy, utilities and transition probabilities were derived from published studies. Resource costs were estimated from 656 individual patient level data from Adelphi 2012 UK patient dataset, using Irish costs, where possible. Time horizon was 20 years and patients were followed until death if it occurred earlier. Costs and outcomes were discounted at 4%. Both one-way and probabilistic sensitivity analyses were conducted.. **RESULTS:** The incremental cost-effectiveness ratio for LCIG vs. SOC was €41,114/QALY (total costs LCIG vs. SoC are €537,276 vs. €465,716 and QALYs are 4.72 vs. 2.98). LCIG is cost-effective at a payer threshold of €45,000. The model is most sensitive to health state costs. **CONCLUSIONS:** LCIG is a cost-effective option in treating APD patients in Ireland.

PND33

THE COST-EFFECTIVENESS OF DISEASE MODIFYING THERAPIES FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS

Bozkaya D[1], Livingston TP[2], Migliaccio-Walle K[1], Mehta S[2], Odom T[2]
[1]*Xcenda, Palm Harbor, FL, USA,* [2]*Biogen Idec, Weston, MA, USA*

OBJECTIVES: To compare the cost-effectiveness of current disease modifying therapies (DMT) for patients with relapsing-remitting multiple sclerosis (RRMS) in the US. **METHODS:** An economic model was created to predict the course of patients with RRMS following initiation of a DMT. Natalizumab (NAT), dimethyl fumarate (DMF), and peginterferon beta-1a (PEG), were compared with fingolimod (FIN), glatiramer acetate (GA, 40 milligrams thrice weekly), and interferon beta-1a (INT, 44 micrograms thrice weekly), respectively. The Markov state transition cohort model predicted disease progression across RRMS Expanded Disability Status Scale [EDSS] states and for secondary-progressive (SPMS) EDSS states in 3-month cycles over a 10-year time horizon. The patient cohort was at risk of death, relapse, or discontinuation (due to reaching EDSS level 7, or following DMT-specific rates) in each cycle. Outcome measures were relapses, relapse-free time, MS progression, and progression and clinical disease activity-free years. Costs included drug, administration, monitoring, relapse, and EDSS state costs. Incremental cost-effectiveness ratios (ICERs) were estimated for each of the outcome measures. **RESULTS:** Costs ranged from $477,158 (DMF) to $526,667 (INT). NAT, DMF, and PEG were less expensive with equal, or better, outcomes. NAT and DMF were dominant (less costly and more effective) compared to FIN and GA, respectively, for all ICERs. PEG dominated INT on progression and clinical disease activity outcomes. Comparable relapse-related outcomes cost more than $30,000 with INT compared to PEG. Variability in drug costs and parameters that affected drug cost accrual (eg, discontinuation rates and the decision to drop out after SPMS conversion) had a considerable impact on ICERs. **CONCLUSIONS:** Results from this analysis suggest that the NAT, DMF and PEG are cost-effective DMT choices compared to FIN, GA, and INT, respectively. The actual impact to a particular plan will vary based on drug pricing and other factors affecting drug cost accrual.

PND34

COST EFFECTIVENESS ANALYSIS OF MOST COMMONLY PRESCRIBED DRUGS IN MIGRAINE

Upreti AR
Kathmandu University, Kathmandu, Nepal

OBJECTIVES: To analyze cost effectiveness of amitriptyline and propranolol in the management of migraine **METHODS:** A total of 60 patients with migraine were enrolled, into the Prospective, observational, exploratory study based on the inclusion and exclusion criteria. Migraine headache frequency, duration and used of over the counter drugs per month migraine headache pain score and headache impact test score were assessed and recorded at baseline by using a suitably designed questionnaire and headache impact test questionnaire. The patients were given either amitriptyline or propranolol . After the completion of one month of drug therapy score of patients were measured using the same questionnaire and in addition cost of prescription drugs and over the counter drugs were calculated.The effectiveness of treatment on patients was evaluated by comparing the mean scores before and after treatment by applying paired sampled T- test and independent sample test to compare means between the two treatment groups. Cost effectiveness analysis was done in terms of reduction of headache frequency per month before and after the treatment . **RESULTS:** The result showed that to prevent single migraine headache patient under amitriptyline group has to pay NRs.8.897 on the drugs (amitriptyline and analgesic)where patient under Propranolol group has to pay NRs.30.11 on the drugs (propranolol and analgesic) to prevent single migraine headache. In addition the study suggests using either amitriptyline or propranolol for treatment of migraine headache is same in terms of reduction of headache frequency and in terms of reduction of headache duration. However amitriptyline was found superior to propranolol in terms of reduction of headache impact test score and used of over the counter drugs. But propranolol was found to significantly lower headache pain score compare to amitriptyline. **CONCLUSIONS:** Amitriptyline is the most cost effective option when compared to propranolol in migraine.

PND35

COST EFFECTIVENESS OF EARLY TREATMENT OF PARKINSON'S DISEASE IN MEXICO

Marquez M[1], Diaz JP[2], Pizarro M[3], Ibarra A[1], Cervantes A[4], Rodríguez M[4], Soto H[1]
[1]*Universidad Autonoma Metropolitana, México D.F., Mexico,* [2]*Universidad Nacional Autonoma de Mexico, México D.F., Mexico,* [3]*Hospital Infantil de Mexico Federico Gomez, Mexico City, Mexico,* [4]*Instituto Nacional de Neurología y Neurocirugía, México D.F., Mexico*

OBJECTIVES: Compare the cost-efectiveness (CE) of levodopa, pramipexole, rasagiline and selegiline in patients with early Parkinson's disease from the perspective of National Institute of Neurology and Neurosurgery (NINN) in Mexico. **METHODS:** We developed a CE model, that linked Unified Parkinson's Disease Rating Scale (UPDRS) Parts II (activities of daily life) and III (motor) scores to disease progression and direct costs (drugs, medical appointments, adverse events, and laboratory studies), which were obtained of clinical records and unit cost of NINN. Data used in the model were obtained from clinical trials and we developed an indirect