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ment levels of these drugs in both countries. RESULTS: Eight OD were identified. In Germany, G-BA decisions related to additional benefit were non-quantifiable for 3 drugs, minor for 4 drugs, and minor in one subgroup and considerable in other subgroup for one drug. In France, one product was not assessed by the TC, and improvement in actual benefit (IAB) was rated as weak for 4 products, moderate for 2 products and important for one product. In Germany all these drugs were 100% reimbursed, while in France, depending on actual benefit (AB) ratings, reimbursement levels varied from non-reimbursement to 100%. At time of analysis, reimbursement status was granted in France for only 4 products (15% for one drug, 65%  $\,$ for one drug and 100% for 2 drugs). In Germany, OD prices were about 20% higher than in France before rebates, and about 20% lower after rebates. **CONCLUSIONS:** Substantial improvement for OD were less frequently acknowledged by German HTA than by French HTA and prices appeared to be lower in Germany than in France. However, price volume agreements in France might have contributed to hidden discounts. Access level of OD appeared higher in Germany.

# HEALTH ECONOMICS AND OUTCOMES DATA REQUIREMENTS IN INDOLENT NON HODGKINS LYMPHOMA (INHL) AND CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) FROM UNITED STATES PAYER PERSPECTIVE

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OBJECTIVES: To understand current considerations and management of the iNHL and CLL disease states and the extent to which health economic outcomes data informs payer decision making process. METHODS: A national level in-depth telephone survey of 45 payers was done in the month of November, 2013. The payer mix included both Commercial (n=20) and Medicare (n=25) payers that were either medical or pharmacy directors to determine clinical, economic and humanistic outcomes data critical for formulary and medical policy deicisons for iNHL and CLL. RESULTS: US Payers are most interested in the endpoints that directly tie to their major cost drivers: hospitalization, re-hospitalization and emergency services in both the disease state. Payers were split on preferring the comparative data of the cost-effectiveness analysis and the simple presentation of a budget impact model. There was no difference in payer types when it came to preference for any particular health economics model. Amongst the various adverse events related to treating iNHL and CLL, neutropenia is the most concerning adverse event from payer perspective, given the associated high cost of related treatments and hospitalizations. Payers consistently reported that the greatest unmet need in the iNHL and CLL today is more treatment options for relapsed and refractory patients, with greater response rates, increased durability of response and less toxicity leading to increased overall survival and progression. CONCLUSIONS: While in iNHL/CLL space payers admit decisions are based more on clinical evaluations rather than cost drivers, payers appreciate the value of demonstrating a reduction in resource utilization costs as they can directly evaluate the impact of this data on their health plan.

### PATIENTS WITH RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC LEUKAEMIA (R/R CLL) INELIGIBLE FOR CYTOTOXIC THERAPYWHO ARE THEY AND WHAT IS THEIR UNMET NEED?

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OBJECTIVES: To identify criteria used to categorize patients with R/R CLL who are ineligible for cytotoxic therapy and the unmet need in these patients. METHODS: Structured searches related to R/R CLL; performance status; comorbidities; organ function; and treatment patterns were performed on PubMed, Google Scholar, and the Cochrane databases and supplemented with hand searches of published literature, clinical guidelines, and online sources. **RESULTS:** 440 publications were identified. 123 were considered relevant to the study. Patients ineligible for cytotoxic therapy were identified by a combination of assessments for performance status (using ECOG), comorbidities (CIRS), and organ function (creatinine clearance (CrCl)). Unfit patients are ">65 years with a comorbidity" (ECOG 3-4 or CIRS >6 or CrCl <70 mL/min). NCCN clinical guidelines do not refer to assessment scores or define unfit: the NCCN categorizes R/R CLL patients as " $\geq$  70 years, or younger with comorbidities" or "frail with significant comorbidity". These criteria are not aligned with others such as slow-go (ECOG 2–4 or CIRS >6 or CrCl <70 mL/min) and no-go (fatal comorbidities with very short life-expectancy). Treatment regimens recommended by the NCCN contain drugs contraindicated for common comorbidities. The RCTs for the recommended regimens did not include patients with contraindicated comorbidities. There is an unmet need in these patients for appropriate treatment. CONCLUSIONS: There exists unmet need in patients identified as unfit using current criteria: they can be restricted from recommended drugs due to contraindications for common comorbidities. Most of these patients also have not been included in RCTs. Criteria used to identify patients with R/R CLL ineligible for cytotoxic therapy are not yet standardized; standardized assessments are needed for uniform identification and RCT enrolment.

### EMERGENCY PHYSICIANS' INTENTION TO USE THE TEXAS PRESCRIPTION MONITORING PROGRAMA PILOT STUDY

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OBJECTIVES: Inappropriate use of prescription opioids costs insurers over \$72 billion annually in direct health care expenses. Prescription monitoring programs (PMP) are state-operated databases which allow authorized clinicians (e.g., prescribers, pharmacists) to query a patient's opioid dispensing history via a secured online connection, during patient care. Since the emergency department (ED) is a

primary target for drug-seeking patients, this pilot study was conducted to validate a survey instrument designed to assess emergency physicians (EPs) intention to use the recently available Texas PMP. **METHODS:** A cross-sectional survey of EPs was conducted at a statewide emergency medicine conference. A 34-item questionnaire, based on the Technology Acceptance Model (TAM), was developed to assess EPs intention to use the Texas PMP. Items related to technology acceptance (perceived ease of use, perceived usefulness, attitude, and intention) were assessed using 5-point Likert scale responses (1=strongly disagree to 5=strongly agree). The survey expanded on a previous exploratory survey of EPs. Correlation analyses were used to validate the survey instrument scales. RESULTS: Of the 45 respondents, most were male (68.9%), attending EPs (57.8%), with 10.8±11.1 years in emergency medicine, from a community hospital setting (55.6%), and were users of the Texas PMP (51.2%). Among those who were not registered, 39.2% reported lack of awareness as the primary reason for not being registered. Standardized Cronbach's alphas for the constructs of perceived ease of use, perceived usefulness, attitude, and intention for PMP users were 0.88, 0.90, 0.74, and 0.84, respectively; and 0.77, 0.87, 0.84, and 0.74, respectively for PMP non-users. CONCLUSIONS: Considering the ED as a source of diversion, it is important to understand EPs utilization of PMPs. EPs use of PMPs may help to mitigate the economic burden associated with the non-medical use of prescription opioids, while improving patient outcomes. Future studies using this survey instrument are needed to further assess the predictive utility.

### AN EVALUATION OF OPIOID OVERUTILIZATION QUALITY METRICS USING RECEIVER OPERATING CHARACTERISTIC CURVES AND PROXIES FOR OVERUTILIZATION

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OBJECTIVES: To evaluate the sensitivity and specificity of opioid overutilization quality measures based on the Centers for Medicare and Medicaid Services (CMS) Controlled Substance Overutilization Monitoring System (OMS) using proxy indicators of potential overutilization. METHODS: Based on the CMS measure (proportion of patients with opioid prescriptions from ≥4 prescribers and ≥4 pharmacies among patients with ≥2 opioid prescriptions), claims from the 2012 IMS LRx database were used to evaluate the metric at different prescriber and pharmacy thresholds. Cash payment of ≥1 opioid prescription was used as a proxy for potential overutilization and set as the dependent variable in logistic regression models to generate separate receiver operating characteristic (ROC) curves for thresholds of 2-8 prescribers and 2-8 pharmacies. Optimal cutpoints for number of physicians and pharmacies were selected as the value on the curve with the shortest distance to perfect prediction. Sensitivity, specificity and positive predictive value (PPV) for every combination were calculated. As a sensitivity analysis, the process was repeated using ≥1 opioid-abuse related diagnosis as a proxy for potential overutilization. RESULTS: Of the 1,213,909 qualified patients, 5.9% met the CMS criteria for overutilization, while 13.8% met the alternative ROC optimal criteria (≥4 prescribers and ≥3 pharmacies). Defining cash payment patients (12.3% of total) as overutilizers, the CMS definition had sensitivity (15.0%), specificity (95.3%) and PPV (31.0%) The ROC alternative had sensitivity (28.0%), specificity (88.2%) and PPV (24.9%). For patients with opioid abuse-related claims defined as overutilizers (2.6% of total), the CMS criteria had sensitivity (16.1%), specificity (94.3%) and PPV (7.0%). The ROC alternative had sensitivity (28.5%), specificity (86.6%) and PPV (5.3%). CONCLUSIONS: Using two proxies for opioid overutilization, analysis of ROC curves suggested optimal criteria similar to the CMS criteria. Quality organizations can use the range of results and their preferences for sensitivity and specificity tradeoffs to develop needed quality measures.

# PSY80

# THE IMPORTANCE OF FACT OVER OPINION IN CHOICE OF CONDITIONS TO BE RECOMMENDED FOR NEWBORN SCREENING (NBS)

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OBJECTIVES: In 2006, the American College of Medical Genetics (ACMG) recommended expanding NBS. Recommendations relied largely on a stakeholder survey on 19 attributes of different rare conditions under consideration. The percentage of respondents agreeing to an attribute's presence determined its score. This research examines one particular attribute and asks how the recommendation of included conditions changes with the substitution of scoring based on the actual facts for that based on surveyed opinion. METHODS: The original report indicated each condition's scores for survey questions. Unlike some questions, that of whether multiplex technologies (allowing multiple conditions to be screened with a single test) were available, had a correct answer. Original scores for the question totaled between 0-200, depending on the respondents' percentage indicating yes. Answers were re-scored 200 or 0 as factually appropriate - existence/non-existence of multiplex screening for each condition. **RESULTS:** After eliminating conditions with missing data, 78 out of the original 84 conditions remained. 42 conditions (54%) increased their scores; 30 (38%) decreased. Of conditions with increasing scores, the mean increase was 85. Of conditions decreasing their scores, the mean decrease was 43. We estimate the potential change in recommendations as 4 conditions moving from the Core to secondary or Not Recommended and 10 moving from Secondary to Core status. CONCLUSIONS: As the only conditions capable of having recommendations altered by this correction were those roughly 200 points +/- category cutoffs and some ACMG rules further limited reclassification, this single correction was limited in its ability to alter recommendations (67% of the conditions could not change). Nonetheless the changes were significant (of those that could change, 50% did). As other questions in the survey were also questions of fact, doing a similar analysis for all such questions could further significantly alter the conditions recommended for the panel.