2013

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

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Recommended Citation

Michna, E., Kirson, N. Y., Shei, A., White, A., Birnbaum, H. G., Ben-Joseph, R., & Rossiter, L. F. (2013). Estimating the payer-specific excess medical costs of opioid abuse in the United States. Value in Health, 16(3), A124.

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 EU. The objective of our study was to determine the access to orphan medicines in Serbia. **METHODS:** Serbian Reimbursement List has been reviewed and identified orphan medicines were crossed with the List of orphan drugs in Europe, published in July 2011, available from Orphanet. The analysis of regulatory traits was based on a review of official documents setting out legislation regarding rare diseases and orphan medicines in Serbia. **RESULTS:** Only 6.5% (4 out of 61) of authorised orphan medicines in Europe with prior orphan designation and 25.0% (17 out of 68) without prior orphan designation were available and reimbursed in Serbia. According to the first level of the ATC Classification System, most of reimbursed orphan medicines belonged to the group L – 'Antineoplastic and immunomodulating agents'. It is estimated that there are approximately 500,000 patients suffering from rare diseases in Serbia. Although the National register for rare diseases does not exist, the Law on Health Care provides for the forming of the official centres of reference for rare diseases that have the obligation of diagnosing, treatment and patient counseling, but also of creation of National register. Neither policy measures nor research incentives for rare diseases exist in Serbia. **CONCLUSIONS:** The low share of reimbursed orphan drugs in Serbia may be due to incomplete compliance with legislation of EU and existence of domestic procedure for authorisation. The EU policy on treatment of rare diseases facilitate the penetration of orphan drugs on the EU market, but apparently there is also considerable budget impact on the availability of orphan medicines.

PSY74

ANALYSIS OF ORPHAN DRUG DESIGNATIONS AND APPROVALS IN THE UNITED STATES AND THE EUROPEAN UNION

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OBJECTIVES: The United States (US) and the European Union (EU) implemented regulations for encouraging the development of drugs for rare diseases. Criteria for Orphan designation is generally based on the number of patients affected by the disease (<200,000 US patients and <5 in 10,000 EU patients). The EU also requires that a satisfactory alternative treatment is not available or that the new drug is significantly better than drugs currently marketed. We examined the characteristics of orphan drug (OD) designations and approvals by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) between 2000 and 2011. **METHODS:** Data for orphan designations and approvals were extracted from the FDA and EMA online databases for the period 2000-2011. Data were updated to September 14, 2012. The time for OD designation to approval was estimated. Descriptive analysis, chi-square test, and group comparison t-tests were used in the analysis. **RESULTS:** The FDA granted 1558 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 FDA and 78% 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 Orphan drug regulatory processes of FDA and EME 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

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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, excess medical costs 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, 2009-2011. Diagnosed abusers were identified using ICD-9 diagnosis codes for opioid abuse/dependence and were matched to non-abusers using propensity score methods. Medical costs were calculated over a 12-month period around the index date, which was the date of the first abuse diagnosis for abusers and the date of a random medical claim for non-abusers. Costs reflected payments by insurers as well as out-of-pocket 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 included inpatient, emergency room (ER), and outpatient services. **RESULTS:** A total of 2510 commercially-insured, 536 Medicaid, and 268 Medicare patients with diagnosed opioid abuse were matched to non-abusers. The annual per patient excess medical costs associated with diagnosed opioid abuse were \$9,456 ($p<0.001$) for commercially-insured patients, \$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. These estimates are comparable to prior research, suggesting opioid abuse continues to impose significant economic burden.

PSY76

OPIOID AND ANTIEPILEPTIC DRUG UTILIZATION AMONG PATIENTS WITH CHRONIC NEUROPATHIC PAIN CONDITIONS

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OBJECTIVES: Opioids, generally recommended as second- or third-line agents for neuropathic pain (NeP), are commonly used. This study characterized opioid and antiepileptic drug (AED) utilization among patients with NeP 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 NeP patients recruited during routine visits with primary-care or specialty physicians. Subjects completed a one-time questionnaire, and investigators completed a case report form based on a 6-month retrospective chart review. Pain severity was based on the Brief Pain Inventory average pain score. **RESULTS:** A total of 624 subjects were enrolled: 71.8% were white; 55.4% were male; mean age was 55.5±13.7 years; with a mean of 7.8±6.8 years since NeP diagnosis. The proportion of patients with each NeP indication was similar (16.0%-17.9%). Pain severity was mild, moderate, and severe in 17.6%, 47.6%, and 33.2%, respectively. The most frequently used NeP medications over the past 6 months were opioids (53.0%) and AEDs (49.0%), ranging from 33.0% (DPN) to 81.1% (CLBP) for opioids, and 28.3% (CLBP) to 64.1% (SCI) for AEDs. Overall, AED use remained unchanged across pain severity categories (46.4%-50.5%), while opioid use increased significantly with greater pain severity: 28.2% mild, 53.2% moderate, 65.2% severe ($p<0.0001$). Opioids were used by substantial proportions of patients across all pain severity levels including 33.3% in SCI, 50.0% in CLBP, and 71.4% in PTPS. Except for DPN, strong short-acting opioids were the most frequently used opioid class, ranging from 14.3% in DPN to 55.7% in CLBP. **CONCLUSIONS:** Patterns of opioid use observed in this study were not fully consistent with published guidelines; opioid use was common across six different chronic NeP conditions and did not appear to be reserved for more severe pain patients.

PSY77

QUANTIFYING THE IMPACT OF DIFFERING MEASURES USED TO STUDY PERSISTENCE AND ADHERENCE WITH THE INFUSIBLE ANTI-INFLAMMATORY BIOLOGIC INFLIXIMAB: UTILIZATION FROM REAL-WORLD MEDICAL PRACTICE

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OBJECTIVES: Evaluation of measures of medication-taking behavior is uncommon with infusible pharmacologic agents. This study evaluated persistence and adherence measures from utilization data on the infusible anti-inflammatory biologic infliximab. **METHODS:** Patients were identified through the electronic health records (EHR) with ICD-9 diagnoses of rheumatoid arthritis (714.xx), psoriatic arthritis (696.xx), ulcerative colitis (556.xx), or Crohn's disease (555.xx). Incident infliximab-treated patients between January 1, 2007 and June 30, 2011, ≥18 years of age, with ≥1 maintanence dose were included. Infliximab dosing data were extracted from medical chart review and the EHR. We employed Kaplan-Meier (KM) analyses to estimate median time to treatment discontinuation and Cox regression to evaluate factors associated with discontinuation. Medication possession ratio (MPR) was calculated as sum of prescribed infusion frequency intervals divided by days from first infusion to last infusion. Compliance was defined as MPR ≥0.80. Proportion of days covered was also explored (data not shown). Sensitivity analyses were performed for various definitions of "treatment gap" and "discontinuation". Analyses are shown for gap of ≥90 days. For all test statistics, a p-value <0.05 was considered statistically significant. **RESULTS:** We identified 122 patients meeting study inclusion criteria. Mean age of patients was 45 years and 61% were female. KM estimated a median treatment duration of 23 months and adjusted Cox regression identified African Americans at significantly greater risk for treatment discontinuation than Caucasians (hazard ratio: 4.95; 95% confidence interval: 1.11, 22.05; P=0.036). A total of 100 patients had a calculable MPR, mean and median MPR were 0.937 and 0.956, respectively, with 93% of patients compliant with treatment. Sensitivity analyses showed varied results depending on definitions. **CONCLUSIONS:** Patients receiving infliximab were overall compliant with therapy during a median of 23 months of treatment. Underlying definitions used with MPR and KM are important, and should be clinically meaningful and transparent.

PSY78

EFFECTIVENESS OF STEP THERAPY POLICIES FOR SPECIALTY PHARMACEUTICALS IN IMMUNE DISORDERS

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