Analysis Group health outcomes professionals have extensive experience helping clients quantify product value in a dynamic and rapidly changing marketplace.

Drawing on our in-depth knowledge of a range of relevant data sources, we undertake U.S. and international pharmacoeconomic and health outcomes research and epidemiologic studies across a wide spectrum of therapeutic areas. Our work frequently results in publication in peer-reviewed journals. Together with prominent scholars from leading universities, we translate state-of-the-art academic theories into compelling results for our clients.

Analysis Group has 24 posters, one workshop presentation, and one educational symposium at the 2015 ISPOR conference.

Please visit our team at Booths #605/607
### ISPOR 2015 Analysis Group Educational Symposium

#### MAY 19, SYMPOSIUM

<table>
<thead>
<tr>
<th>Topic</th>
<th>Panelists</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developments in Medical Big Data Research: United States and China</td>
<td>Birnbaum H (moderator), Pinheiro L, Duh MS, Dasgupta N, Wu EQ</td>
<td>Page 4</td>
</tr>
</tbody>
</table>

### ISPOR 2015 Analysis Group Workshop Presentation

#### MAY 18, WORKSHOP SESSION I

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Discussion Leaders</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>W5</td>
<td>Indirect Comparisons for Single-Arm Trials or Trials Without Common Comparator Arms: What Methods Are Available, How Have They Been Used and How Can We Evaluate Results?</td>
<td>Swallow E, Signorovitch J, Kalsekar A, Yuan Y</td>
<td>Page 4</td>
</tr>
</tbody>
</table>

### ISPOR 2015 Analysis Group Poster Presentations

#### MAY 18, POSTER SESSION I

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Authors</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDB27</td>
<td>Glycated Hemoglobin (HBA1C) Control in Patients with Type 2 Diabetes Mellitus (T2DM) Treated with Canagliflozin in a Real-World Setting</td>
<td>Lefebvre P, Pilon D, Robitaille M, Lefeuille M, Chow W, Pfeifer M, Duh MS</td>
<td>Page 5</td>
</tr>
</tbody>
</table>

#### MAY 18, POSTER SESSION II

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Authors</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH65</td>
<td>Treatment Patterns of Women Diagnosed with Uterine Fibroids 5 Years Pre and Post Diagnosis: A Longitudinal Retrospective Claims Analysis of a Commercially Insured Population in the US</td>
<td>Soliman AM, Fuldeore M, Yang H, Du EX, Wu EQ, Winkel C</td>
<td>Page 6</td>
</tr>
<tr>
<td>PMH33</td>
<td>The Burden of Treatment Switch in Patients with Major Depression: A US Retrospective Administrative Claims Analysis</td>
<td>Perez V, Gauthier G, Guerin A, Francois C, Merkle E</td>
<td>Page 7</td>
</tr>
<tr>
<td>PMH42</td>
<td>Healthcare Utilization and Costs Among Adults with Major Depressive Disorder Treated with Vilazodone vs. Other Selective Serotonin Reuptake Inhibitors</td>
<td>Zhou Z, Sun SX, Chopra P, Zhong Y, Totev T, Signorovitch JE</td>
<td>Page 7</td>
</tr>
</tbody>
</table>

#### MAY 19, POSTER SESSION III

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Authors</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM555</td>
<td>Economic Evaluation of Timely Versus Delayed Use of Anti-Tumor Necrosis Factor (TNF) Biologics in the Treatment of Psoriatic Arthritis (PsA) in the US</td>
<td>Zhou Z, Signorovitch JE, Griffith JM, Zhong Y, Ganguli A</td>
<td>Page 8</td>
</tr>
<tr>
<td>PRS21</td>
<td>Cost and Resource Utilization in Hospital-Treated Cap Patients</td>
<td>Tuttle EG, Llop CJ</td>
<td>Page 8</td>
</tr>
<tr>
<td>PSS41</td>
<td>Association of Obesity with 30-Day Readmission Rates Among Patients Hospitalized with Acute Bacterial Skin and Skin-Structure Infections (ABSSSI)</td>
<td>Ayyagari R, Revol C, Tang W, Faust E, Tuttle EG</td>
<td>Page 9</td>
</tr>
</tbody>
</table>
# ISPOR 2015 Analysis Group Poster Presentations

## MAY 19, POSTER SESSION IV

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Authors</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCN27</td>
<td>Bone Pain, Skeletal Related Events and Opioid Use in Patients with Prostate Cancer and Bone Metastases</td>
<td>Valderrama A, Eapen S, Hennessey KA, Jones C, Wen L, Germiano J, Duh MS</td>
<td>Page 10</td>
</tr>
<tr>
<td>PCN43</td>
<td>A Cost Comparison of Split-Dose Reduced-Volume Oral Sulfate Solution (OSS) and Polyethylene Glycol with Electrolytes Solution (PEG-ELS)</td>
<td>Cleveland M, Yermakov S, Davis M, Campbell R, Huynh L, Farraye F, Yenikornshian M</td>
<td>Page 10</td>
</tr>
<tr>
<td>PGI20</td>
<td>Predictors of High Healthcare Resource Utilization and Liver Disease Progression Among Patients with Chronic Hepatitis C</td>
<td>LaMori J, Tandon N, Laliberté F, Germain G, Pilon D, Lefebvre P, Prabhakar A</td>
<td>Page 11</td>
</tr>
<tr>
<td>PGI35</td>
<td>A Descriptive Analysis of a Real-World Population with Chronic Hepatitis C (CHC) Treated with Simeprevir (SMV)- and/or Sofosbuvir (SOF)-based Regimens: Findings from a US Payer Database</td>
<td>Forlenza J, Fortier J, Laliberté F, Lefebvre P, Tandon N</td>
<td>Page 12</td>
</tr>
</tbody>
</table>

## MAY 20, POSTER SESSION V

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Authors</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>PND41</td>
<td>Description of Prophylactic Drug Utilization Patterns in Migraine Patients</td>
<td>Shei A, Woolley JM, Desai PR, Enloe CJ, Kinson NY, Birnbaum HG, Corey-Lisle PK, Sapra S</td>
<td>Page 13</td>
</tr>
<tr>
<td>PSY64</td>
<td>Treatment Patterns Among Chronic Users of Immediate-Release Oxycodone Initiating Treatment with Extended-Release Opioids</td>
<td>Pergolizzi JV, Kinson NY, Bell J, Jones C, Mantovaneli F, Cummings AG, Birnbaum HG, Ben-Joseph R</td>
<td>Page 15</td>
</tr>
</tbody>
</table>
ISPOR 2015 Analysis Group Abstracts

SYMPOSIUM
DEVELOPMENTS IN MEDICAL BIG DATA RESEARCH: UNITED STATES AND CHINA

Description: The rapid adoption of electronic medical record (EMR) systems and the expansion of health care coverage, combined with burgeoning patient-centric online content, have provided exciting new data sources in the United States and China. As additional dimensions (e.g., vital signs, laboratory results, biomarker and genomics data, physician notes, assessment of patient symptoms) to health care data have become available and are linked to traditional medical and pharmacy care data, they present new opportunities for creating more holistic real-world evidence. Researchers may use these new data elements to characterize quality of health care services, drug effectiveness, adverse event experiences, patient-reported outcomes, disease progression, and functionality. The recent advent of analytical techniques and natural language processing algorithms further provides a channel through which information from text-based data can be efficiently extracted.

Howard Birnbaum, Ph.D., Principal and health care economist at Analysis Group, will serve as moderator. Panelist One – Lisa Pinheiro, M.S., Vice President at Analysis Group, will discuss recent analytical techniques. Panelist Two – Mei Sheng Duh, Sc.D., Managing Principal and pharmacoepidemiologist at Analysis Group, will discuss social media, big data, and patient-reported outcomes in the health care field. Panelist Three – Nabarun Dasgupta, Ph.D., Chief Data Scientist and Co-founder of Epidemico, a public health software firm, will discuss how mobile apps and social media are increasing the efficiency of voluntary adverse event reporting to the FDA. Panelist Four – Eric Wu, Ph.D., Managing Principal and health economist at Analysis Group, will discuss China in the world of big data, referencing Analysis Group’s close collaboration with a network of major Chinese hospitals and research institutions, such as Peking University and Tsinghua University. He will also discuss numerous research projects – including a current lung cancer research study based on EMR data from 16 major cancer centers across China – that aim to help meet the needs of health care providers, payers, and decision makers from industry, government, and the scientific community. Dr. Wu will explain how this research will ultimately help improve the quality, effectiveness, and efficiency of health care delivery in China.

WORKSHOP W5
INDIRECT COMPARISONS FOR SINGLE-ARM TRIALS OR TRIALS WITHOUT COMMON COMPARATOR ARMS: WHAT METHODS ARE AVAILABLE, HOW HAVE THEY BEEN USED AND HOW CAN WE EVALUATE RESULTS?

Purpose: Single-arm trials may be used for regulatory evaluations of efficacy and safety, especially for breakthrough therapies, in rare diseases or in diseases with high unmet medical need. In these settings, single-arm trials can avoid practical and ethical challenges presented by comparator arms. However, once a product is approved, single-arm trials present important challenges for economic evaluations and health technology assessments. In particular, single-arm trials cannot be directly included in traditional indirect comparisons of efficacy and safety that inform economic comparisons. Similar challenges arise when two treatments of interest have only been trialed against different comparators, which often occurs in rapidly evolving therapeutic areas. This workshop will survey different statistical methods for conducting indirect comparisons across single-arm trials and across trials that do not share a common comparator.

Description: A number of methods have been used for indirect comparisons without common comparators, including benchmarking based on historical controls, simulated treatment comparisons (also called regression-prediction), network meta-analyses with multiple indirect links, and matching-adjusted indirect comparisons. We will summarize the practical requirements, advantages and limitations of the approaches, and will illustrate the methods through real-world applications. A framework will be provided for answering the following key questions: Given the available trial data, which method(s) should be used? How do the assumptions and limitations differ from those of traditional anchor- or network-based indirect comparisons? How can the appropriateness, quality and reliability of an analysis be assessed? Examples of publicly available health technology assessment submissions that included each method will also be reviewed and discussed. The audience will be invited to participate in the discussion of the methods and real-world applications.
GLYCATED HEMOGLOBIN (HBA1C) CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) TREATED WITH CANAGLIFLOZIN IN A REAL-WORLD SETTING

**Objectives:** Canagliflozin (CANA), an agent that inhibits sodium glucose co-transporter 2, has been shown to improve glycemic control in patients with T2DM in clinical trials. The current study described the early clinical characteristics and glycemic control of T2DM patients receiving different doses of CANA following approval of CANA in a real-world setting.

**Methods:** Adults with ≥1 diagnosis for T2DM and ≥6 months of clinical activity before first CANA prescription (index) were identified in the Cegedim Strategic Data US electronic medical records database, in which 60% of contributors are primary care providers. Patients were stratified by their first CANA daily dose (100mg [CANA100] or 300mg [CANA300]) observed in the database. Patients’ clinical characteristics were assessed descriptively and HbA1c levels at baseline and 6 months after the index date were compared using paired sample t-test to evaluate glycemic control associated with CANA.

**Results:** A total of 9,805 CANA users were identified, among which 6,571 (67%) were in the CANA100 group (mean age: 59; 48% female; 75% white; mean Charlson Comorbidity Index [CCI]: 1.8; mean Diabetes Complications Severity Index [DCSI]: 0.9) and 3,234 (33%) were in the CANA300 group (mean age: 57; 44% female; 75% white; mean CCI: 1.6; mean DCSI: 0.8). Before the index date, 98% and 97% of patients were prescribed ≥1 antihyperglycemic agent, with a mean number of 5.6 and 5.5 antihyperglycemic agents per patient in the CANA100 and CANA300 groups, respectively. In the 6 months following CANA initiation, mean HbA1c values decreased from 8.4% to 7.9% (p<0.0001) among CANA100 patients and from 8.5% to 7.8% (p<0.0001) among CANA300 patients.

**Conclusions:** Patients treated with CANA in the real-world setting often received multiple prior diabetes treatments and had uncontrolled HbA1c levels. Patients taking CANA significantly improved their HbA1c values, with numerically greater improvement in those with CANA 300mg.

ECONOMIC OUTCOMES AMONG MEDICARE PATIENTS RECEIVING BIOENGINEERED CELLULAR TECHNOLOGIES FOR TREATMENT OF DIABETIC FOOT ULCERS

**Objectives:** To compare the real-world medical services utilization and associated costs of Medicare patients with diabetic foot ulcers (DFU) treated with either of the following two types of skin substitutes: bilayered living cellular construct (BLCC) or human fibroblast-derived dermal substitute (HFDS) with those receiving conventional care (CC).

**Methods:** DFU patients were selected from Medicare de-identified administrative claims using ICD-9-CM codes. The analysis followed an “intent-to-treat” design, with cohorts assigned based on use of (1) BLCC, (2) HFDS, or (3) CC (i.e., ≥1 claim for a DFU-related treatment procedure or podiatrist visit and no evidence of skin substitute use) for treatment of DFU in 2006-2012. Propensity score models were used to separately match BLCC and HFDS patients to CC patients with similar baseline demographics, wound severity, and physician experience measures. Medical resource use, lower-limb amputation rates, and total healthcare costs (2012 USD; from payer perspective) during the 18 months following treatment initiation were compared separately among the two resulting matched samples.

**Results:** Data for 502 matched BLCC-CC patient pairs and 222 matched HFDS-CC patient pairs were analyzed. Relative to matched CC patients, BLCC and HFDS patients had fewer days hospitalized (BLCC: -33.3% p<0.01, HFDS: -42.4% p<0.01) and fewer emergency department visits (BLCC: -32.3% p<0.01, HFDS: -25.7% p<0.01), as well as lower amputation rates (BLCC: -27.6% p=0.04, HFDS: -22.2% p=0.19) during the 18-month follow-up period. While BLCC and HFDS patients did have higher costs for outpatient services (BLCC: +$7,100 p<0.01, HFDS: +$11,947 p<0.01), overall, these patients had lower average per-patient healthcare costs during the 18-month follow-up period compared with their respective matched CC counterparts (BLCC: -$5,253 p=0.49, HFDS: -$6,991 p=0.84).

**Conclusions:** These findings suggest that use of BLCC and HFDS for treatment of DFU may lower overall medical costs through reduced utilization of costly healthcare services.

STATISTICAL IDENTIFICATION OF PATIENT SELECTION BIAS IN RETROSPECTIVE CHART REVIEWS

**Objectives:** Retrospective chart reviews are often used to generate real-world evidence of patient outcomes. Physicians participating in these studies may be asked to randomly select patient charts for inclusion among all charts meeting eligibility criteria. Random selection is important for
obtaining representative samples and unbiased estimates of patient outcomes. This study examined a statistical method for detecting non-random selection of patient charts with an application to real data.

**Methods:** Example data were drawn from a recent retrospective oncology chart review study that estimated overall survival (OS) and progression-free survival (PFS) following the start of treatment. In the study, participating physicians were asked to provide a random sample of their eligible patients. Latent class analysis (LCA) was used to test whether the distribution of PFS and OS was consistent with random selection for all charts (a one class model) versus a mixture in which some physicians selected random charts and others selected non-random, convenient charts (models with >1 class). The best fitting model was identified using information criteria. Physician characteristics, PFS and OS were compared across latent classes.

**Results:** In overall sample of charts, median durations of OS and PFS were significantly longer than published benchmarks drawn from randomized trials. LCA identified evidence for two classes of physicians. One class was consistent with biased selection for recently seen patients who were still alive at the time of chart review, resulting in bias towards longer OS and PFS. The other class was consistent with random selection, and exhibited OS and PFS that were significantly closer to published benchmarks.

**Conclusions:** In this example using data from a retrospective oncology chart review, LCA was helpful in identifying physicians who may have selected convenient but non-random patient charts. LCA warrants further investigation as a way to detect, characterize, and address bias in retrospective samples.

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**PHP175**

**OUTCOMES-BASED PRICING AND REIMBURSEMENT ARRANGEMENTS FOR PHARMACEUTICAL PRODUCTS IN THE US AND EU-5: PAYER AND MANUFACTURER EXPERIENCE AND OUTLOOK**

**Objectives:** Outcomes-based pricing and reimbursement arrangements (OPRAs), a type of performance-based risk-sharing (PBRS) arrangements, have emerged as a promising avenue for payers to share pharmaceutical risk and for manufacturers to improve access. The aim of this study was to explore the U.S. and EU-5 perspectives regarding historical and future activity for OPRAs as well as payers’ and manufacturers’ perceptions of OPRAs.

**Methods:** Our study combined 2 approaches: targeted literature review and primary research with U.S. and EU-5 stakeholders. The targeted literature review included the following sources: University of Washington’s PBRS Database, payer and health technology assessment agencies’ websites, Factiva, PubMed, and congress abstracts. Only schemes relating to pharmaceuticals were included. Twenty-seven experts were interviewed using a structured questionnaire: 14 US payers, 5 EU-5 national payers, 8 manufacturers’ pricing/ market access executives (4 US, 4 EU-5).

**Results:** A total of 117 arrangements were identified from 1994 to 2014. This understates the level of OPRA activity as many schemes are confidential. U.S. and EU-5 interviewees expect that 2 to 10 times more OPRAs will be implemented in the next 5 years than in the previous 5 years. Historically, Italy has accounted for most OPRA activity; however, other nations are expected to increase OPRA activity. Key drivers include the introduction of a national OPRA framework in Spain, potentially a similar framework in the United Kingdom, a growing sick-fund activity in Germany, and a US movement towards accountable care. Motivation for OPRAs varies markedly across markets and stakeholders, with operational feasibility a significant hurdle in the U.S. and France. Cost and risk reduction were the primary focus for payers, while improving access was key for manufacturers.

**Conclusions:** This research suggests high OPRA growth is expected in the EU-5 and, to a lesser extent in the U.S., particularly if clear, uncomplicated OPRA frameworks can be developed.

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**PIH65**

**TREATMENT PATTERNS OF WOMEN DIAGNOSED WITH UTERINE FIBROIDS 5 YEARS PRE AND POST DIAGNOSIS: A LONGITUDINAL RETROSPECTIVE CLAIMS ANALYSIS OF A COMMERCIAL INSURED POPULATION IN THE US**

**Objectives:** To evaluate treatment patterns among women with uterine fibroid (UF) versus matched controls for 5 years before and after diagnosis

**Methods:** Women with a UF diagnosis (International Classification of Diseases 218.xx) aged 18-45 years were identified in Truven Health MarketScan® 2000-2010 data, and matched 1:1 to women without UF (control) by age, region, and insurance type. The first recorded UF diagnosis date was assigned as the index date for the UF patient and matched control. Continuous eligibility in a health plan for ≥1 year pre- and post-index was required. UF-related medications and surgical treatments during the five pre- and post-index years were evaluated annually, and compared between UF patients and controls using McNemar’s tests.
Results: A total of 84,954 matched pairs, with a mean age of 39.3 years at the index date were included in the analysis. During the 3 years prior to the index date, annual medication use (ranging from 18.7-19.5% vs. 16.5-18.4% for combined oral contraceptives and 0.4-0.9% vs. 0.2-0.3% for GnRH agonists) and UF-related surgery use (0.8-0.9% vs. 0.1-0.4% for endometrial ablations), respectively, were significantly higher among UF patients than controls (all \( p \) values <0.05). In the first year post-index, a greater proportion of UF patients than controls were treated with medications (combined oral contraceptives, 17.1% vs. 15.6%; progestins, 10.7% vs. 4.9%; and GnRH agonists, 2.8% vs. 0.2%) and surgeries (hysterectomies, 27.9% vs. 0.5%; endometrial ablations, 6.3% vs. 0.6%; myomectomies, 5.9% vs. <0.1%), respectively (all \( p \) values <0.05). In the next four years following up, the annual utilization difference decreased, but remained higher in UF patients and the differences were significant for GnRH agonist, hysterectomy, and myomectomy use.

Conclusions: Patients with UF used significantly more UF treatments than controls after diagnosis, and also during the period before diagnosis. Treatment usage peaked in the first year post-diagnosis.

PMH33
THE BURDEN OF TREATMENT SWITCH IN PATIENTS WITH MAJOR DEPRESSION: A US RETROSPECTIVE ADMINISTRATIVE CLAIMS ANALYSIS

Background: The rate of remission with treatment in major depressive disorder (MDD) is low; thus, switching medication is common. This study describes MDD patients in the US who switched to selected antidepressants; determines the rates of switching, discontinuation, and adherence; and quantifies the healthcare costs following treatment switch.

Method: Adults with \( \geq 2 \) MDD-related claims (ICD-9 codes: 296.2x, 296.3x) from the Truven Health Analytics MarketScan (1Q2001-4Q2012) database, who switched from an antidepressant to bupropion, citalopram, desvenlafaxine, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, or vilazodone (index AD), were identified. The index date was the date of first treatment switch occurring on or after January 1, 2012. Continuous enrollment for \( \geq 12 \) months prior to and \( \geq 6 \) months following the index date was required. Patient and treatment characteristics during the 12-month baseline (i.e., pre-index) period are described. Index antidepressant discontinuation (defined as a treatment gap of \( \geq 45 \) consecutive days), adherence (defined as \( \geq 80\% \) of days covered with the index antidepressant), and switch rates (from the index antidepressant to another antidepressant) over the 6-month follow-up are reported. Monthly healthcare costs incurred during follow-up are also described.

Results: 9,912 patients were included. On average, patients were 45.9 years old, and 72.7% were female. A mean of 1.9 antidepressants were prescribed during the baseline period. Patients had been on antidepressants for 230.6 days, on average, at baseline. During the 6-month follow-up, 10.1% of patients switched to a new antidepressant and 28.0% discontinued the index antidepressant. The proportion of adherent patients at follow-up was 52.2%. Patients incurred an average total monthly healthcare cost of $9,835 (2013 US$) during follow-up.

Conclusions: Switching is prevalent and a notable financial burden is observed among switchers in the US. Discontinuation rates are high, and adherence is suboptimal. Future research should determine which switching strategies are associated with optimal treatment and costs.

PMH42
HEALTHCARE UTILIZATION AND COSTS AMONG ADULTS WITH MAJOR DEPRESSIVE DISORDER TREATED WITH VILAZODONE VS. OTHER SELECTIVE SEROTONIN REUPTAKE INHIBITORS

Introduction: Selective serotonin reuptake inhibitors (SSRIs) are widely prescribed antidepressants. This claims database study compared healthcare resource use and costs among patients with major depressive disorder (MDD) treated with vilazodone, versus other SSRIs.

Methods: Adults with an MDD diagnosis and \( \geq 1 \) prescription fill for vilazodone, citalopram, escitalopram, fluoxetine, paroxetine or sertraline were identified from the Truven Health MarketScan® Research Databases (January 1, 2010 to December 31, 2012). Patients who concomitantly used adjunctive medication, either a second-generation antidepressant or antipsychotic, were excluded. All-cause and MDD-related healthcare resource use and costs (measured from a payer’s perspective in 2012 US dollars) over a 6 month period post-index date were compared among treatment groups using multivariate robust Poisson regression and robust linear regression, respectively, adjusted for age, gender, insurance type, index year, comorbidities, prior antidepressant treatment, and pharmacy copayment at baseline (12 months pre-index date).

Results: The study cohort included 49,861 patients (mean age: 44.0 years; 70% female). Compared with the vilazodone cohort (N=3,527), patients in the citalopram
(N=12,187), escitalopram (N=8,275), fluoxetine (N=10,142), paroxetine (N=3,146), and sertraline (N=12,584) cohorts had significantly more all-cause inpatient (IP) visits, length of IP stay and emergency room (ER) visits, and MDD-related IP visits and length of IP stay following the index date, after adjusting for baseline characteristics. All-cause medical service costs (IP + outpatient + ER) were significantly higher across all other SSRI cohorts versus vilazodone by $758 to $1,165 (p<0.05). Similarly, all-cause total costs were also significantly or numerically higher across all SSRI cohorts versus vilazodone by $351 to $780 after accounting for prescription costs.

**Conclusions:** MDD treatment with vilazodone was associated with significantly lower rates of inpatient and emergency services, and with significantly lower all-cause medical service and numerically lower total costs to payers compared to other SSRIs included in this study.

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**PMS55**

**ECONOMIC EVALUATION OF TIMELY VERSUS DELAYED USE OF ANTI-TUMOR NECROSIS FACTOR (TNF) BIOLOGICS IN THE TREATMENT OF PSORIATIC ARTHRITIS (PSA) IN THE US**

**Objectives:** Progression of PsA can lead to irreversible damage, functional impairment, and associated healthcare costs. Anti-TNF biologics have been shown to delay PsA progression and seem to have better efficacy compared with apremilast, a phosphodiesterase-4 inhibitor recently approved for PsA. The impact of using apremilast prior to anti-TNF has not been fully understood. This study evaluated the economic impacts of timely versus delayed use of anti-TNF among patients with moderately-to-severely active PsA from a US payer perspective.

**Methods:** A Markov model was developed to evaluate the costs and outcomes of two treatment sequences over a one-year time horizon. PsA patients received either adalimumab (timely use of anti-TNF) or apremilast (delayed use) as initial treatment. Those who did not achieve ACR20 response in the first 12 weeks of treatment or who lost ACR20 response would use subsequent treatments, which included a mixture of anti-TNF biologics, followed by palliative care. Efficacy was based on ACR20 response, changes in the Health Assessment Questionnaire (HAQ), and reduction in skin lesions measured by the Psoriasis Area and Severity Index (PASI). Direct costs, including treatment-related costs and other medical costs, and incremental costs per responder were calculated. Subgroup analyses among patients with moderate-to-severe psoriasis were performed.

**Results:** After one year, patients starting with adalimumab had higher ACR20 response rates and higher costs than apremilast (70.4% vs. 59.6%, $37,732 vs. $31,173). The one-year incremental cost per ACR20 responder was $60,766 for timely vs. delayed use of anti-TNF. Among the subgroup with psoriasis, starting with adalimumab led to higher response rates in both ACR20 and PASI75 and higher costs compared with apremilast (43.2% vs. 30.0%, $39,329 vs. $33,143). The incremental cost per ACR20+PASI75 responder was $46,949.

**Conclusions:** Timely use of anti-TNF is a cost-effective strategy for the management of PsA due to improvements in joint and skin condition.
Conclusions: Use of azi/ceft, the most common antibiotic regimen for hospitalized CAP patients but one that lacks an identical all-oral formulation, is associated with increased LOIV, LOS and cost. Efficacious alternatives with similar (or better) adverse event profiles and an all-oral formulation may yield cost and resource use savings.

PSS41
ASSOCIATION OF OBESITY WITH 30-DAY READMISSION RATES AMONG PATIENTS HOSPITALIZED WITH ACUTE BACTERIAL SKIN AND SKIN-STRUCTURE INFECTIONS (ABSSSI)

Objectives: Obesity is associated with increased risk of soft tissue infection and clinical failure; however, the association between obesity and longer-term clinical outcomes in ABSSSI patients is not well-studied. This study compared hospital readmission rates between obese and non-obese ABSSSI patients.

Methods: Adults (>18 years) hospitalized with ≥1 primary ABSSSI diagnosis were selected from the Cerner HealthFacts electronic medical records database (2009-2013). The first primary ABSSSI inpatient admission was defined as the index admission. Patients were categorized into obese (BMI>30) and non-obese cohorts at the index admission. Proportions of patients with all-cause and ABSSSI-related readmission to the same hospital within 30 days were compared between the cohorts descriptively (in subgroups defined by gender, age, and causative pathogen) and using multivariable logistic regression adjusting for hospital size, demographics, insurance type, causative pathogen, and important comorbidities.

Results: 5,823 obese and 5,882 non-obese patients were identified. Fewer obese patients were male (47.8% vs 55.8%), ≥65 years old (28.2% vs 34.3%), and admitted to teaching hospitals (70.7% vs 73.4%). Same-hospital 30-day readmission rates were higher for obese patients for both all-cause (12.9% vs 11.8%, p=0.085) and ABSSSI-related readmission (5.3% vs 4.0%, p=0.0019) readmissions. ABSSSI-related readmission rates remained significantly higher for obese patients among males (5.1% vs 3.8%, p=0.0086), younger patients (age <65 years, 5.0% vs 3.6%, p=0.0026), and those not infected with methicillin-resistant staphylococcus aureus (MRSA) (5.3% vs 4.2%, p=0.0049). In multivariable regressions, obese patients had higher odds of 30-day readmission for all-cause readmissions (obese vs non-obese: OR=1.10, p=0.0944) and significantly higher odds of ABSSSI-related readmissions (OR=1.28, p=0.0073).

Conclusions: Obese ABSSSI patients experienced higher rates of same-hospital ABSSSI-related readmission compared with non-obese patients. The association persisted in male, age <65, and non-MRSA subgroups and remained significant after adjustment for confounding. Further studies are warranted to estimate total readmission rates, which may be underestimated by same-hospital readmission rates.

PCN14
COMPARATIVE EFFECTIVENESS OF EVEROLIMUS VS. FULVESTRANT MONOTHERAPY AMONG POSTMENOPAUSAL WOMEN WITH HR+/HER2-METASTATIC BREAST CANCER

Objectives: Clinical evidence supports the use of everolimus-based therapy (EVE) and of fulvestrant monotherapy (FUL) among postmenopausal women with hormone receptor-positive human epidermal growth factor receptor-2 negative (HR+/HER2-) metastatic breast cancer (mBC) whose disease progressed on non-steroidal aromatase inhibitor (NSAI). However, direct evidence was lacking on the comparative effectiveness of these agents. This study compared progression-free survival (PFS) between EVE and FUL in a real-world setting.

Methods: This retrospective chart review examined postmenopausal HR+/HER2- mBC patients in community-based oncology practices who received EVE or FUL (index therapy) for mBC as first-line, second-line, or third- or later-lines after NSAI. PFS from index therapy initiation was assessed and compared using Kaplan-Meier analysis and a Cox proportional hazards model adjusting for index therapy line and characteristics at mBC diagnosis and index therapy initiation.

Results: A total of 192 and 156 patients received EVE or FUL, respectively, in a quota-based sample. EVE patients were less likely to have bone metastases, more likely to have visceral metastases or to have received prior chemotherapy for mBC, and had a shorter duration from initiation of last adjuvant endocrine therapy to mBC diagnosis. No significant PFS difference was observed in the unadjusted analysis. After adjusting for baseline characteristics, EVE patients had significantly longer PFS compared to FUL patients (hazard ratio [HR]=0.71, 95% CI [0.51, 0.99], p=0.045). When stratified by treatment line, second-line and third- or later-line EVE patients had significantly longer PFS (second-line: HR=0.52, 95% CI [0.29, 0.91], p=0.023; third- or later-lines: HR=0.48, 95% CI [0.24, 0.93], p=0.031) than FUL patients of the same treatment line.

Conclusions: Among postmenopausal women with HR+/HER2- mBC who progressed on NSAI, the use of EVE was
associated with better PFS, particularly on second-, third- and later-lines of treatment.

**PCN27**  
**BONE PAIN, SKELETAL RELATED EVENTS AND OPIOID USE IN PATIENTS WITH PROSTATE CANCER AND BONE METASTASES**

**Objectives:** Prostate cancer (PC) patients with bone metastases experience symptoms including debilitating pain that is associated with increased morbidity and mortality. Opiates in conjunction with other treatments are recommended for the management of severe pain, but real world data on their use in PC are limited. This study estimates the prevalence of and predictors for opioid use in PC patients with bone metastases.

**Methods:** Electronic medical records (EMR) from US community oncology clinics captured in OncoEMR® database were used to identify PC patients with bone metastases. Opioid use was identified from EMR, while evidence of bone pain and skeletal-related events (SREs), including pathological fracture, surgery, radiotherapy to bone and spinal cord compression were extracted from patients’ medical charts. Prevalence of opioid use was evaluated. Predictors for opioid vs. non-opioid analgesic use for pain were identified using a multivariate logistic model.

**Results:** In the study cohort of 1,520 PC patients with bone metastases, the average age was 73.6 years and mean follow-up from bone metastases was 13.8 months. In the subset with evidence of bone pain (N=927), 63% were opioid users, of whom 14% were chronic users. Multivariate regression analyses revealed that SREs significantly increased the opioid use risk by 3.21-fold (95% CI: 2.38-4.32), with the following additional significant risk factors: Medicare vs. other/no insurance (OR=1.54, 95% CI: 1.13, 2.10), chemotherapy (OR=3.34, 95% CI: 2.17, 5.13), and NSAIDs use (OR=1.90, 95% CI: 1.25, 2.88).

**Conclusions:** SREs are a significant predictor for opioid use. 37% of the patients with bone pain had no documented use of opioids. Pain and symptom palliation is a significant management issue in PC. It is important to choose appropriate treatments for patients that delay or prevent SREs and effectively control pain.

**PCN31**  
**OVERALL SURVIVAL IN POST-MENOPAUSAL WOMEN WITH HR+/HER2- METASTATIC BREAST CANCER TREATED WITH 1ST-LINE ENDOCRINE THERAPY VS. CHEMOTHERAPY**

**Objectives:** As newer treatment options become available to postmenopausal women with HR+/HER2- metastatic breast cancer (mBC), understanding the relative survival benefit of different treatment options and sequencing is of increasing clinical importance. This study compared overall survival (OS) in patients with HR+/HER2- mBC whose 1st-line therapy was endocrine therapy (1st-line endo) vs. chemotherapy (1st-line chemo) in real-world settings.

**Methods:** Data were extracted from a community oncology electronic medical records database from Altos Solutions. Eligible patients were postmenopausal women, with ≥1 medical record with a BC diagnosis, confirmed HR+/HER2- status, and 1st mBC diagnosis (index date) after July 1, 2012. OS between 1st-line endo and 1st-line chemo patients was compared using cumulative proportion of deaths and Cox proportional hazard regressions controlling for age, race, region, insurance type, comorbidities, disease recurrence, and metastatic sites.

**Results:** Among the 1,051 patients meeting the eligibility criteria, 676 (64.3%) received 1st-line endo and 375 (35.7%) received 1st-line chemo. 1st-line endo patients were older (68.1 vs. 64.4 years, p<0.001) and were more often Caucasian (74.1% vs. 65.9%, p=0.005) compared with 1st-line chemo patients. Site of metastases was known in 57.5% of 1st-line endo and 59.2% of 1st-line chemo patients, with bone being the most common site (48.8% vs. 40.3%, p=0.008). The cumulative proportion of deaths was 5.9% vs. 10.7% (p=0.005), 10.4% vs. 14.7% (p=0.039), and 12.0% vs. 17.3% (p=0.016) at 6, 12, and 18 months, respectively. Patients receiving 1st-line endo had better OS at 6 (adjusted hazard ratio [HR]: 0.50, p=0.004), 12 (HR: 0.60, p=0.009), and 18 (HR: 0.58, p=0.002) months compared to patients receiving 1st-line chemo (patients with known site of metastases: 0.51 [p=0.031], 0.61 [p=0.049], and 0.63 [p=0.045], respectively) after adjusting for patient characteristics.

**Conclusions:** Compared to chemotherapy, early endocrine therapy may be associated with better survival in postmenopausal women with HR+/HER2- mBC after adjusting for patient characteristics.

**PCN43**  
**A COST COMPARISON OF SPLIT-DOSE REDUCED-VOLUME ORAL SULFATE SOLUTION (OSS) AND POLYETHYLENE GLYCOL WITH ELECTROLYTES SOLUTION (PEG-ELS)**

**Objectives:** The study aimed to (1) develop a cost model for colonoscopy preparation among patients referred for colonoscopy using split-dose reduced-volume oral
sulfate solution (OSS) and generic polyethylene glycol with electrolytes solution (PEG-ELS), (2) examine cost-savings associated with OSS versus PEG-ELS, and (3) assess the robustness of the cost model.

**Methods:** Clinical efficacy of each agent was based on the results of a 541-patient clinical trial comparing OSS to PEG-ELS. Cleansing agent and colonoscopy procedure costs were calculated from OptumHealth Reporting & Insights claims data for 2010–Q12013. In the cost model, patients’ colonoscopies were tracked until the patient reached age 75. The difference per patient per year (PPPY) in total cleansing agent and colonoscopy procedure costs over the time horizon between the OSS and PEG-ELS cohort was calculated. One-way sensitivity analyses were also conducted to test the robustness of the cost model.

**Results:** The cost model showed that OSS patients had fewer colonoscopies over the time horizon (OSS: 0.158 vs. PEG-ELS: 0.170 PPPY). Total PPPY costs were $280.34 for the OSS cohort and $296.36 for the PEG-ELS cohort, resulting in a cost-saving of $16.01 to the payer for the OSS cohort. Varying the annual colonoscopy completion rate, surveillance intervals, time horizon, and proportion of high risk patients did not change the observation of cost-savings under OSS. Cost-savings switched from the OSS to the PEG-ELS cohort in three cases: (1) base-case cost of a completed colonoscopy decreased by 75%, (2) base-case cost of OSS increased to over $143 per usage, and (3) all non-completers were lost to follow up.

**Conclusions:** From a payer’s perspective, the cost model showed that the use of OSS as the cleansing agent resulted in potential cost-savings compared with PEG-ELS. The cost model was robust and cost-savings under OSS remained under various sensitivity analyses.

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**PCN187**

**TREATMENT PATTERNS OF ENDOCRINE THERAPY AND CHEMOTHERAPY AMONG POST-MENOPAUSAL WOMEN WITH HR+/HER2- METASTATIC BREAST CANCER**

**Objectives:** Initial endocrine therapy (ET) is preferred for most post-menopausal women with hormone receptor positive human epidermal growth factor receptor 2 negative metastatic breast cancer (HR+/HER2- mBC), and guidelines recommend reserving chemotherapy (CT) for patients with symptomatic visceral disease or no clinical benefit after 3 sequential ET regimens. This study describes treatment patterns among post-menopausal HR+/HER2- mBC patients previously treated with adjuvant therapy (recurrent patients) or not (de novo patients).

**Methods:** Charts from a network of US community-based oncology practices were reviewed for post-menopausal women with HR+/HER2- mBC who progressed to mBC between 1/1/2004 and 9/30/2010. Extracted chart data included demographic characteristics, treatment history, and outcomes.

**Results:** Patients (n=144) had a median age of 65 years at mBC diagnosis. They received a median of 2 lines of ET, and <10% had 3 or more lines of ET before receiving CT. De novo patients (n=69) and recurrent patients (n=75) received a median of 2 lines and 1 line of ET, respectively. The recurrent group had a lower proportion of patients receiving 1st-line single agent ET compared with the de novo group (65% vs. 71%). Unlike de novo patients, who had non-steroidal aromatase inhibitors (NSAIs) as the most frequent 1st-line ET (letrozole (35%), anastrozole (26%)), recurrent patients predominantly received fulvestrant (23%) in the 1st-line setting, possibly due to prior adjuvant NSAIs. In addition, a higher proportion of recurrent patients received CT as 1st-line therapy compared with de novo patients (27% vs. 20%).

**Conclusions:** The majority of de novo patients received 1st-line NSAIs, but recurrent patients were less likely to receive NSAIs and more likely to receive 1st-line CT. Recurrent patients also received fewer total lines of ET. Most mBC patients did not receive the guideline-recommended 3 lines of ET. The unmet need for improved ET options was particularly pronounced among recurrent patients.

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**PGI20**

**PREDICTORS OF HIGH HEALTHCARE RESOURCE UTILIZATION AND LIVER DISEASE PROGRESSION AMONG PATIENTS WITH CHRONIC HEPATITIS C**

**Objectives:** Although the high cost burden of chronic hepatitis C (CHC) has been described in the literature, there is a lack of data on the assessment of characteristics associated with high healthcare utilizers. The purpose of this study was to identify demographics and clinical characteristics associated with high healthcare utilizers and liver disease progression among CHC patients.

**Methods:** Health insurance claims from 60 self-insured US companies were analyzed (01/2001-03/2013). Adult patients with ≥2 CHC claims (ICD-9-CM: 070.44 or 070.54), ≥6 months of continuous insurance coverage before the first CHC diagnosis and ≥36 months after were included. Patients with HIV were excluded. Demographics and baseline comorbidities including CHC- and non-CHC-related conditions were described. Generalized estimating equations with logit link for binary outcomes were used to identify the
most predictive demographics and clinical characteristics of being in the 20% of patients with the highest healthcare resource utilization (HRU). Predictive factors of liver disease progression were also identified.

**Results:** The mean age of the study population (N=4,898) was 52.4 years and 39.4% were female. Compensated cirrhosis, ESLD and both CHC- and non-CHC-related comorbidities were strong predictors of high healthcare costs, with odds ratios (ORs; 95%CI) for ESLD, ≥2 CHC-related, and ≥2 non-CHC-related comorbidities of 3.31 (2.80-3.92), 2.78 (2.47-3.12), and 2.18 (1.75-2.71), respectively. CHC- and non-CHC-related comorbidities were also strong predictors of liver disease progression with ORs (95%CI) for ≥2 CHC-related and ≥2 non-CHC-related comorbidities of 2.18 (1.83-2.60) and 1.50 (1.14-1.97), respectively.

**Conclusions:** This real-world study suggests that CHC patients with the highest HRU and costs had a high level of comorbidity at baseline and that non-CHC conditions are strong predictors of high healthcare costs. Liver disease severity alone does not fully predict high consumption of HRU, although when present it is a predictor of high HRU.

**PGI35**  
**A DESCRIPTIVE ANALYSIS OF A REAL-WORLD POPULATION WITH CHRONIC HEPATITIS C (CHC) TREATED WITH SIMEPREVIR (SMV) AND/OR SOfosbuVIR (SOF)-BASED REGIMENS: FINDINGS FROM A US PAYER DATABASE**

**Objectives:** To provide real-world evaluations of newer direct-acting antivirals (DAAs) in CHC patients from large US payer perspectives.

**Methods:** Medical and pharmacy claims linked to lab data from the Humana Database were analyzed for Medicare Advantage or commercially insured adults with ≥2 CHC claims (ICD-9 070.44; 070.54) who received therapy containing SMV and/or SOF through June 2014; those with HIV were excluded. Patients were grouped based on most common regimens in the data: SMV/SOF, SMV/SOF/ribavirin (RBV), SOF/RBV, or SOF/interferon (IFN)/RBV; <3% received other regimens. Baseline (BL) demographics and clinical characteristics (e.g., claims-based cirrhosis or end stage liver disease [ESLD], FIB-4 scores) were described and post-treatment time measured. Methods to control for treatment selection bias were not performed, and comparative analyses were not conducted.

**Results:** There were 715 CHC patients who received therapy with SMV/SOF (n=184), SMV/SOF/RBV (n=37), SOF/RBV (n=269) or SOF/IFN/RBV (n=225); mean age was between 60-62 years; 58%, 68%, 62% and 70% were male; most (85%, 78%, 81% and 80%) had Medicare. For SMV/SOF, SMV/SOF/RBV, SOF/RBV, and SOF/IFN/RBV groups, BL cirrhosis was present in 27%, 27%, 17%, and 24% of patients and ESLD in 48%, 38%, 27%, and 12% of patients, respectively. Slightly over half in each cohort had calculable FIB-4 scores, of which, 56%, 54%, 34% and 35%, respectively, had scores >3.25. Among those with genotype data, 100% (78/78) SMV/SOF, 94.7% (18/19) SMV/SOF/RBV, 24.4% (29/119) SOF/RBV and 95.8% (92/96) SOF/IFN/RBV were genotype 1. Using prior claims history, 10%, 19%, 12% and 17% of respective cohorts were treatment-experienced. Less than half of each cohort had post-treatment data ≥1 week.

**Conclusions:** This analysis of CHC patients predominantly insured through Medicare found that the majority of those who received SMV/SOF +/- RBV had either cirrhosis or ESLD claims prior to therapy and, based on lab data, over half had FIB-4 scores >3.25.

**PHS67**  
**OUT-OF-POCKET MEDICAL COSTS FOR PARENTS WITH CHILDREN WITH DOWN SYNDROME IN THE UNITED STATES**

**Objectives:** Financial considerations may impact the pregnancy decisions of expectant parents who receive a positive prenatal screening test result for Down syndrome (DS). This study estimates the out-of-pocket health care costs for parents associated with raising a child with DS between birth and 18 years of age, using private U.S. health insurance data.

**Methods:** Patients with a diagnosis of DS (ICD-9-CM 758.0x) who were enrolled in their family insurance plan as a child and had an identifiable parent were identified from the OptumHealth Reporting and Insights administrative claims database. A patient’s observation time was divided into clinically relevant age categories for DS. Patients with DS in each age category were matched to controls without diagnoses for chromosomal conditions. Mean annual health care utilization costs were compared between the patient-age cohorts with DS and matched controls using Wilcoxon signed-rank tests.

**Results:** After matching, patient-age cohorts were statistically similar with respect to most demographic and family characteristics. However, patients with DS had significantly higher mean annual out-of-pocket costs than their matched controls within each age and cost category. Total annual incremental costs were highest among patients...
with DS from birth to age 1 ($1,907, p<0.001), when the need for surgery is greatest. The greatest incremental costs were inpatient costs in the first year of life ($925, p<0.001) and outpatient costs in later years (ranging from $623-$183, all p<0.001). Overall, patients with DS incurred incremental out-of-pocket medical costs of $18,248 between birth and age 18 years.

Conclusions: Across all age categories, mean total out-of-pocket annual costs for parents were greater among individuals with DS compared to their matched controls. On average, parents of children with DS pay an additional $84 per month for out-of-pocket medical expenses when costs are amortized over 18 years.

PHS70
ASSOCIATION OF CHANGE IN FORCED VITAL CAPACITY WITH HEALTHCARE RESOURCE UTILIZATION IN PATIENTS WITH NEWLY DIAGNOSED IDIOPATHIC PULMONARY FIBROSIS

Objectives: This study assessed the association between forced vital capacity (FVC) change post-diagnosis of idiopathic pulmonary fibrosis (IPF) and healthcare resource utilization (HRU) in patients with newly diagnosed IPF.

Methods: A retrospective chart review was conducted by US pulmonologists using an online case report form for patients diagnosed with IPF from 01/2011-06/2013. Patient eligibility criteria included: 1) ≥40 years old at IPF diagnosis; 2) IPF confirmed by lung biopsy and/or high-resolution computed tomography; 3) FVC results at diagnosis and ~6 months following diagnosis. Based on relative change in FVC percent predicted (FVC%pred), patients were categorized as stable (decline<5%), marginal decline (5%–9%), or significant decline (decline≥10%). Physician-reported IPF-related HRU included visits for urgent care or suspected acute exacerbation (AEx) and hospitalization. All outcomes were assessed from six months post-diagnosis to end of observation. HRU rates by FVC decline group were estimated and compared using unadjusted negative binomial regression, controlling for varying follow-up periods. A multivariable Cox model was constructed to assess risk of hospitalization post-FVC decline.

Results: The sample included 490 IPF patients from 168 pulmonologists with 250 (51%), 98 (20%), and 142 (29%) patients in the stable, marginal decline, and significant decline groups, respectively. At diagnosis, the mean age was 61±11 years, 68% were male, and the mean FVC%pred was 60±26%. The mean observation time across patients was 583±287 days. Groups with greater FVC decline exhibited higher rates of hospitalization and visits for urgent care or suspected AEx. Multivariable analysis showed that the significant (HR=3.6 [95%CI: 2.0-6.6]) and marginal decline (HR=2.4 [95%CI: 1.2-4.8]) groups were associated with higher risk of hospitalization than the stable group.

Conclusions: Our findings suggest that greater FVC decline in the first six months post-diagnosis is associated with increased IPF-related HRU. Management options for IPF that slow FVC decline may help lessen future IPF-related HRU.

PND41
DESCRIPTION OF PROPHYLACTIC DRUG UTILIZATION PATTERNS IN MIGRAINE PATIENTS

Objective: Describe medication utilization patterns of migraine prophylactics in commercially insured patients.

Methods: Adult migraineurs (ICD-9 code 346.xx) newly initiating migraine prophylactics (no claims for 12 months before first (index) prophylactic prescription) between January 2007 and March 2013 were identified from the OptumInsight employer claims database and followed for 6 months. Prophylactics included antiepileptics (topiramate, divalproex, valproic acid), beta-blockers (propranolol, timolol), antidepressants (amitriptyline) and onabotulinumtoxinA. Continuous enrollment was required for 12 months pre-index and 6 months post-index. To increase the specificity of migraine prophylactics, patients with prior diagnoses for conditions for which their prescribed prophylactics were also indicated (i.e., epilepsy for antiepileptics, hypertension/congestive heart failure for beta-blockers, and depression for amitriptyline) were excluded. Outcomes of interest were medication adherence (medication possession ratio [MPR]), discontinuation (>30-day gap between prescriptions), and switching patterns. Time to discontinuation of initial prophylactic was described using Kaplan-Meier curves.

Results: 19,881 patients initiated prophylactic treatment with 12,136 (61%), 3,037 (15%), 4,163 (21%), and 545 (3%) patients initiating antiepileptics, beta-blockers, amitriptyline, and onabotulinumtoxinA, respectively. Mean (SD) MPR for any prophylactic was 0.49 (0.31) (0.34 (0.27)—valproic acid to 0.67 (0.22)—onabotulinumtoxinA) with a mean (SD) of 89.2 (56.7) days on treatment over 6 months. Discontinuation rates were high ranging from 74% (topiramate and onabotulinumtoxinA) to 90% (valproic acid). Switching rates ranged from 6% (topiramate) to 20% (valproic acid). Between 46% (topiramate) and 68% (timolol) patients discontinued treatment after the first prescription, and median days to discontinuation of initial treatment ranged from 30 (valproic acid, divalproex, timolol, amitriptyline) to 84 days (onabotulinumtoxinA).
Conclusions: Adherence to migraine prophylactic medications was poor with about 50% of patients discontinuing after their first prescription and over 75% discontinuing within 6 months. The large proportion of patients discontinuing after first prescription suggests further research is needed on reasons for discontinuation and better tolerated therapies.

PND69
HEALTHCARE RESOURCE UTILIZATION ASSOCIATED WITH RESCUE MEDICATION USE IN ADULT PATIENTS WITH SEIZURE CLUSTERS: A RETROSPECTIVE CHART REVIEW

Objective: Seizure clusters, defined as multiple distinct seizures that occur over a 24-hour period, are serious medical events that may progress to prolonged seizures and status epilepticus. In this retrospective chart review, use of rescue medication, associated healthcare resource utilization, and costs of seizure clusters were evaluated.

Methods: An online, retrospective chart review of patients with epilepsy and seizure clusters was conducted among 186 US neurologists. Adults (≥18 years old) who were diagnosed with seizure clusters at least 12 months prior to chart abstraction and who experienced ≥1 cluster within the 12 months prior to the abstraction were eligible. Demographics, comorbidities, and seizure-related medical information including treatments, rescue medication, and resource utilization over a 12-month period were abstracted by the neurologist using a web-based form. Costs were estimated from the literature and converted to 2013 US dollars.

Results: 543 patient charts were collected; the mean patient age was 41 years and 58.7% were male. In this patient sample, 363 patients were utilizers of rescue medication (defined as those who consistently used rescue medication for every seizure cluster) and 180 were under-utilizers (not prescribed or failed to use rescue medication for at least 1 seizure cluster). Utilizers and under-utilizers experienced on average 2.4 and 3.1 seizure clusters, respectively. Compared to utilizers, under-utilizers were more likely to progress to status epilepticus (25.0% vs. 15.4%, p<0.01), visit an emergency department (56.7% vs. 45.2%, p=0.012), and require hospitalization (41.1% vs. 25.6%, p<0.01). Healthcare costs were significantly higher for under-utilizers than for utilizers ($21,790 vs. $13,265, p=0.038).

Conclusion: In this study of adult patients with seizure clusters, under-utilizers of rescue medication had significantly higher seizure-related healthcare resource use and costs compared to utilizers of rescue medications.

PSY27
ADHERENCE TO IRON CHELATION THERAPY AND ASSOCIATED HEALTHCARE RESOURCE UTILIZATION AND COSTS IN MEDICAID PATIENTS WITH THALASSEMIA

Objectives: To compare all-cause and thalassemia-related healthcare resource utilization (RU) and costs in thalassemia patients who are adherent vs. non-adherent to iron chelation therapy (ICT).

Methods: Healthcare claims databases from six state Medicaid programs (Florida, Iowa, Kansas, Mississippi, Missouri, and New Jersey) (1997-2013) were analyzed. Patients with ≥1 thalassemia ICD-9 diagnosis code, ≥2 dispensings for deferoxamine or deferasirox, and ≥6 months of continuous enrollment before first ICT dispensing were included. Adherence was defined as a medication possession ratio ≥0.80. All-cause and thalassemia-related RU and costs were evaluated per-patient-per-month (PPPM) during the treatment period. Adherent and non-adherent patients were compared using adjusted incidence rate ratios (aIRR) for RU, and adjusted cost differences (aCD).

Results: Of the 218 eligible thalassemia patients, 137 (62.8%) were adherent. Baseline demographic and clinical characteristics were similar between adherent and non-adherent patients, although adherent patients were younger (20.9 vs. 25.8 years old, p=0.011). The adjusted rate of thalassemia-related outpatient visits PPPM was higher in adherent patients (aIRR: 1.11, p=0.004). However, adherent patients incurred fewer thalassemia-related hospitalizations (0.80, p=0.002) and ER visits (0.64, p<0.001). PPPM thalassemia-related medical costs followed a similar trend with slightly higher outpatient costs (aCD: $113, p=0.504) and lower total costs (aCD: -$1,922, p=0.056), mainly driven by lower inpatient costs (aCD: -$2,504, p=0.052). Similar results were observed for all-cause RU and medical costs. While all-cause pharmacy costs were higher in adherent patients (aCD: $1,506, p<0.001), non-ICT pharmacy costs were slightly lower (-$234, p=0.200).

Conclusions: This study shows that thalassemia patients adherent to ICT incurred more outpatient visits, which may be related to better disease monitoring and management, potentially resulting in the lower rates of acute care visits and related costs observed in this cohort. Enhanced adherence to ICT may reduce downstream costs associated with acute care, thereby reducing the financial burden of thalassemia from a payer’s perspective.
**Objectives:** Tuberous sclerosis complex (TSC) is a rare genetic disorder associated with angiomyolipoma (non-malignant kidney lesions) in the majority of patients. Angiomyolipoma increase in size over time, present risk of acute hemorrhage, and can lead to progressive chronic kidney disease (CKD). Our objective was to document the association between angiomyolipoma and CKD, including the impact on health care resource utilization (HCRU) and health care costs.

**Methods:** This retrospective, longitudinal cohort study used medical chart data from patients with TSC treated at a specialty center in the Netherlands from January 1990 to April 2012. Patients were followed longitudinally and classified into open cohorts based on their CKD stage (estimated from serum creatinine levels) and size and number of angiomyolipoma. Average glomerular filtration rates (GFR) and the proportions of patients reaching advanced CKD stages were compared with a non-TSC reference population. HCRU rates and health care costs (2012€) per patient per year (PPPY) were compared across cohorts.

**Results:** 369 patients were included (median [mean] follow-up time 15.4 [14.3] years). Compared with the non-TSC reference population, the decline in kidney function with age was steeper for patients with TSC (mean change in GFR/year=-1.53 vs. -0.94 mL/min/1.73 m²), and more patients with TSC reached CKD stage 3 or higher (16% vs. 3% of patients <70 years old). Compared with CKD stage 1, CKD stages 2 to 5 were associated with larger and more numerous angiomyolipoma, higher overall HCRU rates (rate ratios=1.5 to 2.3, P≤0.01), and higher health care costs (incremental costs=€737 to €30,641 PPPY, P≤0.004).

**Conclusions:** Our results suggest that impaired kidney function associated with angiomyolipoma imposes a significant burden and remains a key concern in patients with TSC. Treatments that slow the rate of kidney function decline in patients with TSC may substantially reduce the HCRU and costs associated with CKD and angiomyolipoma.

**Objectives:** Many chronic users of immediate-release opioids (IROs) initiating treatment with extended-release opioids (EROs) are steered towards generic options, even if switching molecules is required. Switching may introduce uncertainty for patients regarding dosing, titration and efficacy. This study assessed treatment patterns among patients chronically treated with IR oxycodone who initiate ERO treatment, and describes differences between patients initiating treatment on the same molecule and those who switch molecules.

**Methods:** Commercially insured patients aged <65 were selected from de-identified OptumHealth Reporting and Insights claims data, 2011-2014. Chronic IR oxycodone users were defined as patients with ≥2 continuous prescriptions and ≥60 days supply leading up to initiation of ERO treatment (index). Patients were excluded if they had claims for EROs during a 6-month baseline period or possible opioid replacement therapy (methadone/buprenorphine) during the 6-month follow-up period, and were required to be continuous users of opioids throughout follow-up. The sample was stratified based on whether ER therapy was initiated on the same molecule (ER oxycodone) or different molecules. Treatment patterns and pill count were assessed for both cohorts.

**Results:** During baseline, 2,318 chronic IR oxycodone users initiating EROs were identified, with 933 (40%) initiating ER oxycodone and the remainder switching molecules. Same-molecule patients were more likely to continuously use index therapy (41.9% vs. 33.6%), and less likely to switch to a different ERO (12.3% vs. 26.0%). Among different-molecule patients switching EROs, nearly half switched to ER oxycodone. Concomitant use of IR oxycodone was observed in both groups, but continuous index ERO users in the same-molecule cohort saw a greater decline in IR pill count compared with the different-molecule cohort (-173.3 vs. -105.9).

**Conclusions:** Chronic IR oxycodone patients initiating EROs on the same molecule were more likely to remain on index treatment, and those remaining on treatment experienced a greater decline in IR oxycodone pill count.
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