These analyses suggest that OXY access restrictions such as PA and TC did not result in cost savings.

**PSY70**

**ESTIMATED ERROR IN USING NATIONAL INCIDENCE FIGURES VERSUS STATE ESTIMATES: TECHNOLOGY COST-Effectiveness ANALYSIS:**

OBJECTIVES: To correct overestimated case estimates and cost per case detected in newborn screening (NBS) congenital adrenal hyperplasia (CAH) and congenital hypothyroidism (CH) autopsy data.

Background: We used national incidence data which was compared to state-specific data to correct for the misclassification and cost estimates.

RESULTS: We compared state-specific data to national incidence data for CAH and CH. The estimated case counts were corrected and the cost per case was estimated.

**PSY71**

**INTER-TEMPORAL CHANGE OF BODY MASS INDEX IN BRAZIL: WHAT IS THE ROLE OF FOOD PRICES?**

Background: The Brazilian National Health System (SUS) has expanded its coverage in various health areas over the past decade. The aim of this study was to analyze the impact of food prices on BMI over time.

Methods: We used a panel data analysis approach to examine the relationship between food prices and BMI.

Results: Our results showed a statistically significant effect of food prices on BMI, especially in the upper quantiles of the distribution. There were increases in the right hand tail, indicating a stronger impact on more overweight individuals.

Conclusions: Food prices play a significant role in the distribution of BMI, especially to upper quantiles of the distribution. There are also evidences that OXY access restrictions such as PA and TC did not result in cost savings.

**PSY72**

**AN EUROPEAN OVERVIEW OF THE FUTURE CHANGES IN EVIDENCE REQUIREMENTS FOR THE REIMBURSEMENT OF ORPHAN DRUGS: A STAKEHOLDER ANALYSIS**

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OBJECTIVES: To evaluate the evidence requirements for orphan drugs in Europe.

Methods: We conducted a stakeholder analysis involving interviews with stakeholders.

Results: The interviews revealed the need for more standardized approaches in the reimbursement process of orphan drugs.

Conclusions: There is a need for more standardized approaches in the reimbursement process of orphan drugs.

**PSY73**

**CONSIDERATION FOR RARE DISEASES IN DRUG REIMBURSEMENT DECISION-MAKING**

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OBJECTIVES: To examine the consideration of rare diseases in drug reimbursement decisions.

Methods: We conducted interviews with healthcare professionals and stakeholders.

Results: The consideration of rare diseases in drug reimbursement decisions is limited, and there is a need for more robust evidence and methods.

Conclusions: There is a need for more robust evidence and methods to consider rare diseases in drug reimbursement decisions.

**PSY74**

**THE ECONOMIC AND HUMANISTIC BURDEN OF RELAPSED/REFRACTORY (R/R) INDOLENT NON-INDOLENT NON-HODGKIN’S LYMPHOMA (iNHL): AN EVIDENCE-BASED ANALYSIS**


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OBJECTIVES: To identify research studies that examine the economic and/or humanistic burden of R/R iNHL, and identify evidentiary gaps which could be informed by future research.

Methods: iNHL refers to a group of largely incurable lymphomas present in a relapsed/refractory (R/R) setting, and can lead ultimately to life-threatening complications. Although many therapies are available, patients eventually relapse and become refractory to existing therapies. As such, additional treatment options with improved response rate, durability of response and more manageable toxicity are needed for patients with R/R iNHL. A structured literature search was performed to assess the economic and patient burden of iNHL. English-language articles published since 2009 were systematically reviewed in PubMed, EMBASE, and Cochran databases. Additionally, searches from global HTA organizations and conference abstracts were performed. Research was considered relevant to the economic and humanistic burden of iNHL based on reported outcomes such as resource utilization, costs, or relevant patient-reported outcomes associated with relapsed/refractory iNHL.

Results: Few cost-of-illness studies or HTA’s address iNHL. Evidence was limited to hospital-based direct treatment costs, omitting societal and indirect costs of the disease. Multiple cost-effectiveness analyses were identified focusing on Rituximab; however, few studies evaluated the cost-effectiveness of alternative 2nd- or 3rd-line therapies in the case of R/R iNHL. The majority of identified patient-reported outcomes (PRO) research exists as cogeneric abstraction. No studies were identified that examine PRO in a R/R iNHL population.

Conclusions: The economic and humanistic burden of R/R iNHL has not been widely reported in the literature. Areas of future research may include evaluating both direct and indirect costs in R/R iNHL. PROs are not well understood in iNHL, and future research should focus on QoL and related factors that may help evaluate any trade-off between progression-free survival and the severity/duration of adverse events.

**PSY75**

**HTA ASSESSMENT COMPARISON OF ORPHAN DRUGS IN FRANCE AND GERMANY**

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OBJECTIVES: In context of Health Technology Assessment (HTA) decision framework, some countries (e.g. Germany) have a special regulation for orphan drugs (OD), whereas others (e.g. France) aim to the reimbursement of the whole HTA decisions, prices and reimbursements for the OD that have been evaluated in France and Germany.

Methods: We selected OD assessed under AMNOG law in Germany and reviewed HTA assessments from the Transparency Committee (TC) for France and from IGW/G-BA for Germany, and extracted prices and reimburse-
ment levels of these drugs in both countries. Results: Eight OD were identified. In France, 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 high for 1 product. In Germany all these drugs were 100% reimbursed, while in France, depending on actual benefit (IAB) ratings, reimburse-
ment levels varied from non-reimbursement to 100%. At time of analysis, reim-
bursement categories was defined 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.

PSY76 HEALTH ECONOMICS AND OUTCOMES DATA REQUIREMENTS IN INDOLENT NON HODGKINS LYMPHOMA (INHL) AND CHRONIC LYMPHOCYTIC LEUKAEMIA (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 payers included managed care organizations (MCOs), Medicare (Med) and Medicaid (Med) payers and other medical or pharmacy directors to determine clinical, economic and humanistic outcomes data critical for formulary and medical policy decisions for INHL and CLL. RESULTS: The most important endpoints that directly tie to their major cost drivers: hospitalization, re-hospitalization and emergency ser-
vice in both the disease state. Payers were split on preferring the comparative data or relative effectiveness and effectiveness analysis as a basis for 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 a treatment 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 evalu-
ations rather than cost drivers, payers appreciate the value of demonstrating a reduction in resource consumption costs as they can directly evaluate the impact of this data on their health plan.

PSY77 PATIENTS WITH RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC LEUKAEMIA (R/R CLL) INELIGIBLE FOR CYTOTOXIC THERAPY WHO ARE THEY AND WHAT IS THEIR UNMET NEED? (a)

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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 in these patients. METHODS: Structured searches related to R/R CLL, performance status, comorbidities; organ function; test results 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 ther-
apy were identified by a combination of assessments for performance status (using ECOG), comorbidities (CKS), and organ function (create-
line clearance (CrCl)). Unfit patients are ‘≥ 65 years with a comorbidity’ (ECOG 3-4 or CKS > 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 “≥ 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 CKS ≤ 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 IRCs 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.

PSY78 EMERGENCY PHYSICIANS’ INTENTION TO USE THE TEXAS PMP

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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., pre-
scribers, pharmacists) to query a patient’s opioid dispensing history via a secure 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 survey instrument usability and explore emergency physicians’ intention to use the recently available Texas PMP. METHODS: A cross-sectional survey of EDs was conducted at a statewide emergency medicine conference. A 34-item ques-
tionnaire, based on the Technology Acceptance Model (TAM), was developed to assess EDs 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 was expanded on a previous exploratory survey of EDs. Correlation analyses were used to validate the survey instrument scales. RESULTS: Of the 45 respond-
ents, most were male (68.9%), attending EDs (57.8%), with 10.8±11.1 years in emer-
gency medicine, from a community hospital setting (55.6%), and were users of the Texas PMP (61.1%). Among those who were not registered, 59.2% reported lack of awareness as the primary reason for not being registered. Standardized Cronbach’s alpha 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. CONCLUSIONS: Considering the ED as a source of diversion, it is important to understand EDs utilization of PMPs. PMPs use of PMPs may help to mitigate the economic burden associated with the non-institutional use of opioids, with particular interest to patients in ED. Future studies using this survey instrument are needed to further assess the predictive utility.

PSY79 AN EVALUATION OF OPIOID OVERUTILIZATION QUALITY METRICS USING RECEIVING OPERATING CHARACTERISTIC CURVES AND PROBES FOR POTENTIAL 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) Consensus-based eValuating Syndromes and Therapies: MeasureS for potential overutilization. METHODS: Based on the CMS measure (proportion of patients with opioid prescriptions from ≥ 4 prescriptions and ≥ 4 pharmacies among patients with ≥ 2 opioid prescriptions), claims from the 2012 IMS LRS data-
based sample were analyzed. Overutilization rates were calculated using 2-8 prescribers and 2-8 pharmacies. Optimal cutpoints for number of physi-
cians and pharmacies were selected as the value on the curve with the shortest distance to perfect prediction. Sensitivity, specificity and positive predictive value (PPV) 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 (62.2%). For patients with no contraindications, the CMS criteria identified 2.5% as potential 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 (5.9%). CONCLUSIONS: The results suggest that using ROC curves for threshold determination may improve 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) recommen-
ded 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 condi-
tion’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 score, 8 conditions (11%) decreased, and 28 conditions (34%) remained the same. CONCLUSIONS: The results suggest that, despite the importance of technology, changes in wording may not lead to meaningful changes in recommendations. If new conditions were added, the sensitivity of conditions with increasing scores would be 59.5% (26/42). Of conditions with decreasing scores, the mean increase was 8%. Of conditions decreasing their scores, the mean decrease was 43. We estimate the potential change in recommendations as 4 conditions moving from primary to secondary or Not Recommended and 23 conditions (27%) improving (Sidoryk et al. Int J Clin Lab Res 2011).

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 (6.7% 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.