PCN172

CACH TO MONITOR DRUG SHORTAGES AND THE ROLE OF MARKET ATTRACTIVENESS IN EUROPEAN COUNTRIES

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OBJECTIVES: Drug shortages are a global problem. While extensively studied in the United States, numbers about drug shortages in European countries are scarce. This study aims to investigate publically available data about drug shortages in European countries in order to reveal a typology of drug shortages used in Europe. METHODS: A standardized reporting template was designed based on a literature search to collect and structure information. Countries offering an online reporting system for drug shortages such as Belgium, The Netherlands, England, Italy, France, Germany and Spain were included in the study. The online reporting systems were consulted in May 2013. Typology and causes of drug shortages are mapped and a sub-analysis is performed for essential medicines and oncology drugs. RESULTS: Majority of drugs reported were not essential medicines. 72% (23/32) were FDA designated orphan indications. 78% (25/32) were included all drugs approved by the EMA on this basis except trabectedin. 32 indications were approved under the accelerated approval pathway, only 47% (15/32) were FDA approved under the accelerated approval pathway were sourced and the dates of acceleration were demonstrated. This research aims to define the circumstances under which the FDA and European health policies on the sustainability of the drug market is required to understand the problem. A link between production problems and market attractiveness and market capacity is recognized to be at the root of drug shortages in Europe. Such insights are highly lacking in Europe. Monitoring of the effect of national and European health policies on the sustainability of the drug market is required to present fundamental solutions for the problem of drug shortages in Europe.

PCN173

DOWNSIDES OF THE FDA ACCELERATED APPROVAL PATHWAY – STRIDENT CONTROLS MIGHT BE NEEDED TO ENSURE PROMPT SUBMISSION OF FOLLOW-UP CONFIRMATORY TRIAL DATA

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OBJECTIVES: The European Medicines Agency (EMA) approved 19 oncologics across 38 indications were for lines of therapy or diseases that had no relevant therapeutic alternatives. 72% (23/32) were FDA designated orphan indications. 78% (25/32) were included all drugs approved by the EMA on this basis except trabectedin. 32 indications were approved under the accelerated approval pathway, only 47% (15/32) were FDA approved under the accelerated approval pathway were sourced and the dates of acceleration were demonstrated. This research aims to define the circumstances under which the FDA and European health policies on the sustainability of the drug market is required to present fundamental solutions for the problem of drug shortages in Europe.

PCN174

EVIDENCE FOR A LOWERED THRESHOLD FOR FDA APPROVAL ON ONGOINGS BASED ON SINGLE-ARM PHASE II DATA, COMPARED TO THE EMA

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OBJECTIVES: The European Medicines Agency (EMA) approved 19 oncologics across 38 indications were for lines of therapy or diseases that had no relevant therapeutic alternatives. 72% (23/32) were FDA designated orphan indications. 78% (25/32) were included all drugs approved by the EMA on this basis except trabectedin. 32 indications were approved under the accelerated approval pathway, only 47% (15/32) were FDA approved under the accelerated approval pathway were sourced and the dates of acceleration were demonstrated. This research aims to define the circumstances under which the FDA and European health policies on the sustainability of the drug market is required to present fundamental solutions for the problem of drug shortages in Europe.

PCN175

A RETROSPECTIVE STUDY OF PATIENTS OUT-OF-POCKET COSTS FOR ORAL ONCOLOGY MEDICATIONS FOR MULTIPLE MYELOMA

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OBJECTIVES: To study patient’s out-of-pocket expenditures in patients taking oral oncology medication for the treatment of Multiple Myeloma who are enrolled in a specialty pharmacy program. METHODS: A retrospective analysis of pharmacy claims and reimbursement data for oncology medications for patients enrolled in a specialty pharmacy program from January 1, 2011 to October 31, 2013 was conducted. Patients with a primary diagnosis of Multiple Myeloma (ICD-9 CM: 203.xx) prescription data were included. There were no exclusion criteria. The sample included all claims for patients with a primary diagnosis of Multiple Myeloma. Results were compared using average comparing co-payment responsibility per prescription after insurance to average patient co-pay per prescription after funding assistance. RESULTS: A total of 22,566 prescriptions were included. The average patient co-pay responsibility per insurance was $435.00 and the average patient co-pay after funding assistance was $81.00 per prescription. This resulted in $2,822 (91.17%) of the prescriptions had a patient co-pay of under $10.00 after funding assistance. The patient’s insurance type was as follows: private insurance was 59%, Medicare was 25%, Pharmacy Benefit Manager was 10%, Tricare was 1%, and Medicaid was 5%. CONCLUSIONS: In this retrospective analysis of pharmacy and financial claims data, Multiple Myeloma patients significantly reduced their out-of-pocket expenditures, from an average of $435.00 to $81.00 by the specialty pharmacy gaining funding assistance for the patient.

PCN176

ASSESSMENT OF IMAGING UTILIZATION AND TREATMENT PATTERNS FOR HEAD AND NECK CANCER PATIENTS IN THE UNITED STATES

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OBJECTIVES: To assess imaging and treatment patterns in head and neck cancer (HNC) patients using a large commercial-insurance database from the United States (U.S.). METHODS: We used the Marketscan® Research Databases (2007-2011) to identify adult, paranasal cancer patients enrolled in HNC diagnostic imaging and treatment. We evaluated in 3 steps, the imaging of any type (x-ray, CT, or PET/CT) (OR range: 0.71-0.91). Imaging and treatment intensity and variability by cancer types and geographic regions (Northeast, North Central, South, and West) were assessed using multivariate and multivariable logistic regression. RESULTS: 80,987 patients were analyzed (39% female, mean age: 60 years). During pre-treatment, comparing all cancer types to oral cancer, pharynx cancer patients had the greatest likelihood of single-modality imaging and multiple-modality imaging. Patients with higher comorbidities and fewer index scores were more likely to receive more imaging prior to treatment. Pre-treatment imaging was more likely to occur in other regions compared to West (OR range: 1.07-1.29), with consistent imaging patterns versus the West. CONCLUSIONS: HNC oncology patient’s imaging and treatment patterns are not the same in all regions and multiple intervention patterns. In the post-treatment period, patients receiving multiple treatment interventions, a proxy for advanced cancer, were more likely to undergo PET/CT. A high proportion of patients continue receiving treatment (37%). Pharynx cancer patients were more likely to receive radiation therapy (24%) or chemotherapy (30%). During all phases combined, females were less likely to get imaging of any type (x-ray, CT, or PET/CT) (OR range: 0.71-0.91). CONCLUSIONS: Commercially insured HNC patients in the U.S. vary in imaging patterns in the types of imaging modalities used, prior to and following initial diagnoses. Receiving multiple treatment interventions was associated with undergoing multiple imaging tests and more specifically, PET/CT.

PCN177

DESCRIPTIVE ANALYSIS OF PATIENTS INITIATING RIFABUTIN THERAPY

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OBJECTIVES: To describe treatment patterns among patients initiating rifabutin (RIF), an oral kinase inhibitor indicated for the treatment of metastatic colorectal cancer in patients who have tried other first-line therapies. METHODS: Pharmacy and medical claims for Humana, a large national U.S. payer, were used. The study sample included patients age 19 to 89 years with at least one claim for rifabutin between 9-27-2012 and 6-1-2013. A subset of patients with pharmacy and medical benefits, as well as pre-index continuous enrollment of at least 12 months, was used for pre-index claims analysis, radiology, and biomarker therapeutics. Patients were followed until death, disenrollment or study end date (10-31-2013). RESULTS: A total of 407 patients with claims for rifabutin were identified. The youngest age was 19 years and the oldest age was 89 years (range: 140 days to 0-357 days). Median length of pre-index continuous enrollment was 779 days. The majority resided in the southern (51.6%) and midwestern (26.0%) U.S. and most patients had Medicare Advantage (26.0%) or Medicare Part D (6.9%) coverage. Geographic treatment met and/or drug claim location was not available. Overall, metastatic cancer diagnosis was observed in 93.4% of patients; the majority had liver metastasis. Common pre-index comorbidities included hypertension (72.5%), cardiovascular disease (41.8%), chronic pulmonary diseases (25.3%), diabetes (9.4%), and depression (15.4%). Evidence of chemotherapies, biologic therapies, and