Spain, Taiwan, United States) using iterative, concept elicitation methodology to understand the impacts of caring for a patient with ADPKD. **RESULTS:** Caregivers for patients with ADPKD (66.9% female, 33.1% male) provide assistance with activities of daily living and emotional support. Furthermore, 25 caregivers (88% female, 12% male) were also diagnosed with ADPKD themselves, which elevated their burden. Almost all caregivers in the study provided care or support for immediate family members (94.8%) while a smaller percentage (2.9%) were assisting a distal relative or friend. Caregivers reported impacts on emotional (74.1%), social (38.5%), work/employment (26.6%), financial (23.7%), and physical (17.3%) aspects of their daily lives. There were slight differences in how caregivers in various regions emphasized impacts, and impacts varied depending on the disease stage of the ADPKD patient and the caregiver-patient relationship. **CONCLUSIONS:** Caregivers for patients reported substantial impacts on their daily lives which was globally consistent. Defining caregiver burden is essential to understanding ways of supporting the ADPKD population in the community.

SYSTEMIC DISORDERS/CONDITIONS - Health Care Use & Policy Studies

PSY25
RARE CANCERS, NO RARE SOLUTIONS: RISK SHARING ARRANGEMNTS TO REIMBURSE MEDICINES FOR RARE CANCERS IN AUSTRALIA

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OBJECTIVES: Medicines to treat rare cancers (prevalence <1 in 10,000) often have high cost and an insufficient evidence base to inform their registration and reimbursement decisions. Various risk sharing arrangements (RSA) have been proposed to improve patient access to cancer medicines in Australia. We aimed to examine the Pharmaceutical Benefits Advisory Committee recommendations on submissions made to list rare cancer medicines on the Pharmaceutical Benefits Scheme (PBS). **METHODS:** We reviewed publicly available PBS documents from March 2010 until July 2017 for antineoplastic and immune-modulating agents designated as orphan drugs by the Therapeutic Goods Administration. Data extracted included medicine name, indication, type of supporting evidence provided, source of uncertainty, reason for rejection or deferral, and the special RSA applied to medicines with a positive recommendation. The arrangements were categorised into non-outcome based (i.e., price reductions or rebate), outcome-based (i.e., clinical continuation rule), or data provision (i.e., coverage with evidence development) arrangements. **RESULTS:** We identified 70 submissions for 30 rare cancer indications. Positive recommendations were made in 26 (37%) submissions with an average of 2.2 submissions to approval (range: 1-5). Uncertain clinical evidence was reported in 80% of the rejected/deferred submissions, predominantly due to uncertain overall survival benefit. Other reasons for rejection/deferral included high and/or uncertain cost-effectiveness ratios (75%) and inappropriate comparator (5%). Of the indications with positive recommendation, twenty (77%) had price reduction and/or rebate arrangements and 24 (92%) had a clinical continuation rule; however, only 2 indications (8%) were listed conditional on collecting more data. **CONCLUSIONS:** The majority of RSAs have focused on price reductions and/or rebates and clinical continuation rules; nevertheless, there is limited utilisation of coverage with evidence development arrangements. Provisional PBS listing conditional on collecting additional fit-for purpose evidence is a potential solution to mitigate decision uncertainty and improve patient access to medicines for rare cancers in Australia.

PSY26
REAL-WORLD PRESCRIPTION PATTERNS AND COMORBIDITY BURDENS AMONG ADULTS WITH NONALCOHOLIC FATTY LIVER DISEASE

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OBJECTIVES: Little research to date has examined the drug utilization pattern among patients with nonalcoholic fatty liver disease (NAFLD). The most recent diagnosis and management guidelines for NAFLD published in 2012 recommended pioglitazone as the effective treatment. In this study, we aim to investigate the real-world drug utilization pattern and comorbidity burden among patients with NAFLD from 2012 to 2015. **METHODS:** A retrospective observational study design was employed using the Truven Health MarketScan Commercial Database. Inclusion criteria were: 1) non-elderly patients (age ≥18-<65) who received at least one inpatient or at least two separate outpatient diagnoses of NAFLD (ICD-9: 571.8) between 1/1/2011 and 12/31/2015; 2) available insurance enrollment data for a period of 6-month before and 12-month after the index service date. Patients were excluded if they had one or more claim(s) for type 1 diabetes, chronic hepatitis, alcohol liver diseases, and gestational diabetes. Medications were examined by outpatient prescription claims. The prevalence of each medication was calculated as the number of study subjects taking the specific medication divided by the total number of eligible patients. **RESULTS:** In the overall study population (N= 76,018) diagnosed with NAFLD, the mean[±SD] age of the patients was 48.4[±10.5] years; 46.8% were male, with a mean[±SD] Charlson comorbidity index score of 1.3[±0.8], 16.9% had type 2 diabetes (T2DM) and 21.2% had lipid metabolism disorders. The proportion of pioglitazone users was 6.2% among patients with co-occurring NAFLD and T2DM, which was six times higher than that of NAFLD patients without T2DM. Compared to the low proportion of pioglitazone uptake among study subjects, metformin was the most frequent prescribed medication among NAFLD patients with T2DM (61.3%) or without T2DM (15.2%). **CONCLUSIONS:** The results showed clinical drug utilization pattern for the management of NAFLD diverged from published guidelines, suggesting promotional programs for pioglitazone use among NAFLD patients are needed.

PSY28
COMPARISON OF ORPHAN DRUGS PRICES BETWEEN EUROPE AND JAPAN

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OBJECTIVES: Funding orphan drugs (OD) is a sensitive and challenging endeavour. Payers deal with uncertainty surrounding product benefits while attempting to address high unmet medical needs. At the same time, the industry aims to secure returns on substantial upfront investments while targeting orphan diseases with small and fragmented patient populations. This complex trade-off may lead to differences in OD prices globally. Our objective was to explore the difference in OD prices between European countries (EU) and Japan. **METHODS:** ODs approved, in both Japan and EU, up to 01 March 2018 were identified from the Pharmaceuticals and Medical Devices Agency (PMDA) and the European Medicines Agency (EMA) websites, respectively. The annual OD price per patient was then calculated based on the posology recommended in the summary of product characteristics and the ex-factory price in Japan, France, Germany, and the UK. The Japanese price was compared to the mean price of the 3 European countries. **RESULTS:** Overall, 31 ODs approved in both Japan and EU were identified. The mean price of all ODs was higher in Japan (€189,974) than in the EU (€170,900). However, when considering each OD separately, prices were often higher in EU (21 drugs out of 31) than in Japan. Only 3 ODs had similar prices in EU and Japan with a price ratio close to 1 and only 5 ODs had an EU price lower than 75% of the Japanese price. Using median price shows similar trends while median being higher than mean prices. **CONCLUSIONS:** Our results showed that OD prices are heterogeneous between European countries and Japan. This may be explained by the heterogeneous pricing processes used in the different countries. OD prices are not predictable. Further studies to identify price drivers are warranted.

PSY29
ORPHAN DRUGS PRICES BETWEEN EUROPE AND JAPAN BY DISEASE AREA

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OBJECTIVES: Orphan drugs (OD) have in common a unique pricing framework where payers may accept high prices despite uncertainties surrounding product benefits. Decisions are often based on the lack of approved treatment options, pressing clinical unmet needs and low disease prevalence. Our objective was to explore the difference in OD prices by disease area between European countries (EU) and Japan. **METHODS:** ODs approved in both Japan and EU up, to 01 March 2018 were identified from the Pharmaceuticals and Medical Devices Agency (PMDA) and the European Medicines Agency (EMA) websites, respectively. The annual OD price per patient was then calculated based on the posology recommended in the summary of product characteristics and the ex-factory price in Japan, France, Germany, and the UK. Finally, ODs were grouped by disease area and the mean price for each disease area was calculated. The Japanese price was compared to the mean price of the 3 European countries. **RESULTS:** Overall, 4 disease areas with more than 1 OD approved both in Japan and EU were identified. ODs were grouped into oncology, metabolism disorders, cardiovascular disease and neurology with 17, 6, 3 and 2 products, respectively. Japanese prices were higher in all disease areas (cardiovascular disease: 33,931 vs. 23,640; neurology: €287,461 vs. €212,149; oncology: €68,200 vs. €35,249) except for metabolism disorders (€772,820 in EU vs. €514,541 in Japan). **CONCLUSIONS:** Comparison of ODs prices by disease area support higher price in Japan vs Europe. Oncology in Japan enjoy the highest ratio with about 2-fold the EU price, while the metabolic endocrine products enjoy the highest absolute margin mean difference of € 250,000 per patient year treatment. It is unclear if differences are explained by policy difference or differential value perception of different conditions.

PSY30
TEN-YEAR TRENDS OF NARCOTICS CONSUMPTION IN TAIWAN: A RETROSPECTIVE CROSS-SECTIONAL STUDY FROM 2004 TO 2013

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OBJECTIVES: The aim of this study was to evaluate the consumption of prescription narcotics (including morphine, fentanyl, meperidine, codeine, buprenorphine, tramadol and opium) covered by National Health Insurance in Taiwan during 2004-2013. **METHODS:** Prescriptions and users of narcotics were identified from the Longitudinal Health Insurance Database. Narcotics consumption were calculated as defined daily dose (DDD) per 1,000 beneficiaries per day. In Taiwan, the Controlled Drugs Act divided all controlled substances into four categories based on their public harmfulness, drug addiction, and drug-abuse. We thus further categorized narcotics studied into schedule I, II, III and IV to see whether this categorization had impacts on the consumption. The impact of physician specialty on the consumption of narcotics in each categories was explored as well. **RESULTS:** The total consumption of narcotics decreased from 32.71 DDD/1,000 beneficiaries/day in 2004 to 1.78 DDD/1,000 beneficiaries/day in 2009. These decrease may resulted in the abrupt decreases of schedule IV codeine, which decreased from 32.18 DDD/1,000 beneficiaries/day in 2004 to 0.85 DDD/1,000 beneficiaries/day in 2009. The safety-related regulations on codeine use in children released by Taiwan's Food and Drug Administration and National Health Insurance Administrations may explain the changes. In contrast, we found a steady increase in the consumption of schedule I, II narcotics and tramadol from 2004 to 2013. The total consumption of narcotics increase from 1.78 DDD/1,000 beneficiaries/day in 2009 to 2.07 DDD/1,000 beneficiaries/day in 2013. Physician specialties varied in use of these narcotics. For example, oncologists accounted for the largest proportion of prescribers of fentanyl while orthopedics accounted for the largest proportion of prescribers of tramadol. **CONCLUSIONS:** Our findings could serve as good references to help health professionals and public policy-makers to optimize the use of narcotics.

PSY31
EUROPE-CHINA COMPARISON OF ORPHAN DRUGS APPROVALS

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