with PRS, after controlling for potential confounders, those with LS had a significantly lower likelihood of being hospitalized (OR = 0.639; 95% CI: 0.524-0.848) and having ambulatory services (OR = 0.344, 95% CI: 0.233-0.509). Patients with SSR had a significantly lower likelihood of being hospitalized than those with PRS (OR = 0.859, 95% CI: 0.853-0.864). Among patients who had ambulatory services, those with SSR had significantly less ambulatory services than those with PRS.

CONCLUSIONS: This study suggests that sofostivudine-related treatments without peginterferon are associated with reduced likelihood of being hospitalized. Quasi-experimental studies or randomized clinical trials can address the issue of specific effect and secular trends.

PRESCRIPTION PRICING STUDIES

PR1

MARKET ACCESS AND PRICING DISPARITIES OF ANTICANCER DRUGS MARKETED IN THE OECD COUNTRIES: WHICH REALITY?

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OBJECTIVES: In this study we were to assess trends in prices of anticancer drugs in different OECD (Organization for Economic Co-operation and Development) countries and to examine the impact of the specific regulations on the pricing strategies. This study also analyzed price differences across anticancer drugs across selected OECD countries. METHODS: We start to collect the anticancer drugs authorized by EMA between January 2000 and December 2013 covering a total of 56 drugs. Then, we selected the countries according to their prices regulations (United States (US) and Germany where the pharmaceutical companies freely set their prices. France, Switzerland, Italy, Spain prices are regulated by negotiation. UK and Australia who use a formal economic evaluation to set the prices). All prices were in Euro. The costs per cycle for patient were calculated. The relative difference in costs between US and other countries were calculated. Descriptive statistics were performed. RESULTS: The numbers of anticancer drugs were: 49 in France, 56 in Switzerland, 25 in Italy, 36 in Spain (64 in total). Prices were obtained from the Center for Medicare and Medicaid (CMS) Drug Pricing Files for the entire shortage duration as well as the 12 months preceding shortage onset (pre-shortage period), and adjusted to 2015 US dollars. The average % change in Q-ASP prices per 6 months of shortage duration was calculated. Other shortage/drug characteristics including duration, reason, number of manufacturer, and therapeutic area were also analyzed descriptively. RESULTS: The sample included 29 generic injectable drugs (average shortage duration of 3.7 years; 20.7% single source generics). The greatest proportion of drug shortages were for oncology drugs among generic injectable drugs recently on shortage in the US. This study examines trends in quarterly average sales price (Q-ASP) among generic injectable drugs recently on shortage in the US. Regression analyses were conducted using Stata. RESULTS: The FDA approved 205 orphan drugs from 1983 to 2013 (141 of 487 FDA approval in the study period. Most orphan drugs for chronic use were new drug applications (NDAs) (n=116; 81.8% of the approvals), approved using the priority review process (107; 52.7%), and oral formulations (112; 55.2%). By December 31, 2014, 21.7% (n=44) of the orphan drugs approved in 2014 were orphan drugs at market entry.

Conclusions: A previous study using an econometrics approach are needed to allow us to highlight the differences in the health system regulations but caution must be exercised. More systematic studies are needed to allow us to highlight the determinants of these disparities.

PR2

GENERIC INJECTABLE SHORTAGES AND TRENDS IN AVERAGE SALES PRICE IN THE UNITED STATES

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OBJECTIVES: This study examines trends in quarterly average sales price (Q-ASP) among generic injectable drugs recently on shortage in the US. METHODS: Shortage of generic injectable drugs (excluded vitamins) resolved between 2010 and 2015 were identified using the American Society of Health System Pharmacists (ASHP) “Resolved Drug Shortages” website. Only shortages starting after January 2005 were included. Drug shortage duration was defined as the period from drug shortage resolution from the FDA Orphan Drug Designations and Approvals Database was used to excluded from analysis drugs without orphan designation (n=202). Indication expansions from FDA Orphan Drug Act in 1983. In 2013 across all countries in the study, the highest median cost per cycle ($1,643.58) was in the US and lowest ($2,957.09) was in Spain. Comparing the anticancer drug prices in the US with other countries, the highest difference was in Spain (64% higher in Spain than in Italy). Our study found that the level of pricing disparities, in most cases, may reflect the differences in the health system regulations but caution must be exercised. More studies using an econometrics approach are needed to allow us to highlight the determinants of these disparities.

PR3

PRICES OF DRUGS FOR CHRONIC USE WITH ORPHAN DESIGNATION IN THE UNITED STATES (1983–2014)

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OBJECTIVES: To analyze trends and explanatory factors associated with the average wholesale price (AWP) at market entry for orphan drugs for chronic use approved by the FDA in the period 1983–2014. METHODS: Regulatory information was obtained from the FDA Orphan Drug Designations and Approvals Database. Prices of the drugs were classified using the WHO Anatomical Therapeutic Chemical (ATC) Classification System. Daily doses (DDD) were collected from the FDA-approved labels. AWPs were collected from the Redbook (Truven Health Analytics). Prices were adjusted to 2014 dollars using the consumer price index. Descriptive statistics, compound annual growth rates (CAGR) and multiple linear regression analyses were conducted using Stata. RESULTS: The FDA approved 205 orphan drugs from 1983 to 2014 (141 of 487 FDA approval in the study period. Most orphan drugs for chronic use were new drug applications (NDAs) (n=116; 81.8% of the approvals), approved using the priority review process (107; 52.7%), and oral formulations (112; 55.2%). By December 31, 2014, 21.7% (n=44) of the orphan drugs approved in 2014 were orphan drugs at market entry.

Conclusions: A previous study using an econometrics approach are needed to allow us to highlight the differences in the health system regulations but caution must be exercised. More studies using an econometrics approach are needed to allow us to highlight the determinants of these disparities.