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Estimating the Payer-Specific Excess Medical Costs of Opioid Abuse in the United States

E. Michna

N. Y. Kirson

A. Shei

L. F. Rossiter

William & Mary, lfross@wm.edu

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in 10,000 inhabitants. Although individually rare, together, rare diseases affect significant part of the population. Therefore, patient access to orphan medicines is receiving increasing political attention in the United States, with opioid-related overdoses accounting for over 16,500 deaths per year. OBJECTIVES: In addition, opioid abuse imposes a significant economic burden due to States, with opioid-related overdoses accounting for over 16,500 deaths per year.

METHODS: Data for orphan designations and approvals were assembled for the time period between 2000 and 2011. RESULTS: A total of 624 subjects were enrolled: 71% 18-40 years old, 55% were white, 37.3% females. The time from OD designation to approval was 2.74±2.39 years in the FDA and 3.31±1.99 years in EME (p<0.05). The EU had more restrictive criteria for orphan designation and significantly longer approval to approval was estimated. Descriptive analysis, chi-square test, and group comparison t-tests were used in the analysis. RESULTS: The FDA granted 558 orphan designations for 1133 different products, and 149 approvals (9.6% of designated products), and the EMA 935 designations for 639 different products and 88 (9.4%) approvals during the study period. The time from OD designation to approval was 2.74±2.39 years in the FDA and 3.31±1.99 years in EME (p<0.05). EMA approved a larger number of designations (15.2%) than the FDA (12.3%) for the 569 products designated by both agencies; 67% of these products were first designated by the EMA and 74% of the 50 products approved by both agencies were approved first by EMA (p<0.001). CONCLUSIONS: The EU had more restrictive criteria for orphan designation and significantly longer approval times, less orphan designations, and fewer product approvals than the US. Harmonization of the EU orphan drug regulations and increased numbers of FDA and EMA could result in improved access to ODs in the US and the EU.

PSY75 ESTIMATING THE PAYER-SPECIFIC EXCESS MEDICAL COSTS OF OPIOID ABUSE IN THE UNITED STATES

Michna E1, Ingers NY2, Shi A3, White A4, Ballouk HC, Ben-Joseph R5, Rossiter LF6, Massachussets College of Pharmacy and Health Sciences, Boston, MA, USA,

OBJECTIVES: Opioid abuse is a significant public health problem in the United States, with opioid-related overdoses accounting for over 16,500 deaths per year. In addition, opioid abuse imposes a significant economic burden due to increased health care utilization and costs. This study calculates updated, payer-specific estimates of diagnosed opioid abuse among commercially insured, Medicaid, and Medicare patients with recent prescription opioid (RxO) use.

METHODS: Using de-identified Truven MarketScan medical and pharmacy claims data for commercially-insured, Medicaid, and Medicare patients, we examined the excess costs of diagnosed opioid abuse among patients with at least one pharmacy claim for an RxO during a 12-month period preceding the index date, which was the date of the first archiving diagnosis for opioid abuse and the date of a random medical claim for patients as well as their non-opioid patient costs, measured in 2011USD. The excess costs of diagnosed opioid abuse were calculated as the difference in costs between abusers and non-abusers following matching and including inpatient, emergency room (ER), and outpatient services. The study included 25,100 commercially insured, 136,000 Medicaid, and 34,100 Medicare patients with diagnosed opioid abuse were matched to non-abusers. The annual per patient excess medical costs associated with diagnosed opioid abuse were $9,466 (p<0.05) for commercially insured, $11,501 (p<0.001) for Medicaid patients, and $10,046 (p<0.001) for Medicare patients. Inpatient costs accounted for 63.0%-78.6% of total excess medical costs, and ER costs accounted for 5.6%-12.6% of total excess medical costs. CONCLUSIONS: The excess medical costs of opioid abuse are substantial and reveal a consistent pattern across payers. Overall, our research, suggesting opioid abuse continues to impose significant economic burden.

PSY76 OPIOID AND ANTIETELEPHTIC DRUG UTILIZATION AMONG PATIENTS WITH CHRONIC NEUROPATHIC PAIN CONDITIONS

Ludlow A1, Parsons B1, Schaefer C2, Mann R1, Daniel S1, Baik R1, Nalacamu S1, 3

OBJECTIVES: Opioids, generally recommended as second- or third-line agents for neuropathic pain (NP), are commonly used. This study characterized opioid and anti-epileptic drug (AED) utilization among patients with NP associated with diabetic peripheral neuropathy (DPN), HIV, spinal cord injury (SCI), chronic low-back pain (CLBP), post-trauma/post-surgery (PTPS), and small-fiber involvement (SF) stratified by pain severity (mild, moderate, severe). METHODS: Data were from an observational study of NP patients recruited during routine visits with physicians or treatment centers. Approval of the study was obtained from an Institutional Review Board. Informed consents were obtained from all patients. Random sample was selected from a total of 100 patients. Sensitivity analyses were performed for various key variables. Results: A total of 324 subjects were enrolled: 71.8% 18-40 years old, 55% were white, 37.3% females. The most frequently used AEDs were gabapentin, carbamazepine, and lamotrigine. The low share of reimbursed orphan drugs in Serbia may be due to the restrictive criteria for orphan designation and significantly longer approval time. CONCLUSIONS: The study showed that the low share of reimbursed orphan drugs in Serbia may be due to the restrictive criteria for orphan designation and significantly longer approval time. The EU had more restrictive criteria for orphan designation and significantly longer approval time. The EU had more restrictive criteria for orphan designation and significantly longer approval time. The EU had more restrictive criteria for orphan designation and significantly longer approval time.