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Analysis Group will moderate one podium session, present five podium presentations, and exhibit 24 posters at the 2013 ISPOR conference.

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PODIUM IN4
DIRECT AND INDIRECT COST BURDEN OF CHRONIC HEPATITIS C STRATIFIED BY LIVER DISEASE SEVERITY IN PRIVATELY INSURED PATIENTS

Objective: To assess the direct healthcare and indirect work loss cost burden of chronic Hepatitis C virus (HCV) patients and to stratify the economic burden by disease severity.

Methods: Health insurance claims from 60 self-insured U.S. companies and disability data for employees in 29 of these companies covering the period 01/2001–09/2011 were analyzed. Adult patients with ≥2 diagnosis claims of chronic HCV and no HIV diagnosis were selected. A 6-month baseline period of continuous eligibility preceding HCV diagnosis was imposed. HCV patients were stratified into groups of non-cirrhotic, compensated cirrhotic, and end stage liver disease (ESLD). HCV patients were matched 1:1 with non-HCV controls using an exact factors and propensity score matching algorithm. Matched cohorts were compared for direct (pharmacy dispensings and medical services) and indirect (disability and medically related absenteeism) costs using per-patient per-year (PPPY) cost differences.

Results: Both cohorts (N=9,841 in each cohort) were well matched with respect to age (mean=52 years), gender (female=39%), Quan-Charlson comorbidity index (mean=0.5), share of employees with disability coverage (26%), and non-HCV related co-morbidities. HCV patients incurred significantly greater direct and indirect costs relative to non-HCV patients (PPPY direct costs: $16,721 vs. $6,063, cost difference [95% CI] = $10,503 [9,683–11,361], P<.001; PPPY indirect costs: $3,310 vs. $1,723, cost difference [95% CI] = $1,523 [1,248–1,794], P<.001). The direct incremental cost burden associated with HCV increased with disease severity (incremental direct cost [95% CI]: non-cirrhotic HCV = $5,536 [4,844–6,333]; compensated cirrhotic = $6,833 [5,326–8,474]; ESLD = $22,466 [20,182–24,729], P<.001 for all comparisons vs non-HCV matched controls in each sub-category). Among the subset of employees with disability coverage, the incremental indirect cost burden associated with HCV also increased with disease severity. The incremental cost associated with HCV was 6% of the total PPPY indirect cost burden associated with HCV.

Conclusions: Chronic HCV was associated with a significant direct healthcare and indirect work loss cost burden. The magnitude of the cost burden increased with disease severity.

PODIUM MA2
BEYOND AVERAGE ADHERENCE: TEMPORAL PATTERNS OF MEDICATION ADHERENCE PREDICT HOSPITALIZATION RISK MORE ACCURATELY THAN THE MEDICATION POSSESSION RATIO

Objectives: A patient’s temporal pattern of medication adherence may contain signals for clinical risks that are not captured by aggregate measures such as the medication possession ratio (MPR). We used hierarchical clustering to identify natural adherence patterns to dornase alfa in patients with cystic fibrosis (CF), and assessed whether these patterns were associated with hospitalization risk.

Methods: CF patients with a dornase alfa prescription followed by ≥1 year of health plan enrollment were identified in a national claims database (2005 – 2011). Hierarchical clustering was used to identify common patterns of adherence over time based on prescription fills. To evaluate the clinical and economic meaningfulness of the clusters, their association with CF-related hospitalization risk was assessed using Poisson regression with adjustment for MPR and other characteristics.

Results: A total of 985 CF patients with ≥1 prescription for dornase alfa were included. Average MPR was 45%. Half of the patients experienced hospitalization. Clustering identified six adherence patterns: 1) high; 2) low → high; 3) low → lower; 4) high → low; 5) periodic; and 6) low. MPR distributions overlapped between clusters. In the Poisson regression, each 1% increase in MPR was significantly (p<0.05) associated with an approximate 1% reduction in hospitalization risk. Including effects of cluster membership into the model with MPR significantly improved fit (P<0.001). Even after adjusting for MPR, hospitalization risk varied significantly across clusters, and, relative to cluster 1, was increased by 97%, 115%, 52%, 286% and 57% in clusters 2 through 6, respectively. The predictive significance of the clusters was robust to further adjustment for quadratic effects of MPR.

Conclusions: In this study of CF patients, temporal patterns of medication adherence predicted hospitalization risk more accurately than MPR alone. Temporal adherence patterns beyond MPR may have clinical and economic utility across therapeutic areas and warrant further study.

PODIUM DU1
TREATING ACUTE HEART FAILURE IN THE ELDERLY: A COMPARISON OF THREE INPATIENT TREATMENT ALTERNATIVES IN THE UNITED STATES

Objectives: Heart failure (HF) is the most frequent cause of hospitalization among US elderly. Despite limited evidence, current guidelines recommend the use of IV vasodilators in addition to IV loop diuretics (LD) for the treatment of acute HF (AHF) patients without hypotension. We investigated whether elderly patients...
hospitalized for AHF treated with IV LD combined with IV nitrates (NT) or IV nesiritide (NES) achieved better outcomes compared to those receiving IV-LD alone.

Methods: US hospital billing records (2007–2009) from the MarketScan Hospital Drug Database were analyzed. Patients ≥65 years old, with an AHF diagnosis and no evidence of hypotension and/or cardiogenic shock were included. Patients receiving IV-LD alone were paired with patients receiving IV-LD+NT and with patients receiving IV-LD+NES using propensity score matching. Outcomes included in-hospital mortality, length of stay (LOS), cost, and HF re-hospitalization rate.

Results: Compared to IV-LD alone (N=2,918), patients receiving IV-LD+NT (N=2,918; mean age 78.5 years, 44.7% male) had longer LOS (days, ICU: 1.5 vs. 2.2; total: 5.8 vs. 7.1, p<0.01 for both), higher costs ($8,810 vs. $13,387, p<0.01), but similar rates of mortality (2.2% vs. 2.5%, p>0.05) and one year HF re-hospitalization (37.2% vs. 37.4%, p>0.05). Compared to IV-LD alone (N=1,561), patients receiving IV-LD+NES (N=1,561; mean age 77.8 years, 56.7% male) had longer LOS (days, ICU: 1.9 vs. 2.4; total: 5.9 vs. 7.8, p<0.01 for both), higher costs ($8,775 vs. $13,040, p<0.01), higher one year HF re-hospitalization rates (38.2% vs. 41.8%, p<0.05), but similar mortality rates (2.8% vs. 3.5%, p>0.05).

Conclusions: This study amongst elderly AHF patients indicates that neither NT nor NES in addition to diuretics improve survival compared to diuretics alone, and are associated with longer LOS and higher hospitalization costs. These results raise the question as to whether currently utilized IV vasodilators are of value in the treatment of elderly AHF patients.

PODIUM SB1
BURDEN OF SCHIZOPHRENIA ON SELECTED COMORBIDITIES COSTS

Objective: To evaluate healthcare costs of patients with schizophrenia and specific comorbidities relative to patients without schizophrenia with the same comorbidities.

Methods: Medicaid insurance claims databases from five states (2007–2010) were analyzed. Adults with ≥2 claims for schizophrenia, ≥12 months of continuous eligibility prior to the first diagnosis (index date), and ≥1 claim for important comorbidities (substance abuse, obesity, diabetes, metabolic syndrome, hyperlipidemia, hypertension, coronary artery disease, congestive heart failure, HIV, hepatitis C, and COPD) during the 12 months prior to the index date (baseline period) were selected. Patients with schizophrenia were matched 1:1 with non-schizophrenia control patients based on baseline characteristics (propensity scores) and comorbidities common in schizophrenia (exact matching factors). All-cause and comorbidity-related monthly healthcare costs were calculated and compared between cohorts using nonparametric re-sampling methods. No adjustment was made for multiplicity.

Results: A total of 24,652 schizophrenia and 24,652 patients without schizophrenia were matched. The most common comorbidities were hypertension (48.8%), substance abuse (39.1%), and diabetes (28.4%). The patients with schizophrenia incurred greater all-cause monthly healthcare costs (cost difference [95% CI], $978 [933–1,024]) and comorbidity-related costs (cost difference [95% CI], $288 [269–307]). Schizophrenia was also associated with significantly higher comorbidity-related costs in each comorbidity subgroup (among the three most common comorbidities: 99% higher in hypertension, 293% in substance abuse, and 105% in diabetes).

Conclusion: This study show that patients with schizophrenia and comorbidities common in patients with schizophrenia had higher all-cause and comorbidity-related healthcare costs compared with patients without schizophrenia with the same comorbidities.

PODIUM SB2
MEDICAL, DRUG, AND WORK-LOSS COSTS OF DIABETIC FOOT ULCERS

Objectives: Estimate annual per-patient medical, drug, and work-loss costs of diabetic foot ulcer (DFU) using de-identified administrative claims data.

Methods: DFU patients and non-DFU diabetic patients (controls) were identified using two databases: ages 65+ from a 5% random sample of Medicare beneficiaries (Standard Analytical Files, 2007–2010; DFU N=29,681, controls N= 201,757) and ages 18–64 from a privately-insured population (OptumInsight, 2007–2011; DFU N=5,681, controls N= 113,337). Patients were required to be continuously eligible during the 12 months before (baseline) and 12 months after (study period) the index date (ie, the date of the most recent DFU diagnosis following 12 months without DFU diagnoses (DFU group), or the date of a random medical claim (controls)). DFU patients were matched to controls using propensity scores to account for baseline differences in demographics, comorbidities, resource utilization, and costs. Medical costs during the study period were calculated for both Medicare and privately-insured patients. Because drug and work-loss (absenteeism or disability) data were not available for Medicare patients, these costs were estimated for the privately-insured sample only. Wilcoxon-signed rank tests were used to compare differences in study period costs.

Results: Data for 4,536 matched pairs of privately-insured and 27,878 matched pairs of Medicare patients were analyzed. Incremental medical costs for DFU patients were $11,296 for Medicare ($27,040 vs $15,743) and $15,329 for privately-insured ($25,931 vs $10,602) patients. Two-thirds (66%) of the cost differential among
the privately-insured was attributable to excess inpatient costs. For Medicare, all places of services (eg, inpatient, outpatient/physician, emergency department) contributed approximately equally to the medical cost differential. Among the privately-insured, DFU patients had excess drug costs of $958 ($4,377 vs $3,420) and excess work-loss costs of $3,053 (absenteeism: +$1,490, disability: +$1,564). (Comparisons significant at p<0.0001.)

Conclusions: These findings suggest that presence of DFU imposes substantial burden on payers beyond that of standard diabetes care.

PMH28
PATTERNS OF RELAPSE AND ASSOCIATED COST BURDEN IN SCHIZOPHRENIA PATIENTS RECEIVING ATYPICAL ANTIPSYCHOTICS

Objective: To identify relapse in schizophrenia and the main cost drivers of relapse using a claims-based algorithm.

Methods: Multistate Medicaid data (1997–2010) were used to identify adults with schizophrenia receiving atypical antipsychotics (AAPs). The first schizophrenia diagnosis following AAP initiation was defined as the index date. Baseline weekly cost was assessed during the 12 months before the index date, and weekly costs were calculated for ≥2 years post index. An algorithm was developed to identify relapse episodes based on weeks associated with high cost increase from baseline and high absolute weekly cost. Resource use and costs of relapses during baseline and relapse episodes were compared using incidence rate ratios (IRRs) and bootstrap methods. No adjustment was made for multiplicity.

Results: 9,793 relapers were identified, with a mean of 9 relapse episodes per patient. Duration of relapse episodes decreased over time, with a mean(median) duration of 34(4) weeks for the first and 8(1) weeks for remaining episodes. Compared with baseline, resource utilization during relapse episodes was significantly greater in pharmacy, outpatient, and institutional visits (hospitalizations and emergency room visits), with IRRs ranging from 1.9–2.4 (all p<0.0001). Correspondingly, relapse was associated with a mean(95% CI) cost increase of $2459($2384–$2539)—nearly 6 times larger than mean(median) weekly baseline maintenance cost of $425($148). Institutional visits characterized most (53%) of the relapse episode incremental costs, with hospitalizations (excluding mental institute inpatient admissions) representing 36%.

Conclusions: Relapses in schizophrenia patients were associated with cost on average 6 times higher than the median maintenance costs. Institutional visits characterized most of the cost increase.

PMH73
ASSESSING THE IMPACT OF A MEDICAID PRIOR AUTHORIZATION (PA) POLICY FOR DULOXETINE ON ANTIPSYCHOTIC USE AMONG PATIENTS WITH DEPRESSION

Objective: To evaluate if the Iowa Medicaid duloxetine depression Prior Authorization (PA) policy implemented 5/24/2010, inadvertently increased atypical antipsychotic use in depressed patients. We compare initiations of duloxetine and other relevant medications for depression in Iowa before and after PA implementation and in Missouri, which had no duloxetine PA.

Methods: Using de-identified Iowa and Missouri Medicaid claims data (1999–2010), two cohorts were selected from each state: 2010 policy change cohort (index date: 5/24/2010) and 2009 control cohort (index date: 5/24/2009). Patients had to have ≥1 inpatient or 2 other medical claims with depression diagnosis pre-index; ≥1 antidepressant or antipsychotic claim during the six months pre-index (“baseline period”); and age<65 for six months post-index (“study period”). Baseline characteristics and study period prescription drug initiations (requiring six-month washout) by PA status (Iowa PA policy begun 5/24/2010) were compared between the two cohorts in each state. Logistic models were used to calculate risk-adjusted study period drug initiation rates, controlling for baseline characteristics.

Results: Iowa patients had significantly (p<.05) higher rates of anxiety and lower baseline healthcare costs 2010 vs. 2009 (n=9,429 vs. n=8,443). Missouri patients were significantly younger, had higher rates of mental disorders, and higher baseline healthcare costs in 2010 vs. 2009 (n=19,541 vs. n=13,083). In Iowa, risk-adjusted initiations of antidepressants (2009–2010) without PA increased significantly (17.8% vs. 19.4%); initiations decreased significantly for: duloxetine (2.0% vs.1.6%), other antidepressants with PA (4.2% vs. 1.2%), and atypical antipsychotics without PA (7.5% vs. 6.7%). In Missouri, initiations increased significantly (2009–2010) without PA (21.4% vs. 24.2%) and atypical antipsychotics without PA (10.0% vs. 10.8%); the duloxetine initiation rate was not significantly different (2.9% vs. 2.7%).

Conclusion: The Iowa Medicaid PA for duloxetine reduced the rate of duloxetine initiations, and did not increase atypical antipsychotic use.

PRM194
MATCHING-ADJUSTED INDIRECT COMPARISONS: A SIMULATION STUDY OF STATISTICAL PERFORMANCE

Objectives: When indirectly comparing treatments across separate clinical trials, matching-adjusted indirect comparisons (MAICs) can help avoid bias due to cross-trial
Background: To improve research productivity in an economic environment with limited resources, researchers may need to consider investigator-initiated approaches to design cost-efficient studies.

Objective: A cost function was developed to guide decisions about trade-offs to be made in clinical trial design with the objective of minimizing cost while achieving a given level of power to detect differences in patient-reported outcomes.

Methods: The design and conduct of a clinical study was treated as a constrained optimization problem. A cost function was developed, a Lagrangian function was constructed, and first-order partial derivatives were taken with respect to each choice variable (e.g., number of recruitment sites, number of follow-up visits, and study duration). Comparative statics analysis was used to examine the changes in the choice variables as a result of changes in the exogenous variables.

Results: A necessary condition to minimize cost while achieving a given power is the equivalence of the ratios of the marginal cost associated with increasing each choice variable and the marginal change in power associated with each choice variable; in other words the same cost per unit of output created by each input at the margin. For second-order condition, we made the reasonable assumption that increasing the number of participants recruited leads to a decrease in the marginal rate of change in the Type II error which holds. Comparative statics analysis showed that the increase or decrease in the rate of recruitment, expected percent loss to follow-up, and the cost of interventions lead to different trade-offs between the marginal cost of conducting the clinical trial and the marginal change in the probability of committing a Type II error.

Conclusion: In light of funding challenges, researchers could consider the trade-offs required to achieve a cost-efficient study for a given level of power using methods in economics and optimization.

PIH21

MEDICAL, DRUG, AND WORK-LOSS COSTS OF VENOUS LEG ULCERS

Objectives: Estimate annual per-patient medical, drug, and work-loss costs of venous leg ulcers (VLU) using de-identified administrative claims data.

Methods: Beneficiaries with (VLU) and without VLU (controls) were identified using two databases: ages 65+ from a 5% random sample of Medicare beneficiaries (Standard Analytical Files, 2007–2010; VLU N=60,840, controls N= 699,506) and ages 18–64 from a privately-insured population (Optum Insight, 2007–2011; VLU N=26,096, controls N= 1,300,455). Patients were required to be continuously eligible during the 12 months before (baseline) and 12 months after (study period) the index date (i.e., the date of the most recent VLU diagnosis following 12 months without VLU diagnoses (VLU group); or the date of a random medical claim (controls)). VLU patients were matched to controls using propensity scores to account for baseline differences in demographics, comorbidities, resource utilization, and costs. Medical costs incurred during the study period were calculated for both Medicare and privately-insured patients. Because drug and work-loss (absenteeism or disability) data were unavailable for Medicare patients, these costs were estimated for the privately-insured sample only. Differences in study period costs were compared using Wilcoxon-signed rank tests.

Results: Data for 22,900 matched pairs of privately-insured and 58,616 matched pairs of Medicare patients were
analyzed. VLU patients incurred incremental medical costs of $6,081 in Medicare ($18,246 vs $12,165), with privately-insured VLU patients having excess medical costs of $7,012 ($13,552 vs $6,540). Among the privately-insured, 88.0% of the cost differential was attributable to excess inpatient and outpatient/physician office costs. For Medicare, the excess costs were approximately equally distributed among all places of services. Among the privately-insured, the VLU patients and controls incurred similar drug costs, however, VLU patients had $454 more in work-loss costs (absenteeism: +$366, disability: +$87). (Comparisons were significant at p<0.0001).

**Conclusions:** These findings suggest that VLU patients impose an annual payer burden up to $18 billion.

**PIN1**

**MATCHING-ADJUSTED INDIRECT COMPARISON OF LIPID PROFILE AT 48 WEEKS AMONG TREATMENT NAÏVE HIV-1 PATIENTS TREATED WITH ATAZANAVIR/RITONAVIR VERSUS DARUNAVIR/RITONAVIR**

**Background:** This study estimates lipid profile changes and abnormalities in treatment naïve HIV patients initiating atazanavir/ritonavir (ATV/r) versus darunavir/ritonavir (DRV/r) using a matched indirect comparison.

**Methods:** Two similarly designed randomized trials were identified. Individual patient-level data were available for the CASTLE trial comparing ATV/r (n=430) and lopinavir/ritonavir (LPV/r) (n=438); published summary data were used from the ARTEMIS trial comparing DRV/r (n=343) and LPV/r (n=346). To adjust for cross-trial differences, CASTLE patients were re-weighted to match summary baseline characteristics in ARTEMIS. Lipid profile changes and serious (grade 2–4) lipid laboratory abnormalities (LA) at 48 weeks were compared between balanced trial populations after matching. If significant differences in LPV/r outcomes existed after matching, the differences between active treatments and LPV/r were compared across trials.

**Results:** Data from all patients in the two trials were included. Before matching, CASTLE patients at baseline had a higher proportion of HIV-1 RNA>100,000 copies/mL, a lower proportion CDC class C, and lower median CD4 cell count than ARTEMIS patients. An unadjusted cross-trial comparison at 48 weeks showed that ATV/r and DRV/r had similar changes in total cholesterol, low density lipoprotein (LDL), and triglycerides, but ATV/r had significantly lower rates of total cholesterol LA (7% vs. 13%, p=0.008) and LDL LA (8% vs. 13%, p=0.040). After balancing mean baseline characteristics, ATV/r and DRV/r at 48 weeks had similar changes in total cholesterol, LDL, and triglycerides (adjusted difference [AD]= –7.19, –7.11 and 7.59 mg/dL, respectively) and similar percentages of grade 2–4 triglycerides and cholesterol LAs (AD=0% and 1%, respectively); however, ATV/r had a significantly lower rate of serious LDL LA (AD=–9%, p=0.006).

**Conclusions:** While the overall lipid profiles of ATV/r and DRV/r were similar at 48 weeks in this matching-adjusted indirect comparison, ATV/r had a significantly lower rate of serious LDL LA.

**PIN26**

**BUDGET IMPACT ANALYSIS OF LIPOSOMAL AMPHOTERICIN B AND AMPHOTERICIN B LIPID COMPLEX FOR TREATING INVASIVE FUNGAL INFECTIONS IN HOSPITALIZED PATIENTS**

**Objectives:** To estimate the budget impact of changing the market shares of liposomal amphotericin B (L-AmB) and amphotericin B lipid complex (ABLC) for the treatment of invasive fungal infections (IFIs) in a US hospital.

**Methods:** An Excel-based budget impact model was developed to estimate the costs associated with using L-AmB and ABLC for treating adult patients with Aspergillus, Candida and Cryptococcus spp. infections who are refractory to or intolerant of conventional amphotericin B. The model was built from a hospital perspective, and included drug acquisition costs and costs for treating drug-related adverse events (AEs) within a hospital stay. The treatment duration of L-AmB and ABLC and rates of AEs for these two treatments were mainly obtained from a retrospective study of these two drugs in the target population using Cerner’s Health Facts data. Treatment costs of AEs were obtained from publicly available sources. The budget impact (2011USD) was evaluated by changing the market share of L-AmB and ABLC from 50/50% to 80/20%. One-way sensitivity analyses were conducted by varying drug cost, treatment duration, and rates and costs of AEs.

**Results:** The per-patient costs associated with L-AmB and ABLC during one hospital stay were $14,563 and $16,748, respectively. Cost of AEs attributed to 68.7% of the costs for L-AmB and 85.4% for ABLC. In a hypothetical hospital with 100 annual admissions of patients using one of these two drugs for fungal infections, changing the market shares from 50/50% to 80/20% yielded a cost saving of $65,561. Sensitivity analyses indicated that the results were robust to changes in input parameter values.

**Conclusions:** This study suggests that hospitals can realize cost savings by substituting ABLC with L-AmB in the treatment of invasive fungal infections. The cost savings are driven by the lower rates of AEs associated with L-AmB compared to ABLC.

**PSY8**

**A META-ANALYSIS OF EFFICACY AND SAFETY OF PRESCRIPTION OPIOIDS, INCLUDING FORMULATIONS WITH TAMPER-RESISTANT TECHNOLOGIES, IN NON-CANCER PAIN MANAGEMENT**

**Objectives:** This meta-analysis was conducted to compare pain intensity and adverse event (AE) outcomes between
opioids formulated with technologies designed to deter or resist tampering (tamper-resistant technologies [TRTs]) and non-TRTs for commonly prescribed long-acting opioids (LAOs) and short-acting opioids (SAOs) for treatment of non-cancer pain in adults.

**Methods:** Sixteen journal articles [13 non-TRT vs. placebo, 3 TRT vs. placebo] from a systematic literature review (9/1/2001–8/31/2011) meeting eligibility criteria were included in the meta-analyses. Summary estimates of standardized pain intensity outcomes [difference in mean change of pain intensity from baseline to end of study (DMCPI), difference in sum of pain intensity difference over the study period (DSPID)] and of odds ratios (OR) of 7 AEs were computed through random effects meta-analyses using DerSimonian-Laird method. Additional analyses included stratified analyses by treatment duration (<2 months, 2–3 months, ≥3 months) and by LAO/SAO, and indirect comparisons to contrast TRTs vs. non-TRTs.

**Results:** Summary estimates for standardized DMCPI and for standard DSPID indicated that TRTs and non-TRTs showed significantly greater efficacy than placebo in reducing pain intensity [(Standardized DMCPI) Non-TRT vs. placebo: −0.59(95% CI: −0.94, −0.24), TRF vs. placebo: −0.21(−0.35, −0.07); (Standardized DSPID) Non-TRT vs. placebo: 0.73(0.26,1.20), TRF vs. placebo: 0.51(0.30,0.72)]. TRTs and non-TRTs had similar safety profiles—both were associated with higher odds of AEs than placebo. ORs from indirect analyses comparing AEs for TRTs vs. non-TRTs were not significant different [nausea: 0.87(0.24,3.12), vomiting: 1.54(0.40,5.97), dizziness/vertigo: 0.61(0.21,1.76), headache: 1.42(0.57,3.53), somnolence/drowsiness: 0.47(0.09,2.58), constipation 0.64(0.28,1.49), pruritus 0.41(0.05,3.51)].

**Conclusions:** Pain intensity and ORs of AEs between non-TR Ts/TRTs and placebo did not vary by treatment duration and opioid formulation (p-values>0.05). TRTs and non-TRTs had comparable safety profiles and both were more efficacious than placebo in reducing pain intensity. Since TRTs are designed to reduce misuse/abuse due to tampering, they may be a means to reduce public health burden of opioid abuse.

**PSY32**

**HEALTHCARE RESOURCE UTILIZATION (HRU) AND COSTS ASSOCIATED WITH DISEASE ACTIVITY IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): A RETROSPECTIVE OBSERVATIONAL COHORT ANALYSIS**

**Objectives:** To estimate the economic consequences of changes in disease activity on HRU and costs.

**Methods:** An observational cohort study of SLE patients who received care in a regional integrated health delivery system from January 2004 through March 2011 was conducted using medical and hospital electronic health records, medical chart review, and health plan claims. Eligible patients were ≥18 years old, had ≥1 rheumatologist-confirmed SLE diagnosis and ≥1 eligible rheumatology-encounters, i.e., SLE visits in rheumatology, nephrology or emergency department. Patients were continuously enrolled ≥90 days before and after the encounters. Charts were manually reviewed to estimate SLEDAI scores (SS). Average unit costs of each medical procedure, facility use, and per-unit prescription were estimated from a payer perspective from a third-party managed care claims database. HRU and costs were calculated for the 30-day period surrounding every SS date (10 before and 19 days after) and the entire period of health plan enrolment. Relationships between HRU/costs and SS were estimated using mixed-effect models.

**Results:** A total of 178 SLE patients were included; mean age was 50.6 years, 91% female, and 95.5% Caucasians. Patients had a total of 1,343 encounters with valid SS (average observation period: 1,035 days). SLE patients incurred average annual costs of $18,839. Reductions of SS were significantly associated with reductions in HRU and costs. SS reductions of 4 points were associated with 10% and 14% reductions of HRU and costs over a 30-day period; reductions of 8 points were associated with 19% and 26% reductions of HRU and cost; and reductions of 10 points were associated with 23% and 31% reductions of HRU and cost. Annualized, these changes of SS scores are associated with changes of $5,579 (SS change from 10 to 0), $4,624 (10–2), and $2,485 (10–6), respectively.

**Conclusions:** Reductions in disease activity were associated with substantial reductions of HRU and costs.

**PSY75**

**ESTIMATING THE PAYER-SPECIFIC EXCESS MEDICAL COSTS OF OPIOID ABUSE IN THE UNITED STATES**

**Objectives:** Opioid abuse is a significant public health problem in the United States, with opioid-related overdoses accounting for over 16,500 deaths per year. In addition, opioid abuse imposes a significant economic burden due to increased health care utilization and costs. This study calculates updated, payer-specific, excess medical costs of diagnosed opioid abuse among commercially-insured, Medicaid, and Medicare patients with recent prescription opioid (RxO) use.

**Methods:** Using de-identified Truven MarketScan medical and pharmacy claims data for commercially-insured, Medicaid, and Medicare patients, we examined the excess costs of diagnosed opioid abuse among patients with at least one pharmacy claim for an RxO, 2009–2011. Diagnosed abusers were identified using ICD-9 diagnosis codes for opioid abuse/dependence and were matched to non-abusers using propensity score methods. Medical costs were calculated over a twelve-month period around the index date, which was the date of the first abuse diagnosis.
that SCD patients can have “catastrophic” costs, and rank responsible for the majority of costs. Payers also revealed of costs, and nearly 80% of total inpatient days. Physicians accounted for 75% (Medicaid) and 83% (privately insured) utilization by SCD patients reported that 25% of patients of resource utilization and costs. Studies assessing resource utilization and costs. An annual per patient excess medical costs associated with diagnosed opioid abuse were $9,456 (p<0.001) for commercially-insured patients, $11,501 (p<0.001) for Medicaid patients, and $10,046 (p<0.001) for Medicare patients. Inpatient costs accounted for 63.0%–78.6% of total excess medical costs, and ER costs accounted for 5.6%–12.6% of total excess medical costs.

Conclusions: The excess medical costs of opioid abuse are substantial and reveal a consistent pattern across payers. These estimates are comparable to prior research, suggesting opioid abuse continues to impose significant economic burden.

PSY85
KEY COST DRIVERS IN THE COST OF CARE FOR SICKLE CELL DISEASE PATIENTS: RESULTS OF A SYSTEMATIC LITERATURE SEARCH AND A SURVEY OF PAYERS AND KEY OPINION LEADERS

Objectives: Treating the approximately 100,000 patients in the United States today with sickle cell disease (SCD) can be costly. Identifying the main cost drivers of SCD is essential to developing appropriate interventions and improving patient outcomes. Real-world insights into the main cost drivers of SCD were gathered from the perspective of payers and physicians actively treating patients.

Methods: A systematic literature review was conducted on resource use and cost drivers associated with SCD, guiding our questionnaire development. Three physicians from academic and private practice and nine payers (medical, pharmacy or case management directors of large regional or national plans with commercial, Medicaid and/or managed Medicaid patients) were interviewed about their SCD patient management, resource utilization, and cost drivers experiences.

Results: Evidence from the published literature suggests that a small number of patients account for the majority of resource utilization and costs. Studies assessing resource utilization by SCD patients reported that 25% of patients accounted for 75% (Medicaid) and 83% (privately insured) of costs, and nearly 80% of total inpatient days. Physicians and payers indicated that about 10–30% of patients are responsible for the majority of costs. Payers also revealed that SCD patients can have “catastrophic” costs, and rank among the plan’s top 20 most costly patients. Payers and physicians all reported that SCD patients faced barriers to accessing primary care, leading to hospitalization and emergency department overuse. Barriers included low Medicaid reimbursement rates, lack of transportation, and low health care literacy.

Conclusions: Results from this systematic literature review and interviews with physicians and payers identify barriers in access to care as a key driver for hospitalization and emergency department overuse by SCD patients. This suggests that effectively designed disease management programs can help patients avoid acute care utilization, delivering better patient care with lower costs.

PCN12
META-ANALYSIS OF THE EFFICACY AND SAFETY OF BORTEZOMIB (BTZ) RETREATMENT IN PATIENTS (PTS) WITH MULTIPLE MYELOMA (MM)

Objective: BTZ is administered for a finite course; thus, MM pts may remain sensitive to BTZ-based therapy at relapse. We conducted a meta-analysis to assess efficacy and safety of BTZ-based retreatment in studies of pts with relapsed (rel) and/or refractory (ref) MM.

Methods: The proportion of BTZ-ref pts was identified where available. Other prognostic factors were extracted and used in weighted stratified analyses of TTP, PFS, and OS. Random-effect pooled estimates were calculated for ORR (≥PR) and rates of common AEs.

Results: 23 studies (N=1051 pts) were identified. BTZ was given IV in all studies. Retreatment comprised BTZ ± dex in 4 studies and BTZ-based combination therapy in 19. BTZ-ref pts were included in 11 studies; 6 studies included only rel pts. Across studies with data available, pooled, weighted average ORR was 39% (95% CI: 31–47) and median TTP, PFS, and OS were 7.5, 5.8, and 16.6 months. Stratified univariate analyses showed outcomes were generally consistent across groups while pts with ≤4 prior therapies and rel (but not ref) pts had higher ORRs of 43% and 57%, respectively. By random-effects meta-regression analysis, compared to ref pts, rel pts were associated with a higher ORR by 28–41 percentage points. The most common grade 3/4 AEs were thrombocytopenia (35%), neutropenia (15%), anemia (14%), pneumonia (10%), and peripheral neuropathy (3%).

Conclusions: Based on these findings, BTZ retreatment is efficacious and well tolerated in rel pts. In an era of new and emerging treatment options, these data indicate BTZ retreatment continues to be a highly effective option in previously treated pts.
Objectives: To characterize real-world medical resource utilization and costs following initiation of anti-cancer treatments for patients with Stage IB-IV Non-Small Cell Lung Cancer (NSCLC).

Methods: A retrospective, longitudinal, open-cohort study design was chosen using Medicare linked Surveillance Epidemiology and End Results (SEER) data. All Medicare-eligible patients in the SEER registry who were diagnosed with NSCLC during 2005–2007 and treated with anti-cancer therapy were identified. The observation period spanned from NSCLC diagnosis through the earliest date of end of anti-cancer therapy, data end date, or death. All-cause and NSCLC-related utilization and costs were reported, stratified by hospitalization, emergency room (ER), and outpatient visits. Results were stratified by patients with non-advanced cancer (Stages IB-IIIA) and advanced cancer (Stages IIIB-IV). Pharmacy costs were reported for patients diagnosed with NSCLC in 2007.

Results: The study population consisted of 6,365 patients; mean (SD) age was 73.7 (5.4) years, 54% were males, and median follow-up was 351 days. The all-cause rate per patient per month (PPPM) was 0.14, 0.10, and 4.08; NSCLC-related PPPM rate was 0.12, 0.05, and 2.86 for hospitalization, ER, and outpatient, respectively. The median monthly length of stay (days) for hospitalization was 1.25 for all-cause and 1.0 for NSCLC-related stays. The mean all-cause PPPM costs were $4,989 (hospitalization: $2,278, ER: $54, outpatient: $2,657). The mean NSCLC-related PPPM costs were $4,032 (hospitalization: $1,721, ER: $23, outpatient: $2,288). The mean all-cause PPPM costs were $3,805 ($2,873 NSCLC-related) for patients with non-advanced cancer and $5,822 ($4,847 NSCLC-related) for patients with advanced cancer. All-cause PPPM prescription drug costs were $560.

Conclusions: The SEER-Medicare database analysis found that in Stage IB-IV NSCLC patients, NSCLC-related costs accounted for over 80% of all healthcare costs while patients were on anti-cancer therapies. Higher costs were incurred by patients diagnosed with advanced NSCLC as compared to patients diagnosed with non-advanced disease.

Objectives: The prognosis of melanoma patients with brain metastases is poor, with median overall survival of approximately 4–5 months. This is the first study aiming at quantifying medical resources utilization and direct healthcare costs associated with brain metastases among metastatic melanoma patients in the U.S.

Methods: A retrospective pre-post design was implemented using data from the Truven MarketScan claims database (2000Q1–2011Q3). Patients with ≥1 diagnosis of melanoma (ICD-9-CM: 172–173, 198.2), ≥1 diagnosis of brain metastases (ICD-9-CM: 198.3), and ≥18 years as of the first observed brain metastases diagnosis (index date) were identified. The pre-period was defined as the 6 months prior to the index date and post-period as the period following the index date up to the earliest of 12 months, recorded death, or loss to follow up. All-cause and brain metastasis-related medical resources and healthcare costs were compared on a per patient per month (PPPM) basis between the pre- and post-periods.

Results: The study population consisted of 6,076 patients; mean (SD) age was 63.4 (13.4) years and 57.6% males. Significant differences were observed between the post- and pre-period in mean all-cause PPPM hospitalizations (0.21 vs. 0.08), emergency department visits (0.12 vs. 0.08), and outpatient visits (4.48 vs. 3.74) (p<.0001 for all). Similar results were found for brain metastasis-related hospitalizations (0.15 vs. 0.04), emergency department visits (0.02 vs. 0.01), and outpatient visits (2.00 vs. 1.17) (p<.0001 for all). Significant post- vs. pre-period differences were also observed in the PPPM all-cause healthcare costs (total: $14,489 vs. $7,277, inpatient: $6,330 vs. $1,900, outpatient: $6,609 vs. $4,449, p<.0001 for all) and brain metastasis-related costs (total: $6,542 vs. $1,933, inpatient: $2,976 vs. $472, outpatient: $3,451 vs. $1,413, p<.0001 for all).

Conclusion: The economic burden associated with brain metastases in melanoma is significant and underscores the need for newer therapies improving outcomes among these patients.
date. Population characteristics, number of abiraterone acetate fills, daily dose, refill interval, and Medication Possession Ratio (MPR) were summarized with descriptive statistics (n, %, mean±SD, median).

Results: A total of 1,545 PC patients with ≥1 abiraterone acetate prescription and prerequisite claims activity were identified. The majority were ≥65 years of age; 82% were treated by an oncologist; 58% had abiraterone acetate claims covered by commercial insurance and 38% by Medicare; 49% had ≥6 months of post-index clinical activity. The median abiraterone acetate dose was 1,000 mg (mean±SD =995.6±48.6 mg). The median refill interval was 29.8 days between dispensings (mean±SD=34.3±16.4 days). MPR was 0.96±0.10.

Conclusions: This retrospective study of early abiraterone acetate utilization in a large cohort of PC patients showed median abiraterone acetate dosing and refill intervals consistent with the product label.

PDB31
HEALTHCARE RESOURCE USE AND COSTS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AFTER TREATMENT INITIATION WITH SAXAGLIPTIN OR SITAGLIPTIN

Objectives: Compare healthcare resource use and costs in patients with type 2 diabetes mellitus (T2DM) treated with saxagliptin or sitagliptin in the 6 months following treatment initiation.

Methods: Patients with T2DM treated with saxagliptin (N=13,929) or sitagliptin (N=36,813) in 2010 or later were identified in the Truven MarketScan database of commercially insured beneficiaries. Patients were required to have no claims of saxagliptin or sitagliptin in the 6 months prior to treatment initiation, ≥6 months of continuous eligibility before and after treatment initiation (baseline and study period, respectively), and be 18 or older. Demographic characteristics and comorbidities were evaluated in the baseline period. All-cause and diabetes-related resource use and costs were evaluated during the study period. Chi-squared and Wilcoxon rank sum tests assessed differences in resources use rates and costs. GLM regression with a log link and gamma distribution estimated the treatment effect on study period costs, adjusting for baseline characteristics and costs.

Results: During the study period, compared with sitagliptin patients, saxagliptin patients experienced lower rates of all-cause hospitalization, emergency department visits, and other medical visits (7.2% vs. 10.6%, 14.1% vs. 17.5%, and 67.0% vs. 70.4%, respectively; p<0.001). All-cause medical and total costs were lower for saxagliptin patients than sitagliptin patients ($4,555 vs. 5,921; $7,346 vs. $8,797; all p<0.001). Substantial costs were attributable to hospitalizations, which were less costly for saxagliptin patients ($1,477 vs. $1,992; p<0.001). Diabetes-related medical and total costs were also significantly lower for saxagliptin patients ($1,084 vs. $1,454; $2,445 vs. $2,828; all p<0.001). After adjusting for baseline characteristics, significant differences in medical and total costs persisted (all-cause: $5,073 vs. $5,535; $7,802 vs. $8,302; diabetes related: $1,149 vs. $1,387; $2,510 vs. $2,772; all p<0.001).

Conclusion: Patients initiating treatment with saxagliptin had lower resource use and costs in a 6-month follow-up period than patients initiating with sitagliptin.

PDB34
TREND IN ECONOMIC BURDEN OF DIABETES IN URBAN CHINA FROM 2009 TO 2011

Objectives: To estimate the trend in direct and indirect costs among patients with diabetes in urban China from 2009 to 2011.

Methods: Data were obtained from the 2009–2011 Urban Resident Basic Medical Insurance (URBMI) household survey in 9 cities. Households were sampled to be representative of all households in these cities. Patients who self-reported to have a diabetes diagnosis were included. Annual costs per patient were estimated from the societal perspective, which included direct medical, direct non-medical and indirect costs. Direct medical costs included outpatient service, outpatient drug and inpatient costs. Outpatient service and drug costs were reported for the past 2 weeks and extrapolated to 1 year. Inpatient costs were estimated based on the number of hospitalizations during the past year and costs for the most recent hospitalization. Direct non-medical costs included transportation, accommodation costs, etc. Indirect costs due to absenteeism were estimated for employed patients based on mean annual national wage of urban employees in China. All costs were inflated and converted to 2011 USD.

Results: A total of 3,253 patients with self-reported diabetes diagnosis (N=1,078 in 2009, 1,114 in 2010 and 1,061 in 2011) were included, with 49.1% female and a mean age of 64.0 years. Mean annual direct medical costs were $1,303.2, $1,460.1 and $2,072.0 in 2009, 2010 and 2011, respectively. Mean outpatient drug costs were $565.8, $683.7 and $1034.5 in the three years, respectively. Mean outpatient drug costs were $565.8, $683.7 and $1034.5 in the three years, respectively. Insurance covered 42.8% to 45.5% of the direct medical costs. Medication costs included direct medical, direct non-medical and indirect costs. Direct medical costs included outpatient service, outpatient drug and inpatient costs. Outpatient service and drug costs were reported for the past 2 weeks and extrapolated to 1 year. Inpatient costs were estimated based on the number of hospitalizations during the past year and costs for the most recent hospitalization. Direct non-medical costs included transportation, accommodation costs, etc. Indirect costs due to absenteeism were estimated for employed patients based on mean annual national wage of urban employees in China. All costs were inflated and converted to 2011 USD.

Conclusion: Patients initiating treatment with saxagliptin had lower resource use and costs in a 6-month follow-up period than patients initiating with sitagliptin.
**PDB91**  
**ECONOMIC OUTCOMES ASSOCIATED WITH HBA1C AND LDL-C GOAL ACHIEVEMENT IN PATIENTS WITH TYPE 2 DIABETES MELLITUS**

**Objectives:** To examine the economic outcomes associated with dual-goal achievement of reaching glycated hemoglobin (HbA1c <7%) and low-density lipoprotein cholesterol (LDL-C <100mg/dL) targets in patients with type 2 diabetes mellitus (T2DM).

**Methods:** Adult T2DM patients (ICD-9 codes: 250.x0, 250.x2) were identified from the South Central Veterans Affairs Health Care Network (01/2004–06/2010) and followed until the end of data or death. A longitudinal design was adopted with patient information recorded in six-month cycles. Goal achievement status in each cycle was determined based on the average HbA1c and LDL-C levels using the area under the curve method. Economic outcomes included diabetes-related utilization events (inpatient (IP) days, number of outpatient (OP) visits) and diabetes-related medical service costs. The association between goal achievement status in a given study cycle and economic outcomes in the following cycle were assessed using multivariate generalized linear models, controlling for within-patient correlation.

**Results:** A majority of the 75,646 patients selected for the study were male (97.4%); average age was 64.7 years, mean BMI was 31.6 kg/m2, and median follow-up time was 4.5 years. Compared with achievement of only the LDL-C goal, dual-goal achievement was associated with significantly fewer diabetes-related IP days (Incidence Rate Ratio (IRR): 0.93; 95% Confidence Interval (CI): 0.87–1.00), and OP visits (IRR: 0.88; CI: 0.87–0.89), and incurred significantly lower diabetes-related medical service costs (difference: –$330.89, p=0.02). Compared with achievement of only the HbA1c goal, dual-goal achievement was associated with significantly fewer OP visits (IRR: 0.98; CI: 0.97–1.00) but no statistical difference in the number of hospitalization days (IRR: 0.98; CI: 0.89–1.07) or diabetes-related medical service costs (difference: –$56.17, p=0.40).

**Conclusions:** In this study of US Veterans with T2DM, dual-goal achievement was associated with fewer utilization events and lower costs when compared with only LDL-C goal achievement.

**PDB93**  
**CLINICAL CHARACTERISTICS, QUALITY MEASURE ATTAINMENT, AND DIABETES-RELATED HEALTHCARE COSTS IN ELDERLY VS OVERALL PEOPLE LIVING WITH TYPE 2 DIABETES MELLITUS (T2DM) RECEIVING METFORMIN (MET) AND SULFONYLUREA (SU)**

**Objective:** This study examined the demographics, comorbidities, clinical characteristics, and treatments of people with T2DM and an elderly subgroup. Additionally, attainment of quality goals and its correlation with diabetes-related costs were assessed.

**Methods:** Health insurance claims and electronic medical records from 14,532 adults with T2DM (2007–2011) were used to identify a sample receiving MET+SU. The index date was defined as the first dispensing of MET+SU after 6 months of eligibility. Clinical characteristics were assessed during baseline and quality measure attainment, defined as no values above specific thresholds (HbA1c <8%, body mass index [BMI] <30 kg/m2, blood pressure [BP] <140/90 mmHg, low-density lipoprotein cholesterol [LDL-C] <100 mg/dL), was evaluated during a 12-month landmark period after the index date. Association between quality measure attainment and diabetes-related costs, calculated after the landmark period, was evaluated using non-parametric bootstrap methods adjusting for imbalance in baseline characteristics between cohorts.

**Results:** 2,044 patients (mean age: 67 years; female: 46%), including 1,283 (62.8%) patients ≥65 years, were identified. Baseline comorbidities included cardiovascular disease (all patients: 25.5%; ≥65 years: 33.4%), congestive heart failure (5.9%; 8.1%), hypertension (66.5%; 74.2%), hyperlipidemia (73.9%; 78.1%), and neuropathy (16.0%; 20.2%). Statins and loop and non-loop diuretics were taken by 60.5%, 10.5%, and 21.1% of all patients, and 66.9%, 13.8%, and 24.5% of patients ≥65 years, respectively. The proportions meeting various quality goals were: 82.9% (≥65 years: 88.2%) for HbA1c, 34.4% (42.1%) for BMI, 31.6% (27.7%) for BP, and 68.2% (73.3%) for LDL-C. Quality measure attainment was associated with significantly lower diabetes-related costs per-patient per-year (adjusted mean cost differences: –$1,445 for HbA1c; –$1,218 for BMI; –$2,073 for HbA1c, BMI, and BP; all P<0.05) compared to non-attainment.

**Conclusion:** This study highlights the high incidence of comorbidities and potential financial benefits of attaining T2DM quality outcomes at the population level.

**PUK20**  
**IMPACT OF MIRABEGRON TREATMENT AND SYMPTOM SEVERITY ON WORK PRODUCTIVITY AND ACTIVITY IMPAIRMENT IN PATIENTS WITH OVERACTIVE BLADDER**

**Objectives:** Mirabegron, a novel selective beta-3 adrenergic agonist, has recently been approved in the United States for the treatment of overactive bladder (OAB). This study aimed to assess the impact of mirabegron on Work Productivity and Activity Impairment (WPAI) and the associations between WPAI outcomes and OAB symptom severity.

**Methods:** Data were obtained from a 12-week phase III randomized trial (NCT00662909) comparing mirabegron 50mg and placebo for OAB treatment. WPAI outcomes were measured using the WPAI-Questionnaire for OAB,
including employment and total activity impairment (TAI) for all patients, and absenteeism, presenteeism and total work productivity impairment (TWPI) for employed patients. OAB severity measures included number of incontinence and micturition episodes/day. Analyses of covariance were used to assess the effects of mirabegron on baseline-week 12 changes in WPAI. Longitudinal generalized estimating equations and Pearson correlation coefficients were used to assess associations between WPAI and OAB severity. Subgroup analyses were conducted for patients who discontinued prior OAB medication due to insufficient efficacy.

Results: Among the study sample (total N=858, employed N=394), mirabegron-treated patients experienced significantly greater improvement in TAI (12.3% vs. 6.7%, p<0.01) and greater but non-significant improvements in absenteeism (0.2% vs. −0.5%), presenteeism (8.6% vs. 6.0%), and TWPI (8.2% vs. 5.8%) than placebo-treated patients at week 12. Based on the association analyses, 2.0%, 1.4% and 1.4% increases per additional incontinence episode and, 1.2%, 1.1% and 1.1% increases per additional micturition episode were observed in TAI, presenteeism, and TWPI respectively (p<0.01). Baseline-week 12 change in TAI was significantly correlated with changes in OAB severity (incontinence: r=0.17, micturition: r=0.11; p<0.01). Similar trends were observed in the patient-subgroup with prior treatment non-response.

Conclusions: Patients treated with mirabegron experienced significantly reduced total activity impairment. Impairments in work productivity and activity outcomes are associated with OAB symptom severity, suggesting that treatments that improve symptom severity may also improve productivity impairment.

PHS1 RISK OF VENOUS THROMBOEMBOLISM COMPLICATIONS ASSOCIATED WITH RECURRENT VENOUS THROMBOEMBOLISM

Objective: Venous thromboembolism (VTE) increases the risk of developing several complications, including recurrent VTE. This study quantifies the long-term risk of complications associated with the development of an index recurrent VTE.

Methods: An analysis of healthcare insurance claims from the Ingenix IMPACT database was conducted. Between 01/2004 and 09/2008, subjects aged ≥18 years on the date of first recurrent VTE diagnosis requiring hospitalization (index recurrent deep vein thrombosis [DVT], pulmonary embolism [PE], or both) with ≥ 12 months of baseline observation prior to the index recurrent VTE were matched 1:1 with control VTE patients without recurrence, based on exact matching factors and propensity scores. The risk of developing thrombocytopenia, superficial venous thrombosis, venous ulcer, pulmonary hypertension, stasis dermatitis, and venous insufficiency for up to 1 year after the index recurrent VTE event was compared between the recurrent VTE and the VTE control group.

Results: The recurrent VTE and VTE cohorts (8,001 subjects in each group) were well-matched with respect to age, gender, comorbidities, and VTE risk factors distributions. The absolute risks of developing thrombocytopenia, superficial venous thrombosis, venous ulcer, pulmonary hypertension, stasis dermatitis, and venous insufficiency were 7.1%, 4.4%, 1.5%, 5.3%, 1.4%, and 7.2% for the recurrent VTE group and 2.5%, 1.3%, 0.8%, 2.0%, 0.9%, and 3.8% for the VTE group, respectively. The corresponding risk ratios indicated that the risk of developing any complications was significantly higher for the recurrent VTE group compared to the VTE group (risk ratio [95% CI]: thrombocytopenia: 2.8 [2.4 – 3.3], superficial venous thrombosis: 3.3 [2.7 – 4.1], venous ulcer: 1.9 [1.4 – 2.6], pulmonary hypertension: 2.7 [2.2 – 3.2], stasis dermatitis: 1.5 [1.1 – 2.0], and venous insufficiency: 1.9 [1.6 – 2.2], all p-values<.01).

Conclusions: In this large matched-cohort study, recurrent VTE patients had significantly higher risk of complications compared to VTE control patients.

PHS15 ALL-CAUSE AND DISEASE-RELATED COSTS ASSOCIATED WITH RECURRENT VENOUS THROMBOEMBOLISM

Objective: To describe the real-world clinical complications associated with recurrent venous thromboembolism (VTE) and to quantify the incremental direct all-cause and disease-related healthcare costs associated with recurrent VTE.

Methods: An analysis of healthcare insurance claims from the Ingenix IMPACT database was conducted. Between 01/2004 and 09/2008, subjects aged ≥18 years on the date of first recurrent VTE diagnosis requiring hospitalization (index recurrent deep vein thrombosis [DVT], pulmonary embolism [PE], or both) with ≥ 12 months of baseline observation prior to the index recurrent VTE were matched 1:1 with control VTE patients without recurrence, based on exact matching factors and propensity scores. The proportion of patients with post-thrombotic syndrome (PTS) was calculated for up to 1 year and compared between the two groups. All-cause health care and disease-related costs (thrombocytopenia, superficial venous thrombosis, venous ulcer, pulmonary hypertension, stasis dermatitis, and venous insufficiency) per patient per year (PPPY) were also calculated and compared between the two groups.

Results: The recurrent VTE and VTE control cohorts (8,001 subjects each) were well matched for age, gender, comorbidities, VTE risk factors distributions, and baseline healthcare costs. The risk of PTS was 18.1% for the recurrent VTE group and 6.8% for the no recurrent VTE cohort (risk ratio: 2.7 [2.4 – 2.9]). Patients with recurrent VTE had significantly higher average PPPY
all-cause costs compared to control patients (mean: $86,744 versus $37,525, cost difference=$49,219; 95% CI=46,253–51,989). Corresponding disease-related health care costs PPPY were also significantly higher for the recurrent VTE group (mean $11,120 versus $1,262, cost difference=$9,858, 95% CI=$9,081–$10,476) and represented 20.0% ($9,858 of $49,219) of the all-cause cost difference between the two groups.

**Conclusions:** In this large matched-cohort study, recurrent VTE patients had a significantly higher risk of PTS compared to VTE control patients and were also associated with a significant health care cost burden.

**PHS72**

**AGE-RELATED EMERGENCY DEPARTMENT RELIANCE (EDR) AND HEALTHCARE RESOURCE UTILIZATION IN PATIENTS WITH SICKLE CELL DISEASE (SCD)**

**Objectives:** For SCD patients, inadequate care during pediatric to adult transition may result in increased emergency department (ED) utilization. Emergency department reliance (EDR: total ED visits/total ambulatory [outpatient + ED] visits) identifies the proportion of ED visits in relation to all ambulatory visits. This study aimed at investigating age-related patterns of EDR and associated healthcare costs in SCD patients.

**Methods:** State Medicaid data from Florida, New Jersey, Missouri, Iowa, and Kansas were analyzed. Patients with ≥2 SCD diagnoses (ICD-9 282.6x) and ≥1 blood transfusion were included. Quarterly rates of EDR and SCD complication-related ED visits as well as healthcare costs were evaluated. Based on published thresholds, high EDR was defined as >0.33. Regression analyses were used to assess risk factors for high EDR and calculate adjusted costs difference between patients with high vs. low EDR.

**Results:** 3,208 patients were identified; mean (SD) observation period was 6.5 (3.2) years. Mean ED visits/quarter increased from 0.76 to 2.23 between age 15 and 23, reaching a peak of 2.9 at age 36. The most common SCD complication-related ED visits were pain, infection, and pneumonia. EDR rose from 0.15 to 0.29 between age 15 and 23, and remained high thereafter. Patients were more likely to have high EDR during the post-transition period (≥18 years old, odds ratio [OR]: 2.38, p<0.001) and when experiencing an SCD complication (OR: 4.18, p<0.001). Patients with high EDR incurred higher inpatient and ED costs, resulting in higher total costs (high vs. low EDR, adjusted costs difference, OP: –$285; IP: $3,485; ED: $120; Rx: –$91; total: $3,086, p<0.001 for all).

**Conclusion:** Compared to children, SCD patients transitioning to adulthood relied more on ED for their care and those with high EDR incurred higher healthcare costs, highlighting the need to improve access to care for transitioning and adult SCD patients.

**PG16**

**BUDGETARY IMPACT OF LINACLOTIDE IN THE TREATMENT OF US ADULT PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) OR CHRONIC CONSTIPATION (CC)**

**Objectives:** To estimate pharmacy and overall budgetary impact of introducing linaclotide to a hypothetical one-million-member managed care plan.

**Methods:** A decision-tree model (one-year time horizon) was constructed to estimate the budgetary impact of linaclotide. Model inputs include plan population, treatment costs, estimated current and future monthly prescription utilization, response rates, and potential medical cost offsets. Model outputs are per-member per-month (PMPM) pharmacy and medical costs. Treatment options include linaclotide, lubiprostone, and other prescription therapies. The proportion of patients who respond to linaclotide are assumed to incur lower healthcare costs due to less healthcare utilization. Treatment costs are based on published prices (polyethylene glycol, the most common prescription therapy is used as a surrogate for other generically-available prescription therapies). Daily net treatment costs (payer perspective) are $5.50, $6.37, and $0.29 for linaclotide, lubiprostone, and polyethylene glycol, respectively. Current prescription utilization (14% lubiprostone, 86% other therapies) and potential annual per-patient medical cost offsets (IBS-C: $1781, CC: $2002) are derived from retrospective database analyses; future prescription utilization (8% linaclotide, 10% lubiprostone, 82% other) is assumed. Linaclotide response rates (IBS-C: 33.6%, CC: 18.6%) are from primary endpoints of Phase III clinical trials. Budgetary impact is calculated as the cost difference between current and future scenarios. One-way sensitivity analyses were performed.

**Results:** Introducing linaclotide to a managed care formulary is estimated to increase the pharmacy budget by $0.007 PMPM; when potential medical cost offsets are included, the resulting overall budgetary impact is estimated to be $0.003 PMPM. In sensitivity analyses, number of linaclotide patients, IBS-C cost offsets, and conversion from other therapies to linaclotide had the greatest influence on budgetary impact; however, results did not vary substantially from base-case.

**Conclusions:** Linaclotide is expected to result in a slight increase in pharmacy budgets which may be partially offset by medical cost savings.
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