Meeting Abstracts

AMCP Managed Care & Specialty Pharmacy
Annual Meeting 2017

Denver, Colorado
March 27-30, 2017
The AMCP Abstracts program provides a forum through which authors can share their insights and outcomes of advanced managed care practice through publication in AMCP’s Journal of Managed Care & Speciality Pharmacy (JMCP). Poster presentations are Tuesday, March 28, from 5:45 pm to 7:30 pm. The posters will also be displayed on Wednesday, March 29, from 11:45 am to 2:45 pm. Podium presentations for the Platinum award-winning abstracts are Wednesday, March 29, from 4:30 pm to 5:45 pm. The reviewed abstracts are published in the JMCP Meeting Abstracts supplement.

The AMCP Managed Care & Speciality Pharmacy Annual Meeting 2017 in Denver, Colorado, is expected to attract more than 3,800 managed care pharmacists and other health care professionals who manage and evaluate drug therapies, develop and manage networks, and work with medical managers and information specialists to improve the care of all individuals enrolled in managed care programs.

Abstracts were submitted in the following categories:

**Research Report:** Describe completed original research on managed care pharmacy services or health care interventions. Examples include (but are not limited to) observational studies using administrative claims, reports of the impact of unique benefit design strategies, and analyses of the effects of innovative administrative or clinical programs.

**Economic Model:** Describe models that predict the effect of various benefit design or clinical decisions on a population. For example, an economic model could be used to predict the budget impact of a new pharmaceutical product on a health care system.

**Solving Problems in Managed Care:** Describe a problem or issue that exists in managed care; the goal for the intervention or practice; and the intervention or best practice implemented to address a specific issue (e.g., introduce a needed change, develop and implement a new system or program, plan and organize an administrative function, or solve other types of problems in managed care settings). Describe what was observed after or when the intervention or best practice was implemented. Provide a general overview of subjective and objective findings and recommendations for future research. Procedures for abstracts in this category are not as rigorous as those for a research report when describing the outcomes of an intervention and do not contain hypothesis testing, thus, they do not have firm conclusions.

**Abstract Review Process**

Twenty-eight reviewers and 3 JMCP editorial reviewers were involved in the abstract review process for the 2017 AMCP Managed Care & Speciality Pharmacy Annual Meeting. Each abstract (with author name and affiliation blinded) was reviewed by reviewers and scored using a 1-5 scale on the following 3 criteria (15 rating scores per abstract) used by JMCP to evaluate manuscripts for publication:

- Relevance
- Originality
- Quality
- Bias
- Clarity

Each of the reviewers also made an independent accept/reject recommendation. The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a JMCP editorial reviewer, who made an accept/reject decision. These decisions were further reviewed by the JMCP editor-in-chief to ensure consistency in decision making. The mean rating scores were used to award Platinum, Gold, Silver, and Bronze medals for the best abstracts submitted. The abstract reviewers for the 2017 Annual Meeting were as follows:

**Reviewers**

- Jennifer W. Baker, PharmD, BCACP, BCPS, VA Tennessee Valley Healthcare System
- Brandon K. Bellows, PharmD, MS, University of Utah Dept. of Pharmacotherapy
- Joseph Couto, PharmD, Cigna Healthcare
- Pooya Desai, PhD, Amgen
- Beckie A. Fennick, PharmD, Cambridge Advisory Group
- Patrick Gleason, PharmD, Prime Therapeutics
- Boris Gorsht, PharmD, GlaxoSmithKline
- Bonnie C. Greenwood, PharmD, BCACP, BCPS, UMass Medical School, Clinical Pharmacy Services
- James Grzegorczyk, RPh, MS, Blue Cross Blue Shield of Michigan
- Tiance Jiao, PhD, L. S. Skaggs Pharmacy Institute, University of Utah
- Shellie Keast, PharmD, PhD, University of Oklahoma College of Pharmacy
- Donald Klepsner, PhD, MBA, University of Nebraska Medical Center College of Pharmacy
- Jeff Lee, PharmD, FCCP, Lipscomb University College of Pharmacy
- Greg Low, RPh, PhD, Massachusetts General Hospital
- Rohan Mahabaleshwarkar, PhD, Carolinas HealthCare System
- Josephine Mauskopf, PhD, Health Economics
- Hemalkumar Mehta, MS, PhD, Department of Surgery, University of Texas Medical Branch
- Arinze Nkemdirim Okere, PharmD, MS, MBA, BCPS, Florida A&M University College of Pharmacy and Pharmaceutical Sciences
- Elan Rubinstein, PharmD, MPH, EB Rubinstein Associates
- Natalia Ruiz-Negrón, PharmD, University of Utah Department of Pharmacotherapy
- Craig S. Stern, PharmD, MBA, Pro Pharma Pharmaceutical Consultants
- Kent Summers, PhD, Astellas Pharmaceuticals
- Andy Szczotka, PharmD, Emdeon
- Patty Taddei-Allen, PharmD, WellDyne
- Alexandra Tungol Lin, PharmD, Blue Cross Blue Shield of Michigan
- Karen Worley, PhD, Humana
- Joanne Wu, MD, MS, University of Southern California

**JMCP Editorial Reviewers**

- Robert P. Navarro, PharmD, University of Florida College of Pharmacy
- Karen L. Rascati, PhD, The University of Texas College of Pharmacy
- Kaen M. Stockl, PharmD, OptumRx

**AMCP Abstracts Program**

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At AbbVie, we build bonds with oncologists, patients, payers, advocacy groups, health authorities, and other pharmaceutical companies, because we know that advancing the science of this devastating disease is not something that one person, or even one company, can do alone.

Together we can conduct research that deepens our understanding of the disease and its pathways, to ultimately develop new molecules that make a transformational improvement in cancer care.

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N4 Refill Gaps and Dose Reductions in Patients with Prostate Cancer and Visceral Metastases Treated with Abiraterone Acetate Plus Prednisone or Enzalutamide

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Medal-Winning Abstracts

Each abstract was assessed by reviewers using a 1-5 scale on the following 5 criteria: relevance, originality, quality, bias, and clarity. These are the same criteria used by JMCP to evaluate manuscripts. The abstract's mean score on the 5 criteria was used to award Platinum, Gold, Silver, and Bronze medals.

**Cynthia L. Gong, PharmD, [C10]** Applying Pharmacoeconomic Modeling to Formulary Decision Making: The Case of Trabectedin

**Manish Mittal, PhD, [Z3]** Effect of Adalimumab Initiation at a Specialty Pharmacy on Adherence, Persistence, and Cost Outcomes Across Autoimmune Diseases

**Yang Qiu, MS, [U49]** Does Consumer Purchasing Data Improve Medication Adherence Predictions for the CMS Star Categories?

**JaeJin An, PhD, [D2]** Economic Evaluation of Patient-Centered Medical Homes Among Long-Term Cancer Survivors in the United States

**Richard A. Brook, MS, MBA, [D3]** U.S. Medical and Pharmacy Director Cancer Concerns

**Laurence M. Djatche, PharmD, [C18]** Evaluating Value-Based Frameworks Used for Relapsed or Refractory Multiple Myeloma Regimens: ICER Report, ASCO Value Framework, and NCCN Evidence Blocks

**Jackie Gladman, BPE, [U6]** How Do Payers Utilize the AMCP eDossier System for Preapproval Information and Could It Qualify as a Safe Harbor?

**Marc A. Hixson, MBA, [K7]** The Impact of Piscanatide on Quality of Life for Patients with Chronic Idiopathic Constipation: Results from Two Phase 3 Clinical Studies

**Nicholas J. Keeling, MS, [Z9]** Preemptive Pharmacogenetic Testing: Exploring the Knowledge and Perspectives of U.S. Payers

**Maryam Khazraee, PharmD, [Z8]** Thinking Outside the Bottle: How a Clinical Pharmacist Team Adds Value and Saves Money in a Managed Care Plan

**Thomas Lodise, PharmD, PhD, [J2]** Medical and Pharmacy Costs associated with the Treatment of Adult Patients with Community-Acquired Pneumonia in the Outpatient Setting

**Donna Mildvan, MD, [J1]** Relationship Between Antibiotic Treatment Failure and 30-Day Mortality in Adult Outpatients with Community-Acquired Pneumonia

**Kathy L. Nguyen, PharmD Candidate, [U32]** Risk of Emergency Department Use and Hospitalization in Patients Without Access to Medications in the United States

**Victor Nguyen, PharmD, [U3]** Relative Versus Absolute Risk Framing in Health Care Decision Making: A Survey of U.S. Payers

**Catherine I. Starner, PharmD, [F2]** Impact of a Managed Care Pharmacist Consultation Program on Controlled Substance Drug Cost, Emergency Room Visits, and Hospitalizations

**Melissa E. Stauffer, PhD, [I1]** Statins Are Differentially Sensitive to the Medication Possession Ratio

**Jennifer Strohecker, PharmD, [Z10]** The Impact of Medication Therapy Management and Text Message Reminders on Medication Adherence and Health Care Utilization in a Disabled Medicaid Population

**Christie Teigland, PhD, MA, [Z13]** Comparing Adherence to Treatment Guidelines after an Opioid Dependence Hospitalization in Medicaid and Commercially Insured Populations

**David L. Veenstra, PharmD, PhD, [I18]** A Cost-Effectiveness Analysis of Patiromer and Spironolactone Therapy in Heart Failure Patients with Hyperkalemia

**Katie Wilbers, PharmD, [R2]** How Pricing Changes and Dose Optimization Affected Compound Pharmaceutical Use in the Missouri Medicaid Population

**Douglas C. Wolf, MD, [K6]** Health Care costs of Patients with Crohn's Disease Receiving Certolizumab Pegol with and Without Home Health Nurse Assistance: Results from a Retrospective Analysis of Patient Claims Data
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Kevin Bowen, MD, MBA, [E10] Total 2014 and 2015 Claims Expense by Drug, Diagnosis, and Procedure Codes: 250,000 Commercially Insured Members with Diabetes Compared with 1,000,000 Matched Members Without Diabetes

Steven M. Brunelli, MD, MSCE, [N1] Economic Burden of Anemia in Patients with Nondialysis-Dependent Chronic Kidney Disease

Chelsey M. Campbell, PharmD, MBA, MS, [U42] Recent Trends in Payer Perception and Use of Value Frameworks in the United States

Huang-Chia Chang, PharmD, [U41] Retrospective Analysis of Pregabalin and Gabapentin Concomitant Utilization in a Medicaid Population

Ilia Ferrusi, PhD, [D1] Health Care Resource Utilization and Costs in Women with Symptomatic Uterine Fibroids: A Cohort Analysis

Vaidyanathan Ganapathy, PhD, [J11] Prescription Fill Patterns After Reaching the Medicare Part D Coverage Gap Among Chronic Obstructive Pulmonary Disease Patients on Maintenance Bronchodilators

Cynthia L. Gong, PharmD, [C24] Daratumumab Compared to Pomalidomide for Refractory Multiple Myeloma: A Cost-Effectiveness Analysis

Svetlana Krasnokutsky Samuels, MD, [E32] Osteoarthritis and Gout: Real-World Evidence Evaluating Patient Characteristics, Treatment Patterns, and Health Care Utilization

Eugene Daniel Kreys, PharmD, PhD, [C25] Medication Adherence and Persistence of Dasatinib and Nilotinib in a National Cohort of Veterans


Sagar Makanji, PharmD, [E1] The Impact of Various Clinical Strategies on Achieving 5 Stars for the MTM Program Completion Rate for CMR Star Rating Measure

Joseph Martinez, RPh, PDE, PPD, [E2] Evaluating Frequency and Cost Impact of Pharmacist Interventions in Phase 3 Clinical Trials for Patients with Suboptimally Controlled Diabetes

Rohan Medhekar, MPharm, [F28] Association between Physician Care Coordination and the Use of Psychotropic Polypharmacy in the Management of Pediatric Mental Disorders

Cathrine Misquitta, PharmD, MBA, BCPS, CGP, FCSHP, [U10] Impact of Motivational Interviewing on Medication Adherence

Breanna Popelar, PharmD, MS, [U38] FDAMA 114 for the Exchange of Health Care Economic Information: Payer Experiences, Attitudes, and Perceptions of Current Legislation and Future Directions

Sujith Ramachandran, PhD, [U45] Impact of Cash Prescriptions and Use of Affiliate Provider Identifiers on Measures of Opioid Use from Multiple Providers

Catherine I. Starner, PharmD, [F7] Prevalence of Concurrent Opioid and Benzodiazepine Use Among 19 Million Commercial Members

Jan Tack, MD, PhD, [K5] Patient-Reported Outcomes with Naldemedine Long-Term Treatment of Opioid-Induced Constipation in Subjects with Chronic Noncancer Pain
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Blessing O. Adodo, PharmD, [E13] Primary Care Physician Perception of the Diabetes Empowerment Education Program Within a Medicare Advantage Plan

Tim Batholow, MD, [M3] Adverse Event Data as Proxy to Determine Total Medical Costs for TNF-Alpha Inhibitors

Seth J. Baum, MD, FASCP, [I8] Time to Approval in Patients Requesting Access to PCSK9i Therapy by Payer Type

Lauren Belemjian, PharmD, [C8] Evaluation of Medications for Malignant Melanoma in Medicare Beneficiaries: A Utilization Review and Cost Analysis

Kevin Bowen, MD, MBA, [E9] Any Statin Use Among Commercially Insured Members with Diabetes Age 40-64 Without History of Atherosclerotic Cardiovascular Disease and Association Between Adherence to Statin Therapy in 2014 and Adverse Cardiovascular Events in 2015

Anand A. Dalal, PhD, MBA, BSPharm, [C4] Treatment Patterns and Costs Associated with Patients with Anaplastic Lymphoma Kinase-Positive Non-Small Cell Lung Cancer Receiving Ceritinib: Analysis of Administrative Claims Data

Steven R. Feldman, MD, PhD, [L4] Treatment Patterns with Systemic Therapy or Phototherapy in Patients with Moderate-to-Severe Psoriasis

Sameer R. Ghate, PhD, [C15] Real-World Economic Outcomes During Time on Treatment Among Patients Who Initiated Pazopanib or Sunitinib as First Targeted Therapy for Advanced Renal Cell Carcinoma: A Retrospective Analysis of Medicare Data

Jerrold Hill, PhD, [I7] Primary Medication Nonadherence inPatients Prescribed Statins, Ezetimibe, or Statin + Ezetimibe Combination Therapy

Leanne L. Lai, PhD, [Z6] Undertreatment of Chronic Interstitial Cystitis in the United States: A Population-Based Study

Jeetvan Patel, PhD, [I23] Impact of Having a Single Preferred Agent with Exclusive Contracts Versus Parity Access for Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors on Cost and Product Uptake in Medicare Plans

Trevor J. Pike, PharmD, [E29] Evaluating Physician Perceived Benefit of Lumacaftor/Ivacaftor in Patients with Cystic Fibrosis

Dominic Pilon, MA, [N4] Refill Gaps and Dose Reductions in Patients with Prostate Cancer and Visceral Metastases Treated with Abiraterone Acetate Plus Prednisone or Enzalutamide

Dominic Pilon, MA, [N5] Potential Drug-Drug Interaction Events in Patients Treated with Abiraterone Acetate Plus Prednisone or Enzalutamide


Francine Snyder, PharmD, [U8] Assessment of Health Care Providers’ Training, Awareness, and Management Practices for Chronic Opioid Therapy


Patty Taddei-Allen, PharmD, [G26] Implementing a Pharmacist-Led Multiple Sclerosis Specialty Pharmacy Clinical Outreach Program

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C10 Applying Pharmacoeconomic Modeling to Formulary Decision Making: The Case of Trabectedin

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1Stanford Health Care; 2Stanford University Medical Center

BACKGROUND: Trabectedin was recently approved for metastatic soft-tissue sarcoma, which is a hard-to-treat disease with few therapeutic options. Cost-effectiveness models are often not developed for formulary decision support.

OBJECTIVE: To determine the cost-effectiveness of trabectedin vs. dacarbazine for metastatic soft tissue sarcoma from an institutional perspective using internal cost and outcomes data, and to apply the results to guide formulary decision-making.

METHODS: Trabectedin was approved for formulary addition in April 2016. Six months later, we developed a Markov model with lifetime horizon to simulate a patient with metastatic soft tissue sarcoma moving between the health states of stable disease, progressed disease, and death. Transition probabilities and quality-of-life utilities were derived from the literature. Costs were based on our institution’s finances and included drug acquisition and administration, lab, nursing, and ancillary support costs. Because of trabectedin’s marginal effectiveness compared to dacarbazine, the model was also run over a shorter time horizon until all patients had either progressed or expired. Discounted total costs, quality-adjusted life years (QALYs), and the incremental cost-effectiveness ratio (ICER) of trabectedin relative to dacarbazine were calculated, and robustness of these estimates assessed through one-way sensitivity analyses. Internal patient outcomes were collected and presented to the oncology specialist prescribing the drug, along with the economic model. Data were then presented to the P&T specialty committee for review.

RESULTS: Dacarbazine dominates trabectedin due to trabectedin’s higher costs and poorer outcomes over a lifetime perspective. Trabectedin remained beyond the threshold of cost-effectiveness based on a US willingness-to-pay of $150,000/QALY even at a shorter time horizon (ICER of $516,656/QALY). At our institution, fewer patients than expected were treated, and their outcomes were significantly worse than those in the clinical trial. Based on the economic model, low utilization, and real-world outcomes, trabectedin was removed from formulary, and a treatment pathway with a set of clinical restrictions for non-formulary use was developed by the primary prescriber.

CONCLUSIONS: Internal cost-effectiveness models in combination with real-world patient outcomes data can be effective formulary management tools.

SPONSORSHIP: None.

U49 Does Consumer Purchasing Data Improve Medication Adherence Predictions for the CMS Star Categories?

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Prime Therapeutics

BACKGROUND: The three drug categories that CMS assesses adherence in comprise approximately 28% of the Part D plan (PDP) sponsor and 11% of the Medicare Advantage (MAPDP) total Star score. When performing adherence predictive modeling, little is known about the additional predictive value of consumer purchasing data to already available pharmacy benefit manager (PBM) member information.

OBJECTIVE: Identify adherence predictors in the three Medicare Star ratings drug categories with and without consumer purchasing data and assess the added value of consumer purchasing data.

METHODS: Adherence was calculated using the CMS proportion of days covered (PDC) method in 2013 and 2014 among 1 million Medicare members for drug categories: diabetes, cholesterol (statins), and hypertension (RAAS antagonists). The 2013 dataset was partitioned into training and validation datasets to fit the best model. The models incorporated 80 potential predictors from each individual’s pharmacy claims, demographic derived from zip code, pharmacy risk group (PRG) severity of illness score, insurance type (MAPDP or PDP), cost share (copay), and enrollment data. The consumer purchasing data consisted of an additional 300 potential predictors. Logistic regression models were developed with and without the consumer purchasing data, to identify significant adherence predictors and to make model accuracy comparisons using the receiver operator curve (ROC) with a range of 0 to 1 where 1 is a perfect prediction.

RESULTS: The predictive models consisted of 166,593 diabetes, 607,374 statin, and 585,656 hypertension members. The predictive models without consumer purchase information found the following independent predictors of future adherence (PDC ≥ 80%): prior year adherence, a 90 day supply claim, generic drug category cost share of $4 or less, PRG score, zip code derived: percent of white, percent of high school graduate and median income; enrollment in a Medicare Advantage plan, not receiving a low income subsidy, younger age, and new enrollment to the plan in the previous year. Consumer purchasing data was matched to 48% of members and resulted in two new predictors: self-reported household income and interest in changing auto insurance policy. The ROC scores with and without consumer purchasing data were: diabetes 0.720 vs. 0.711, cholesterol 0.727 vs. 0.704, and hypertension 0.708 vs. 0.703.

CONCLUSIONS: In this Medicare Star medication adherence categories predictive modeling study, the addition of consumer purchasing data did not substantially change the list of independent predictors or improve the predictive model accuracy.

SPONSORSHIP: Prime Therapeutics.

Z3 Effect of Adalimumab Initiation at a Specialty Pharmacy on Adherence, Persistence, and Cost Outcomes Across Autoimmune Diseases

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BACKGROUND: Patients using specialty pharmacies (SPs) to fill adalimumab (ADA) prescriptions have greater refill adherence than those using retail pharmacies (RPs) [1] suggesting that SPs may offer better medication management. The effect of early fill at SPs compared with RPs on ADA adherence and medical costs has not been studied.

OBJECTIVE: To examine the relationship between initiation of ADA at SPs vs. RPs and outcomes (adherence, persistence, and medical costs) in patients with an indicated autoimmune disease: rheumatoid arthritis, Crohn’s disease, ulcerative colitis, psoriasis, psoriatic arthritis, or ankylosing spondylitis.
METHODS: A longitudinal retrospective cohort study was conducted using OptumInsight database from 1/2008 to 12/2015. Date of first ADA claim was the index date. Patients were included if they were ≥ 18 years with ≥2 claims for an indicated disease and biologic-naïve in the 12 months before the index date. Medical and pharmacy coverage ≥12 months before and after index date was required. Patients were placed into 2 cohorts: SP patients (patients who initiated ADA within 3 months at SP and refilled ADA at SP for 12 months) and RP patients (patients who initiated and refilled ADA at RP for 12 months). SP and RP patients were propensity score matched based on age, sex, Charlson Comorbidity Index, diagnosis, year of ADA initiation, and baseline medical costs and copayment. Outcomes were assessed for 12 months after index date (follow-up). Adherence was analyzed by calculating medication possession ratio (MPR). Persistence was assessed using Kaplan-Meyer analysis of discontinuation rates. Medical, drug, and total costs were calculated.

RESULTS: Data from 2,364 patients (1,182 per cohort) were analyzed. Baseline characteristics were similar between cohorts after matching; mean age was 46 years, 60% were female, 40% had rheumatoid arthritis. Compared with RP patients, SP patients had a significantly greater MPR (71% vs. 60%, P<0.0001) and a lower discontinuation rate (40% vs. 52%) with mean time to discontinuation being 291 vs. 255 days (P<0.0001). Yearly total costs did not differ significantly between cohorts ($43,908 vs. $43,228, P=0.15), whereas medical costs in SP patients were 17% lower ($12,986 vs. $15,641, P<0.0001).

CONCLUSIONS: Patients who initiate ADA at an SP have better treatment adherence and lower medical costs than those who initiate therapy at an RP. Further research is required to understand this relationship better.

SPONSORSHIP: Support for this study were provided by AbbVie.
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A health impact model was developed to compare the one-dose live attenuated HZ vaccine compared to the investigational two-dose HZ/su vaccine. VE assumptions were taken from a study in Kaiser Permanente Northern California (P024) for the one-dose vaccine. VE efficacy (VE) assumptions were taken from a study in Kaiser Permanente Northern California (P024) for the one-dose HZ vaccine. VE assumptions for the investigational vaccine were taken from publications. Data on the investigational vaccine’s first dose efficacy are unavailable; we assumed a VE range of 25%-65% and a constant efficacy duration of one year. Based on adherence rates reported for Hepatitis vaccines in adults, series completion assumptions with the two-dose vaccine varied from 45%-75%. Two different VE waning scenarios were assumed for the one-dose vaccine and the two-dose investigational vaccine: (a) 15 years for both vaccines, (b) 15 years for the one-dose vaccine/20 years for the two-dose investigational vaccine until the efficacy of both vaccines fully wane to zero.

RESULTS: Out of 1,000 vaccinated individuals, the one-dose HZ vaccine prevented five more cases of HZ (34 vs. 29) than the two-dose investigational HZ/su vaccine when both vaccines were assumed to have equal time to loss of efficacy, a two-dose adherence rate of 45% and a first-dose efficacy of 65% for the investigational HZ/su vaccine. Keeping these assumptions constant except changing duration of efficacy for the investigational vaccine to 20 years resulted in the two-dose vaccine preventing two more cases of HZ than the one-dose vaccine (34 vs. 35).

CONCLUSIONS: When series completion rates are 45% for the two-dose investigational HZ/su vaccine, the approved one-dose live attenuated HZ vaccine could prevent more HZ cases over a 15 year period. Given the unknown one-dose efficacy and uncertainty around adherence rates for multi-dose vaccines in real world settings, further analyses are needed to determine overall impact of the two-dose investigational HZ/su vaccine.

SPONSORSHIP: Merck & Co.
Prevalence of Baseline Hepatitis C Virus NS5A Polymorphisms Observed in Molina Health Care Medicaid and Health Insurance Exchange Populations

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BACKGROUND: Elbasvir-grazoprevir is a combination product used for the treatment of hepatitis C virus (HCV) infection. Reduced treatment efficacy has been demonstrated in phase 2 and 3 clinical trials when certain NS5A polymorphisms have been detected with an 11.1% prevalence nationwide. To date, no studies have been published evaluating post-marketing prevalence associated with NS5A polymorphisms. Molina Health Care (“Molina”) is a multi-state managed care organization that focuses on government-funded programs including Medicaid, Health Insurance Exchanges, and Medicare.

OBJECTIVE: To determine the prevalence of NS5A polymorphisms, specifically M28, Q30, L31, and Y93, in Molina Medicaid and Health Insurance Exchange populations that have been diagnosed with hepatitis C infection and to assess if this prevalence is consistent with reported clinical trial data in the literature.

METHODS: This was a retrospective cohort study of Molina Medicaid and Health Insurance Exchange members from ten states diagnosed with HCV genotype 1a infection whose administrative claims data were evaluated during March through November 2016. Members included in the analysis were >18 years of age with documented baseline NS5A testing. Demographic data included the member’s age, gender, and previous treatment exposure. Subsequent analysis included a percent of prevalence of the polymorphisms which was stratified by state, gender, and age.

RESULTS: Of the 28 members enrolled (all GT1 infection, 93% treatment naive, 61% male, mean age 59 years, 36% African American), 27 completed 8 or 12 weeks of DMO use. Most (82%) had <$25,000 annual income; 39% had a current or prior drug abuse history; and 46% had psychiatric comorbidities. Patients were connected to the DMO for 92% of expected days (1,838 cumulative days). Adherence results were as follows: 89% of patients were ≥95% adherent to therapy (1 patient was <90% adherent); mean ingestion adherence (DMO measured) was 94%. Providers used the DMO data for timely adherence counseling in 30% of patients. In this interim analysis, SVR data were available for 10 patients; 9 patients achieved SVR and 1 patient relapsed (documented suboptimal adherence of <90%). In a satisfaction survey, 92% of patients agreed that the DMO was easy to use in their daily routine, and 88% agreed that the DMO helped them understand the importance of taking their medications regularly.

CONCLUSIONS: The DMO provided data to target opportune adherence interventions in patients; high rates of adherence were noted even in patients with risk factors for poor compliance. These early data suggest that the DMO may be a tool to optimize the real-world clinical value of specialty medications.

SPONSORSHIP: The study was sponsored by Proteus Digital Health.

Incidence of Significant Drug Interactions with Direct-Acting Antiviral Hepatitis C Drugs in the Medicaid Population

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BACKGROUND: With the introduction of direct-acting antivirals (DAAs), treatment for Hepatitis C Virus (HCV) infection has changed significantly in the past few years, with patients’ Sustained Virologic Response around 95%. The DAAs are known to have many potential drug interactions (DIs) when co-administered with other drugs. It is important to identify members taking DAAs concurrently with other drugs that can affect the efficacy of HCV therapy.

OBJECTIVE: The primary objective is to determine the incidence of significant DIs with DAAs in patients with HCV in a Medicaid population. The secondary objective is to implement an intervention and evaluate its impact on the incidence of significant DIs with DAAs in a Medicaid population.

METHODS: First, an HCV drug report will be generated targeting members taking DAAs from the time period of November 22, 2013 through

Wirelessly Observed Therapy to Optimize Adherence and Target Interventions for Oral Hepatitis C Treatment

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BACKGROUND: Real-world data on adherence with the new direct-acting agents (DAAs) to treat chronic hepatitis C virus (HCV) are limited, and suboptimal adherence can lead to unnecessary treatment failures. Refill methods to measure adherence are inaccurate and do not allow
through August 31, 2016 to determine the number of DAA utilizers. Subsequently, detailed claims data will be populated with a focus on two interacting agents selected from four drug classes (anticonvulsants, anti-retrovirals, proton pump inhibitors, and HMG-CoA Reductase inhibitors). After populating eight drug-interaction reports, overlapping pharmacy claims will be assessed to further identify affected members, respective health plans, and the year in which claims were paid. An affected member is defined as a patient taking a DAA and an interacting drug at the same time. Next, incidence of affected members within each health plan will be calculated. An intervention will be implemented and evaluated based on its effect on the incidence of affected members in the selected health plans.

RESULTS: From November 22, 2013 through August 31, 2016 there were 2,084 DAA utilizers who were identified. Within the 2,084 utilizers, 342 members (16.6%) had pharmacy claims for DAs and interacting drug agents filled within the specified time period. Furthermore, 135 members (7.4%) were identified to have overlapping DIs with the DAs. The medications that had the highest percentage of affected members are high-dose omeprazole and pantoprazole, followed by efavirenz and azatavir. Six health plans were identified as having a higher incidence of affected members compared to others. The calculated incidence based on overall membership ranged from 0.0002% to 0.58%.

CONCLUSIONS: An initial analysis in determining incidence of DDIs in a Medicaid population shows that although the incidence per health plan is low, there are drug interacting agents that are being continuously filled with DAs.

SPONSORSHIP: Aetna Medicaid Administrators.

B7 Real-World Clinical Outcomes with Newer Hepatitis C Drugs for Patients Receiving Care from a Specialty Pharmacy

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BACKGROUND: Hepatitis C costs have risen dramatically in recent years. New treatments for this non-organ condition were introduced in the U.S. market at exorbitant, orphan-drug prices in the past two years. It is important to examine whether desired clinical outcomes follow this significant price increase. Outside of clinical trials, there has been a gap in real world evidence demonstrating cure rates of new treatments among patients.

OBJECTIVE: To ascertain cure rates of two new treatments—Harvoni and Viekira Pak—among hepatitis C patients.

METHODS: A cohort study was conducted of hepatitis C patients who filled their first prescription on or after Jan 1, 2015 and last prescription on or before Aug 31, 2015 and completed therapy on either of the two drugs. Data included claims based patient-level information from a large, nationally representative pharmacy benefit manager, specialty pharmacy clinical data for 2015, and prescriber survey information collected in 2016. Patients were grouped based on the treatment drug. Patients covered by workers’ compensation insurance or having claims for both drugs were excluded. Sustained virologic response (SVR)—cure rate—as reported by prescriber, was the primary outcome. Overall SVR and matched sample [genotype and severity of illness (cirrhosis/advanced fibrosis/excluding Child-Pugh B or C status)] SVR were computed. Descriptive analyses (t-test for continuous and chi-square test for categorical variables) were used to examine differences between SVR, demographic characteristics and patient out-of-pocket costs in the two groups.

RESULTS: The final study sample consisted of 1,305 patients (Harvoni: 551 and Viekira Pak: 754). Unadjusted SVR was 95.6% (Harvoni: 93.8%, Viekira Pak: 96.8%, P<0.05). Harvoni group had significantly (P<0.05) older patients and greater proportion of men (58.0 years, 70.6% men) compared to Viekira Pak (56.7 years, 63.1% men) and insignificant difference in patient out-of-pocket costs. About 99.0% of both groups of patients were Genotype 1 and had SVR of 95.6%. Matching for severity of illness, Harvoni and Viekira Pak patients had comparable SVR (94.4% for n=90 and 94.1% for n=152, respectively; P=0.9).

CONCLUSIONS: Real world SVR for hepatitis C patients receiving care from specialty pharmacy, on either drug, were very high and consistent with those reported in clinical trials. However, considerable costs of these drugs necessitate continued collaboration between payers, specialty pharmacies, benefit managers and pharmaceutical manufacturers to ensure appropriate use and support patient adherence to care.

SPONSORSHIP: Internally funded by Express Scripts.

B8 Real-World Analysis of Harvoni Therapy Completion Rates and Members Achieving Sustained Virologic Response

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BACKGROUND: Hepatitis C therapy completion is crucial for cure. There is a paucity of data examining how often Hepatitis C laboratory testing data are collected and additionally, the rates of Hepatitis C cure.

OBJECTIVE: To examine the real world Hepatitis C sustained virologic response (SVR) among commercially insured members completing at least 8 weeks of Harvoni therapy.

METHODS: Hepatitis C members receiving specialty pharmacy drug management from November 2014 through February 2016 were eligible for the analysis. Harvoni length of therapy was based on the number of days of Harvoni supply in the member’s claims history. If a member had at least 56 days (8 or more weeks) of therapy, without a 90 or more day gap, they were considered a completer. Hepatitis C SVR laboratory data results obtained voluntarily from the prescriber via a specialty pharmacy request (when available) were merged with member-level Harvoni pharmacy claims data to evaluate SVR “cure rates”. To determine Hepatitis C cure, members were required to have an SVR laboratory test completed between 12 and 24 weeks following Harvoni therapy completion which was calculated by subtracting the Hepatitis C SVR laboratory test date from the last Harvoni claim date plus days supply. A Hepatitis C SVR result of 15 IU per mL or less was considered a Hepatitis C cure.

RESULTS: 969 members received Hepatitis C specialty pharmacy drug management from November 2014 through February 2016. 611 (66.2%) members had SVR laboratory data (test result and date) and 520 (81.1%) of the 641 members used only Harvoni therapy for their Hepatitis C therapy. 514 (98.8%) members completed at least 8 weeks of therapy, of which 311 (60.5%) met the eligibility criteria for Hepatitis C cure assessment defined as the specialty pharmacy having a Hepatitis C SVR laboratory result from the prescriber. 301 (96.8%) of the 311 members had a Hepatitis C SVR value of 15 or less indicating Hepatitis C cure and 10 members had a Hepatitis C SVR greater than 15, indicating active Hepatitis C virus infection.

CONCLUSIONS: The 96.8% Hepatitis C SVR cure rates found in this real world analysis are similar to those reported in clinical trials of 94% to 99%. With one-third of individuals’ Hepatitis C SVR laboratory results not being voluntarily reported to the specialty pharmacy providing care, further assessment is required to identify alternative processes to ensure individuals completing their Hepatitis C virus treatment are cured.

SPONSORSHIP: Prime Therapeutics.
B9 Real-World Experience in Treating Non-Cirrhotic Patients with Genotype 1 Chronic Hepatitis C Using Paritaprevir/Ritonavir, Ombitasvir, and Dasabuvir with or Without Ribavirin: A Prospective Study in a Large Community-Based U.S. Health Care System

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BACKGROUND: Phase 3 registration trials evaluating the safety and efficacy of Paritaprevir/ritonavir, Ombitasvir, and Dasabuvir (PrOD) ± ribavirin (RBV) have shown high efficacy and excellent tolerability. However, when new treatment regimens are widely used in “The Real World”, the safety and efficacy may not be as good as that seen in clinical trials.

OBJECTIVE: The aim of this study was to evaluate the efficacy and tolerability of PrOD prospectively in a real world setting, within Kaiser Permanente Southern California (KPSC), a large U.S. based Health Care Delivery System. Efficacy was determined by a measure of sustained virologic response at post-treatment week 12 (SVR12).

METHODS: N = 200 patients were enrolled at four sites within KPSC. Inclusion criteria: Chronic hepatitis C, genotype 1 (GT1), age ≥ 18, treatment-naïve (TN) or treatment-experienced (TE) with interferon-based therapy. Exclusion criteria were non-GT1 chronic hepatitis C, co-infection with HIV or HBV, prior treatment with direct-acting antiviral agent(s), glomerular filtration rate < 30 mL/minute, hemoglobin < 12 for males and < 11 for females, and/or evidence of cirrhosis and/or hepatocellular carcinoma. Cirrhosis was defined as Metavir score ≥ 3 or Ishak score > 4 on liver biopsy, Fibroscan score > 12.5 KPa, APRI score of > 1.5, clinical evidence of cirrhosis and/or history of hepatic decompensation. Genotype 1a (GT1a) patients were treated with PrOD + weight-based RBV × 12 weeks and Genotype 1b (GT1b) patients were treated with PrOD × 12 weeks.

RESULTS: Of the 200 patients enrolled, 191 have completed enrollment and 9 remain in active follow up. 170 patients have achieved SVR12, with an intention-to treat (ITT) SVR12 rate of 89% (170/191). Of the 21 failures to achieve SVR12, 10 patients completed treatment with an End of Treatment (EOT) response and had a relapse of hepatitis C viral load (HCV VL) during post-treatment follow up, 3 patients with an End of Treatment (EOT) response and had a relapse of hepatitis C viral load (HCV VL) during post-treatment follow up, 3 patients were lost to follow up, and 8 patients discontinued treatment early due to side effects. For those patients that who completed treatment and had post-treatment week 12 HCV VL results available, 94.4% (170/180) achieved SVR12.

CONCLUSIONS: In this prospective study conducted in a “Real World” care delivery setting, treatment of genotype 1 chronic hepatitis C with PrOD±ribavirin was well tolerated and highly effective. Sustained virological response rates have been comparable to those seen in the registration trials. This prospective study in a single care delivery system, supports findings from prior large retrospective studies reported in the “Real World” treatment setting.

SPONSORSHIP: Supported by a grant from AbbVie, paid to institution only.

B10 Outcomes Evaluation of Medicaid Insured Hepatitis C Patients Coinfected with HIV After 8 Weeks of Treatment with Ledipasvir/Sofosbuvir

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BACKGROUND: New hepatitis C virus (HCV) drugs have demonstrated excellent therapeutic results in clinical studies; however, the high costs of the medications have led to significant challenges for Medicaid Managed Care plans. In additional, real world studies to determine the effectiveness of the novel products in HIV/HCV co-infected population have been limited. The German hepatitis C prospective cohort study (GECCO) demonstrated a high HCV cure rate of 96.4% in the cohort of 28 HIV/HCV co-infected patients who were prescribed 8 weeks of Ledipasvir/Sofosbuvir. The results of this study are promising and could lead to shortening the duration of treatment of Ledipasvir/ Sofosbuvir from 12 weeks to 8 weeks in non-cirrhotic, genotype 1 HCV/HIV co-infected patients with HCV Viral Load<6 million.

OBJECTIVE: The objective of this retrospective observational study is to evaluate the effectiveness of shorter duration of treatment with Ledipasvir/Sofosbuvir for 8 weeks for co-infected patients.

METHODS: An observational retrospective evaluation, this study describes the outcomes for those members who received 8 weeks of treatment for HCV using Ledipasvir/Sofosbuvir. The primary endpoint is SVR-12, defined as undetectable HCV viral load 12 weeks post-treatment. Inclusion criteria include all co-infected members who have received HCV treatment with Ledipasvir/Sofosbuvir for 8 weeks.

RESULTS: Of the 29 patients included in the analysis, only 20 were able to be evaluated for treatment success. The majority (70%) were successfully treated and cured while 30% failed treatment. The characteristics of those who were successfully treated were compared to those who did not achieve treatment cure.

CONCLUSIONS: In this study of co-infected patients who received treatment with ledipasvir/sofosbuvir for 8 weeks, the overall success rate was 70%. The results suggest that 8 weeks of treatment for the co-infected population may provide a benefit in those who cannot complete the full 12 weeks. In addition, it highlights the role of polymorphisms in predicting outcomes in the treatment of Hepatitis C. These results warrant further studies of a larger population which includes stratifying for subtype and IL28B to evaluate the use of Ledipasvir/ Sofosbuvir for 8 weeks in select treatment naive, co-infected HCV/HIV patients. If proven effective for the HCV/HIV co-infected population, the shorter treatment course would result in a significant decrease in costs of care for the health care system.

SPONSORSHIP: Amida Care Health Plan.

B11 An Updated Estimate of Chronic Hepatitis C Prevalence in the Managed and FFS Medicaid Population During the Era of Oral Direct-Acting Antivirals

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BACKGROUND: Previous studies have reported chronic hepatitis C (CHC) prevalence as 1% in the overall U.S. population during 2003-2010 and 1.1% in a managed Medicaid population during 2012-2013. Updating HCV prevalence since the advent of oral DAAs in 2013 is important for state Medicaid coverage decisions.

OBJECTIVE: To determine the longitudinal prevalence rate and incidence proportion in 2009-2015, and to describe the demographics, comorbidities, and baseline health care resource utilization of CHC patients in Medicaid.

METHODS: Adults with ≥1 inpatient (IP) or ≥2 outpatient (OP) CHC claims (ICD-9-CM diagnosis codes: V02.62, 070-44, 070-54, 070-70, 070-71) or ≥1 CHC therapy claim in 7/1/2009-6/30/2015 were extracted from MarketScan Medicaid Database, which includes
longitudinal data from 13 fee-for-service and managed Medicaid states and 14 million patients. Patients had continuous enrollment (CE) of ≥12 months before and ≥6 after the CHC diagnosis or treatment date (index date). Total health care utilization and costs (medical and pharmacy) during the 12-month pre-period were reported as 2015 US$. CHC prevalence and incidence proportion were assessed in each year 2009-2015. Prevalence was the proportion of patients in the year with ≥1 CHC diagnosis or treatment. Incidence was the proportion of at-risk patients (no previous evidence of CHC) with ≥1 diagnosis or treatment for CHC in the year. Both measures required CE for the full year of interest.

RESULTS: CHC prevalence ranged from 1.42% in 2009 to 1.69% in 2015 and incidence proportion ranged between 0.56%-0.64%. CHC patients had a mean age of 46.9 years, were primarily female (53%), white (60%), and eligible for Medicaid due to blindness/disability (62%). Common comorbidities were mental health/substance abuse (67%), hypertension (46%), and cardiovascular disease (34%). During the pre-period, 83% of CHC patients used psychotropic medications, 12% statins, and 9% proton pump inhibitors. During pre-period, 30% of patients had an IP admission, 67% had an emergency room visit, and 94% had ≥1 pharmacy claim. Monthly health care costs in the pre-period were $2,200, with medical costs being the largest contributor (62%).

CONCLUSIONS: Prevalence of CHC in the Medicaid population during 2009-2015 was higher than previously reported, suggesting an unmet need for CHC treatment in this population. High prevalence of concomitant conditions, such as substance abuse, highlights the challenges of treating this patient population and the need to evaluate sobriety requirements as potential treatment barriers.

SPONSORSHIP: Research funded by Gilead Sciences.

B13 Budget Impact Analysis of Tenofovir Alafenamide, a Novel Nucleotide Reverse Transcriptase Inhibitor, for the Management of Chronic Hepatitis B in the United States

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BACKGROUND: The lack of curative chronic hepatitis B (CHB) therapy, with consequent chronic antiviral use, poses a substantial unmet medical need in the aging CHB U.S. population and their evolving comorbidities. Therefore, antiviral therapy with excellent potency, high resistance barrier and improved safety profile has been of interest. Tenofovir alafenamide (TAF), recently approved by the FDA, is an efficacious CHB treatment with similar viral suppression and resistance rates, improved ALT level normalization, and improved renal and bone safety profile compared with tenofovir disoproxil fumarate (TDF), as well as better resistance profile compared to entecavir (ETV).

OBJECTIVE: To estimate the projected budget impact of addition of TAF in Commercial, Medicare and Medicaid formulations over three years.

METHODS: A budget impact model generated from cost-effectiveness analyses was developed using DICE simulation. Inputs were drawn from published randomized trials, other peer-reviewed literature, real-world database analyses and expert opinion. Model structure/assumptions/inputs were validated by 5 hepatologists and via a survey of 30 hepatologists. Market scenarios included TAF, branded/generic ETV and TDF. The cost of TAF was set at price parity with TDF. Assumed annual market uptake of TAF was 7.9%, 8.9%, and 5.9% for Commercial, Medicare and Medicaid, respectively, and the plan size was assumed to be 1 million members, with 0.3% HBV prevalence and 2.5% of CHB patients getting treated with antiviral therapy.

RESULTS: Across all payers, the addition of TAF was estimated to be cost-neutral or generate cost savings on the overall budget, beginning in year 1. When compared to current scenario, the change in per member per month (PMPM) cost was negligible with less than 0.01% in the first year across all analyses. Cost savings observed starting in year 2 were driven by lower number of renal, bone and liver complications observed with TAF when compared to alternatives. Differences in rates of liver complications were due to differences in viral suppression and/or ALT normalization rates for TAF versus TDF and/or ETV as derived from the published algorithm from the REVEAL.
study data. Over 3 years, TAF produced incremental budget savings PMPM ranging between $0.0006 to $0.0010. Results were consistent across payers and were robust against sensitivity analyses.

CONCLUSIONS: The formulary addition of TAF may lead to negligible budget impact of up to 0.01% change in spending in year 1, and lead to cost savings of up to -0.12% over 3 years.

SPONSORSHIP: Gilead Sciences.

B20 An Evaluation of Persistence and Adherence in Treatment-Naive Human Immunodeficiency Virus-Infected Patients on Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate Versus Other Recommended Single-Tablet Regimens

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BACKGROUND: The advent of single-tablet regimen (STR) antiretroviral therapy has been associated with increased adherence and persistence in treatment naive human immunodeficiency virus (HIV) infected patients. Efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF) has demonstrated high levels of efficacy and adherence, but has been associated with central nervous system (CNS) symptoms which generally resolve after the first 2-4 weeks of therapy. Assessment of adherence and persistence after an initial period is needed to evaluate the long-term effectiveness of EFV/FTC/TDF in the majority of patients who do not experience CNS symptoms or in whom it resolves. We hypothesize that long-term persistence and adherence with EFV/FTC/TDF would not differ from other recommended STRs.

OBJECTIVE: The goal of this study is to compare long-term persistence and adherence for treatment naive patients initiating EFV/FTC/TDF versus other STRs.

METHODS: This retrospective cohort study used data from the MarketScan EarlyView Commercial Database. Patients were ≥18 years old, HIV treatment-naïve, initiated an index STR between 1 January 2011 and 30 October 2015, and had at least 6 months of continuous enrollment data before and after STR initiation. Adherence and persistence to STR were measured using outpatient pharmacy claims. Patients were considered adherent if the proportion of days covered (PDC) was ≥0.80. Non-persistence was defined as a ≥ 30 day gap without index STR or a prescription claim for a non-index HIV therapy. Adjusted logistic regression and Cox proportional hazard regression were fit to compare adherence and non-persistence, respectively, between EFV/FTC/TDF and the other STRs.

RESULTS: The index STRs included EFV/FTC/TDF (n = 4,733), rilpivirine (RPV)/FTC/TDF (n = 1,367), elvitegravir/cobicistat (EVG/c)/FTC/TDF (n = 1,980) and dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) (n = 422). The mean age was 40 years and 86% were male. At 1-year follow-up the crude persistence rate was 57% for EFV/FTC/TDF compared to 64% for DTG/ABC/3TC. At 3-year follow-up, the crude persistence rate was 30% for EFV/FTC/TDF compared to 31% for EVG/c/FTC/TDF and 33% for RPV/FTC/TDF. No statistically significant differences in overall adherence were observed between EFV/FTC/TDF and the other STRs.

CONCLUSIONS: In a commercially insured population, patients on EFV/FTC/TDF had no significant differences in adherence and similar persistence at 3 years compared to other STRs, demonstrating the long-term utility of EFV/FTC/TDF in the treatment of HIV in a real world setting.

SPONSORSHIP: Bristol-Myers Squibb.

B21 Estimated Cost of HIV Treatment Failure Based on Pill Burden Among HIV-Infected Individuals in the United States

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OBJECTIVE: To evaluate adherence among Medicaid beneficiaries living with human immunodeficiency virus (HIV) who were initiated on selected ARVs.

METHODS: A retrospective cohort study was conducted using Medicaid data from 6 states (IA, KS, MO, MS, NJ, WI) between 09/2012 and 03/2015. Adults diagnosed with HIV-1 and newly initiated on darunavir 800 mg, atazanavir 300 mg, raltegravir 400 mg, elvitegravir 150 mg, or efavirenz 600 mg (initiation date was the index date) after a 6-month washout period were identified. Patients had to have ≥1 claim for ≥2 nucleoside reverse transcriptase inhibitors within 14 days of index date and ≥6 months of continuous eligibility pre-index. Adherence to any ARV, including ARVs. Beyond the 5 selected, was measured using medication possession ratio (MPR) and proportion of days covered (PDC). MPR was evaluated over the exposure to ARV treatment among patients with ≥2 ARV claims. PDC at 6 and 12 months was calculated for patients having ≥6 and ≥12 months of follow-up, respectively. Treatment gaps of ≥30 or ≥60 days were also evaluated. Patients were followed up to the first of Medicaid disenrollment or end of data availability.

RESULTS: A total of 3,477 patients were identified (darunavir 800 mg [N = 580]; atazanavir 300 mg [N = 596]; raltegravir 400 mg [N = 587]; elvitegravir 150 mg [N = 664]; efavirenz 600 mg [N = 1,101]). Mean age was 44.9 years (standard deviation [SD] = 10.9), 55.7% were black, 59.1% were men, and 73.5% were naïve to any ARV during the 6 months pre-index. Mean (SD) follow-up period was 12.9 (7.8) months and patients had 14.2 (14.2) claims for any ARV on average. Among evaluable patients, mean (SD) MPR was 0.78 (0.26), 61.0% had MPR ≥80%, and 40.8% had MPR ≥95%. Mean (SD) PDC at 6 months was 0.71 (0.27), 48.9% had PDC ≥80%, and 30.0% had PDC ≥95%, for PDC at 12 months, these values were 0.78 (0.31), 33.9%, and 17.2%, respectively. 41.0% had ≥1 gap in ARV treatment of ≥30 days, and 30.8% had ≥1 gap of ≥60 days.

CONCLUSIONS: Results suggested suboptimal adherence to ARVs. Among Medicaid beneficiaries living with HIV as indicated by low MPR and PDC, and high proportions of patients with treatment gaps. Regimens that can facilitate adherence and have a low risk of developing drug resistance should be considered for these patients.

SPONSORSHIP: Janssen Scientific Affairs.
BACKGROUND: Combination antiretroviral therapy has dramatically improved morbidity and mortality for persons living with HIV. However, sustained virologic control depends on a number of factors including patient adherence. Although data suggest that patients receiving low-pill-burden regimens will have improved short-term adherence levels and reduced downstream costs associated with both loss of virologic control and therapy switching, the long-term effects are unknown.

OBJECTIVE: To estimate the long-term medical expenditures associated with loss of HIV viral control by varying degrees of pill burden and treatment adherence.

METHODS: A closed cohort Markov model was developed with parameters derived from the existing literature for treatment naive HIV+ patients who were followed for fifty years. In the model, patients were considered to have switched therapy following two consecutive months of virologic failure. The model assessed the impact of single tablet regimens (STRs), two-pill, and three-pill regimens on non-treatment medical expenditures and treatment switching. The effect of pill burden and adherence on the outcomes of interest was explored while holding individual components of the regimen constant.

RESULTS: At 5 years, STRs generate an estimated $21.7 million in medical cost savings compared to 3-pill regimens, with savings increasing to $54.7 million and $95.5 million after 10 and 25 years, respectively. Additionally, patients receiving an STR were more likely to maintain virologic suppression compared with patients who received either a 2- or 3-pill regimen. Consequently, patients on STRs progress to higher lines of therapy more slowly (56% of patients have switched therapy at least once after 5 years, compared with 66% of patients on 3-pill regimens). Patients on STRs are also less likely to have switched therapy compared to patients on 3-pill regimens after 10 years (82% versus 89%), but by 25 years, the proportion who have switched is similar (99% versus 100%). Two-pill regimens also generate some medical expenditure savings relative to three-pill regimens ($2.1 million after 10 years and $3.4 million after 25 years). However, STRs generate substantial savings compared to two-pill regimens ($52.6 million after 10 years).

CONCLUSIONS: These findings demonstrate the value of lower pill burden in maintaining viral suppression and reducing medical expenditures. Streamlining regimens, even from 3 to 2 pills, is beneficial, but the most substantial clinical and economic benefits are estimated to occur when patients are prescribed STRs.

SPONSORSHIP: This analysis was sponsored by ViV Health Care.

C2 Clinical and Economic Impact of Hypersensitivity Reactions in Patients Receiving First-Line Chemotherapy for Metastatic NSCLC

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BACKGROUND: Drug hypersensitivity is defined as an immune-mediated response to a drug agent in a sensitized patient (pt) that is inappropriate or excessive. Hypersensitivity reactions (HSRs) account for 5-10% of all adverse events. Although HSRS to chemotherapy drugs are rare, they could impose a substantial clinical and economic burden if they do occur.

OBJECTIVE: The objectives of this study are to examine frequency, clinical burden and economic burden of HSRS in pts with stage IV NSCLC on first-line (1L) chemotherapy.

METHODS: This retrospective cohort study used Truven Health MarketScan databases to identify adult pts on 1L chemotherapy (index date) during January 1, 2012-June 30, 2015. Patients were required to have ≥1 claim with a secondary malignant neoplasm (ICD-9-CM 196.XX-198.XX), ≥2 claims with a lung cancer diagnosis (ICD-9-CM 163.XX), and be continuously enrolled in their health plans for ≥6 months prior and 3 months following the index date. To be identified as an HSR, >1 code specific to HSR (963.1X, 995.X, 999.81, 999.82) or >2 ICD-9-CM codes describing clinical manifestations of an HSR (dermatologic, respiratory, or cardiovascular) were required, or if >2 doses of Benadryl or >1 dose of epinephrine were given on the day of chemotherapy. Outcomes examined were median time to first HSR, percent of patients who modified treatment immediately following an HSR, severity of HSR (mild/moderate=requiring outpatient care, severe=requiring ER visit or inpatient admission), health care utilization and costs associated with a HSR.

RESULTS: 12,772 pts met the inclusion criteria as metastatic NSCLC pts initiating 1L chemotherapy. Of these, 666 (5.2%) were identified as having an HSR. In total, 1,269 HSR events were identified, as some pts experienced multiple HSRs. Median time to first HSR was 22 days and 58% of pts modified their treatment regimen following an HSR. Severe HSRs occurred in 11% of pts and for pts who were admitted into the hospital, average length of stay was 6.6 days. Of the 1,269 HSR events, 94% were treated in the outpatient setting. Mean costs associated with an HSR were $6,118, $4,874, and $28,993 in the outpatient, ER and inpatient settings, respectively. Mean costs associated with medications to treat an HSR were $1,037, $989 and $3,847 in the outpatient, ER and inpatient settings, respectively.

CONCLUSIONS: HSRs impose significant clinical burden to the patient, potentially leading to changes to pts’ chemotherapy regimens and hospitalizations for severe HSRs. Moreover, HSRs are associated with substantial economic burden which varies by setting of care.

SPONSORSHIP: Celgene.

C3 Economic Analysis of Molecular Mutation Testing in Real-World Practice Using Claims Data: Costs of Single Gene Versus Panel Tests in Patients with Lung Cancer

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BACKGROUND: In lung cancer, BRAF mutation, as well as other driver mutations, can be detected by single gene tests (e.g., reverse transcription polymerase chain reaction [RT-PCR]) and panel tests (e.g., next-generation sequencing [NGS]). No information exists in the literature on the costs of genetic testing from a payer perspective for patients with BRAF mutated lung cancer.

OBJECTIVE: To assess time to BRAF testing, compare characteristics between patients tested versus not tested for BRAF mutation, and describe amount reimbursed for BRAF tests, as well as the total cost for BRAF testing following a sequential versus an NGS approach.

METHODS: Patients with lung cancer diagnosed after January 1, 2013, were identified from two U.S. administrative claims databases. Patient characteristics were assessed during the 12 months preceding the first lung cancer diagnosis (index date). Molecular tests were analyzed from index date to end of continuous health plan enrollment or end of data availability (12/2015), whichever occurred first, based on combinations of CPT procedure codes recorded within 7 days. Time to BRAF mutation test was assessed using Kaplan-Meier analysis. Costs were analyzed from a payer’s perspective; thus, claims with no amount reimbursed ($0) were excluded.

SPONSORSHIP: Novartis.
RESULTS: A total of 28,011 patients newly diagnosed with lung cancer were identified. Among them, 1,260 (4.5%) were tested for BRAF, at 6 and 12 months following index date, 3.2%, and 4.2% were tested. Compared to non-tested patients, tested patients were younger (58.3 vs. 65.3 years old, P < 0.001), had a lower Charlson Comorbidity Index (2.8 vs. 2.9, P = 0.005), and a higher proportion had metastases (70.9% vs. 43.4%, P < 0.001). In 76.0% of the cases, BRAF was tested along with KRAS mutation. Other procedure codes commonly billed with BRAF mutation included microdissection and molecular pathology procedure (level 5). BRAF was tested using NGS test in 6.6% of cases. Depending on the combination of procedure codes, average reimbursed amounts for the 10 most common combinations ranged from $207 to $2,074. When considering costs for each test individually, sequential testing that comprised KRAS, EGFR, ALK, ROS1, and BRAF mutation tests was estimated at $3,763 ($464, $696, $1,070, $1,127, and $406, respectively) while NGS testing was estimated at $2,860.

CONCLUSIONS: Amounts reimbursed for BRAF mutation tests highly vary based on the combination of procedures. Findings suggest that NGS testing is associated with cost savings compared to sequential testing of individual mutations.

SPONSORSHIP: This study was sponsored by Novartis Pharmaceuticals.

C5 Comorbidities in Patients with Extensive Disease Small Cell Lung Cancer

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BACKGROUND: Small cell lung cancer (SCLC) has the poorest prognosis of all lung cancers owing in part to the rapid growth rate and early distant metastatic disease. Despite well-defined treatment guidelines, patients with extensive diseases (ED)-SCLC tend to be older with deteriorating functional status and increased comorbidities that can affect the course of disease and treatment decisions. The prevalence and incidence of comorbidities in patients with ED-SCLC are not well characterized, but require careful attention during disease management to avoid unreasonable exposure to risk.

OBJECTIVE: To describe the incidence and prevalence of comorbidities over time among patients with ED-SCLC.

METHODS: This study used Surveillance, Epidemiology, and End Results data linked to Medicare claims data between 1/1/2006 and 12/31/2013. Patients aged ≥66 years with a first, primary, microscopically confirmed ED-SCLC diagnosis between 1/1/2007 and 12/31/2011 were included. The incidence and prevalence of 34 identified comorbid conditions were estimated at the time of diagnosis, 3 and 12 months (mo) post diagnosis, and upon initiation of first-line (1L) and second-line (2L) therapy.

RESULTS: A total of 5,498 patients met inclusion criteria. At least 1 of 34 conditions was present in 82% (4,530/5,498) at diagnosis, 91% (2,735/3,014) at 1L initiation, and 92% (1,069/1,163) at 2L initiation. Several acute comorbidities were more common in patients initiating 2L chemotherapy than in all patients at diagnosis: infectious disease (57% vs. 43%), electrolyte disorder (50% vs. 22%), anemia (49% vs. 19%), neutropenia (17% vs. 0.1%), thrombocytopenia (12% vs. 2%), and diarrhea (7% vs. 3%). Differences for non-acute conditions were in chronic obstructive pulmonary disease (67% vs. 49%), thromboembolism (9% vs. 2%), and depression (11% vs. 7%). Prevalences of all other conditions were comparable in patients at diagnosis and at 2L initiation. In general, 12-mo incidence rates were lower than 3-mo incidence rates.

CONCLUSIONS: Patients with ED-SCLC routinely presented with comorbid conditions at diagnosis and at the time of initiating 1L and 2L chemotherapy. The lower incidence rates at 3 mo compared with 12 mo are likely to be related to the thorough physical evaluation and workup around diagnosis. However, the prevalence differences for acute conditions are likely to be related to ED-SCLC and the common therapy-associated toxicities (e.g., neutropenia), emphasizing the high unmet need in this population and the importance of monitoring comorbid conditions when making treatment decisions.

SPONSORSHIP: Funding provided by Bristol-Myers Squibb.
C6 Economic Impact of Immunotherapy Choice in the Treatment of All-Comer Metastatic Non-Small Cell Lung Cancer

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BACKGROUND: Immune checkpoint inhibitors represent important options for metastatic non-small cell lung cancer (mNSCLC) patients. Atezolizumab (ATEZo) and nivolumab (NIVO) have demonstrated significant improvements in survival and tolerability compared to docetaxel in mNSCLC patients who progress after platinum-containing chemotherapy and regardless of their PD-L1 status. Given increasing pressure for cost containment, initiatives to change payment and delivery models for oncology care have been explored recently.

OBJECTIVE: This study examines differential costs when ATEZO and NIVO are the treatments (Tx) of choice, to understand their fiscal impact at a societal level.

METHODS: A comparative cost framework was developed in MS Excel from the societal perspective. This model calculated costs per course of ATEZO or NIVO, assuming Tx until progression or loss of clinical benefit. Pembrolizumab was excluded due to FDA approved indication in mNSCLC patients whose tumors express PD-L1 (TPS ≥ 1%) only. Base case Tx duration reflects the mean 10.34 cycles of ATEZO from OAK, the pivotal, randomized phase III trial. NIVO Tx reflects the same time period to allow conservative cost comparison. Calculations also include administration, infusion time (ATEZO: Q3W, 60 min initial, 30 min subsequent; NIVO: Q2W, 60 min), and management of select all-cause Grade 3/4 adverse events (AEs). All-cause AE rates were derived from clinical trials. Costs reflect 2016 Medicare reimbursement, wholesale acquisition costs (WACs) for base case analysis, and average sales price (ASP) for secondary analysis.

RESULTS: In the base case, ATEZO costs are $90,720 vs. $96,028 for NIVO over equivalent time. Per patient, average costs to manage AEs are $179 for ATEZO vs. $572 for NIVO. Tx administration costs are $1,410 and $2,114 for ATEZO and NIVO, respectively. Patients have 5.2 fewer visits and 9.84 fewer infusion hours for ATEZO. The total difference in costs over a course of care is $5,308 per Pt. ATEZO remains cost saving when ASP is assumed ($3,501 less). Assuming 50% of second-line (2L) mNSCLC patient (approx. 21,450) are treated with immunotherapies per year, this difference of approximately 7% translates to over $114 million in potential savings to the U.S. healthcare system.

CONCLUSIONS: Immunotherapies are valuable Tx options in mNSCLC. This analysis suggests ATEZO may be less costly among cancer immunotherapies in 2L mNSCLC, with time savings for patients (fewer office visits, less infusion time). Additional research is required to characterize real world utilization and outcomes of immunotherapies.

SPONSORSHIP: ARIAD Pharmaceuticals.

C7 Indirect Naïve Comparison of Anaplastic Lymphoma Kinase Inhibitors for Non-Small Cell Lung Cancer with Anaplastic Lymphoma Kinase Gene Rearrangement After Crizotinib Failure

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BACKGROUND: Approximately 5% of patients who are diagnosed with non-small-cell lung cancer (NSCLC) have anaplastic lymphoma kinase gene (ALK) rearrangement (ALK+NSCLC). Lack of comparators in pivotal trials of ALK inhibitors after crizotinib failure impedes comparison in the second-line setting.

OBJECTIVE: To explore results for the investigational ALK inhibitor brigatinib and the available agents alectinib and ceritinib in ALK+NSCLC (post-crizotinib), an indirect naïve comparison was performed.

METHODS: Patient characteristics and study outcomes for pivotal alectinib (NP28761 [NCT01871805], NP28673 [NCT01801111]), brigatinib (phase 1/2 [NCT01499461], ALTA [NCT02094573]), and ceritinib (ASCEND-1 [NCT01283516], ASCEND-2 [NCT01685060]) trials were gathered from a systematic literature review, alectinib prescribing information, and brigatinib data on file (for 180 mg once daily with 7-day lead-in at 90 mg). Independent review committee assessments were used where possible.

RESULTS: Trials were multicenter and open label. Median age and disease stage were similar among trials at baseline, while performance status and presence of CNS metastases differed slightly. For brigatinib, objective response rates (ORRs) were 76% (19/25; 95% CI, 55%-91%) in the phase 1/2 trial and 53% (58/110; 43%-62%) in ALTA. ORRs for alectinib and ceritinib were: 52% (35/67; 40%-65%), NP28761, 51% (62/122; 42%-60%), NP28673; 56% (92/163; 49%-64%), ASCEND-1; and 36% (50/140; 28%-44%), ASCEND-2. Median progression-free survival was numerically higher in brigatinib trials (16.3 mo [95% CI, 9.2-not reached], phase 1/2; 15.6 mo [11.0-not reached], ALTA) vs. other trials (8.1 mo [6.2-12.6], NP28761; 8.9 mo [5.6-12.8], NP28673; 6.9 mo [5.6-8.7], ASCEND-1; 7.2 mo [5.4-9.0], ASCEND-2). 95% CIs did not overlap between brigatinib and ceritinib trials. Adverse event-related dose reductions were most frequent with ceritinib (46%-62%; 62% includes crizotinib-naive patients) vs. brigatinib (19%-20%) and alectinib (23% in the pooled safety population).

CONCLUSIONS: Based on a naïve comparison, brigatinib may have a favorable efficacy and acceptable safety profile compared with available therapies, and ceritinib may require dose reductions most frequently. Further work would be needed to assess the magnitude and direction of potential bias.

SPONSORSHIP: ARIAD Pharmaceuticals.

C8 Evaluation of Medications for Malignant Melanoma in Medicare Beneficiaries: A Utilization Review and Cost Analysis

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BACKGROUND: Malignant melanoma, one of the most immunogenic types of solid tumors, is the most dangerous form of skin cancer due to the genetic links and high risk of metastasis. In the United States in 2016, an estimated 76,380 people were diagnosed with melanoma, with 10,130 mortalities. However, melanoma can be treated with immunotherapy or targeted therapy if genetic testing shows a BRAF gene mutation.

OBJECTIVE: To evaluate the resource use of Medicare Part B and Part D in Medicare beneficiaries receiving oral and injectable medications for malignant melanoma using the Centers for Medicare and Medicaid Services (CMS) claims data for 2013 and 2014.

METHODS: Medicare beneficiaries who underwent treatment for malignant melanoma between calendar years 2013 and 2014 were included in this study. Medicare Provider Utilization Payment Data were utilized including Part D Prescriber Public Use Files (PUF), Medicare Physician and Other Supplier Data, and Medicare Outpatient Prospective Payment System (OPPS) Means Files. Medications were identified by drug name and Health Care Common Procedure Coding System (HCPCS) code sets. Oral medications included Melkin, Taliun, and Zelboral. Injectable medications included Sylatron and Yervoy.
RESULTS: Total Medicare spend on oral and injectable medications for malignant melanoma in the study population was $224 M in 2013 and increased to $301 M in 2014. While the largest portion of drug spend was under Medicare Part B, Part D spend accounted for $51 M (22.9%) and $124 M (29.9%) of the treatment options in 2013 and 2014, respectively. In the study population, Medicare Part B spend was comprised exclusively of Yervoy, totaling $69 M in 2013 and $86 M in 2014 in the provider office setting and $103 M and $124 M in the hospital outpatient setting. Markedly, Yervoy accounted for $2.9 M (1.60%) of the total Medicare Part D spend in 2013 and $3.8 M (1.73%) in 2014.

CONCLUSIONS: The study findings suggest a notable difference in utilization of Yervoy and resource distribution between Medicare Part B and Part D benefit programs. Total Medicare spend on Yervoy was primarily in the hospital outpatient setting in both 2013 (58.8%) and 2014 (58.1%). Yervoy accounted for 1.29% of all Medicare spend on malignant melanoma medications in 2013 and 1.25% in 2014.

SPONSORSHIP: This study was conducted without funding.

C9 Economic Burden of Patients with Advanced Melanoma in the United States: Comparisons by Insurance Types and Geographic Regions

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BACKGROUND: There is little information on the variation in health care costs among patients with advanced melanoma on commercial and Medicare-supplemental insurance types and in different geographic regions in the United States of America (USA).

OBJECTIVE: To evaluate the economic burden of patients with advanced melanoma in the USA by comparisons between commercial and Medicare-supplemental insurance types, and geographic regions.

METHODS: Patients ≥18 years old with a diagnosis of stage III/IV melanoma who initiated a cancer therapy (index date) were identified from the MarketScan Commercial and Medicare databases (1/1/2011-8/31/2015). Patients were grouped into cohorts stratified by insurance type and by geographic region. Patient demographic and clinical characteristics were evaluated at baseline (12 months). All-cause and melanoma-related health care costs were measured as per patient per month (PPPM, 2015 dollars) at baseline and follow-up (up to two years) and compared across the cohorts.

RESULTS: Of the study population (N=2,671) with advanced melanoma, 85.3% had stage IV melanoma, 52.7% (mean ± SD age: 68.6 ± 9.1 years) had Medicare insurance. Among the overall population, 13.4% resided in South, 22.5% in North Central, 19.3% in West, and 17.8% in Northeast regions. The mean ± SD all-cause total health care cost (PPPM) at follow-up was greater among commercially-insured patients than among those with Medicare insurance ($54,778 ± $48,358) vs. $39,306 ± $42,853, P<0.001, with cost for outpatient medical services ($45,271 ± $48,649) vs. $33,413 ± $42,927, P<0.001) being the greatest contributor. Also, the mean ± SD melanoma-related total health care cost (PPPM) at follow-up was greater among commercially-insured patients than among those with Medicare insurance ($44,758 ± $46,941) vs. $31,788 ± $41,128, P<0.001. The mean ± SD all-cause total health care cost difference (PPPM) between baseline and follow-up was the most among patients in the Northeast ($33,093 ± $59,191), followed by those in the North Central ($41,450 ± $44,233), West ($41,174 ± $43,389), and South ($37,849 ± $42,178, P<0.001) regions.

CONCLUSIONS: The health care economic burden of patients with advanced melanoma is substantial and differs by insurance types and geographic regions, with commercial payers and the Northeast region of the USA having the highest burden.

SPONSORSHIP: This abstract was sponsored by Bristol-Myers Squibb.

C11 Progression-Free Survival with First-Line Endocrine-Based Therapies Among Postmenopausal Women with HR+/HER2- Metastatic Breast Cancer: A Network Meta-Analysis

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BACKGROUND: Although numerous emerging and currently available endocrine-based therapies (ETs) for postmenopausal women with newly diagnosed hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) advanced breast cancer (ABC) exist, their comparative efficacy has not been well-studied.

OBJECTIVE: To synthesize the available evidence on progression-free survival (PFS) with ETs as first-line treatments for postmenopausal HR+/HER2- ABC using a mixed treatment comparison (MTC).

METHODS: A systematic literature review was conducted to identify randomized clinical trials of ETs for HR+/HER2- ABC. Pairwise hazard ratios (HRs) and 95% credible intervals (CrIs) comparing regimens were obtained via a Bayesian MTC model. The probability that each treatment was the most efficacious was estimated. Subgroup MTCs were conducted among late progressors (patients with disease free interval ≥12 months from the completion of [neo]adjuvant therapy) and among de novo patients to explore comparative efficacy in more homogeneous settings.

RESULTS: A total of 5 trials and 5 regimens (palbociclib + an aromatase inhibitor [PAL+AI], ribociclib + AI [RIB+AI], fulvestrant 250 mg + AI [FUL+AI], fulvestrant 500 mg [FUL], and AI) were eligible. PAL+AI, RIB+AI, FUL+AI, and FUL had significantly longer PFS vs. AI (95% CrI upper bound ≤1). PAL+AI and RIB+AI both had 31% and 30% reduced hazard of progression or death vs. FUL+AI and FUL (95% CrI upper bound ≤1), respectively. No other significant differences in PFS between treatments were found. The probability of being the most efficacious of these treatments was 51% for RIB+AI and 49% for PAL+AI. Subgroup analysis among late progressors included 2 trials and 3 regimens (PAL+AI, RIB+AI, AI, and FUL+AI). RIB+AI had a 4% reduced hazard of progression or death vs. PAL+AI, although this reduction was not statistically significant. Three trials and 4 regimens (PAL+AI, RIB+AI, FUL, AI) were included in the de novo analysis; PAL+AI and RIB+AI had a 29% and 40% reduced hazard of progression or death vs. FUL, respectively, although these reductions were not statistically significant. In both subgroup analyses, all eligible therapies had significantly longer PFS as compared to AI.

CONCLUSIONS: These analyses consistently found that postmenopausal women with HR+/HER2- ABC receiving PAL+AI, RIB+AI, FUL+AI, or FUL as first line treatment had longer PFS than those who received AI alone.

SPONSORSHIP: Novartis Pharmaceuticals.
C12  Budget Impact Analysis of the PARP Inhibitor Rucaparib in the Third-Line Treatment of Patients with Deleterious BRCA Mutation-Associated Advanced Ovarian Cancer in the United States

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BACKGROUND: Rucaparib is a PARP inhibitor recently approved in the U.S. for monotherapy treatment of patients with deleterious BRCA-mutated advanced ovarian cancer (AOC) who have been treated with two or more chemotherapies. Patients are selected for therapy using an FDA-approved tumor tissue based companion diagnostic assay that detects both somatic and germline BRCA mutations, allowing identification of a larger number of patients who could benefit from treatment with a PARP inhibitor as compared to a test that detects germline BRCA mutations only.

OBJECTIVE: To estimate the budget impact of adding rucaparib to a U.S. health plan formulary for the third-line (3L) treatment of patients with AOC inclusive of both germline and somatic BRCA mutations.

METHODS: An Excel-based analytical model was developed to estimate the incremental budget impact on a hypothetical health plan with one million covered lives over a 3-year horizon. The model compared the difference in annual total cost of treatment with and without the availability of rucaparib. Other treatment options were olaparib, bevazuzamab plus chemotherapy, composite of other chemotherapy regimens, and best supportive care (BSC). The size of the eligible patient population was estimated using an incidence-based approach. Modeled costs included those associated with drug acquisition, IV drug administration, BRCA mutation and laboratory testing, and medical management of adverse reactions (ARs). Patients were assumed to receive BSC after 3L therapy to focus the model on the impact of 3L treatment. Dosing schedules, duration of treatment, and AR rates are obtained from publications referenced in NCCN Guidelines.

RESULTS: The model estimated that a plan of one million members (combined 75% commercial and 25% Medicare) would include 26 patients in the target population (AOC and 3L therapy). Average total health expenditures were estimated to be $3,789,425 with rucaparib available versus $3,739,381 without rucaparib, implying an incremental budget impact of $50,044 or $0.0042 PMPM averaged over years 1-3. The incremental budget impact is smaller in commercial plans and larger in Medicare plans due to higher incidence of ovarian cancer in the over 65 year old population. Sensitivity analyses showed that results were most sensitive to the number of patients treated with rucaparib.

CONCLUSIONS: Under current model assumptions, adding rucaparib for the 3L treatment of patients with BRCA-mutated AOC would result in minimal budget impact to a U.S. health plan regardless of insurance type.

SPONSORSHIP: Clovis Oncology.

C14  The Number Needed to Treat to Achieve 1 Additional Patient with Metastatic Castration-Resistant Prostate Cancer Free of Clinical Event: Comparison of Enzalutamide and Bicalutamide in the TERRAIN Trial

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BACKGROUND: Enzalutamide (ENZ), a second-generation androgen receptor inhibitor, is approved for use in metastatic castration-resistant prostate cancer (mCRPC) and has shown significant survival benefits over placebo in two Phase 3 trials. Bicalutamide (BIC), a first-generation androgen receptor inhibitor, is used in clinical practice for the treatment of mCRPC. In the Phase 2 TERRAIN trial (NCT01288911), a head-to-head comparison of ENZ with BIC, ENZ demonstrated superiority over BIC in progression-free survival (PFS) (i.e., free of progression or all-cause death), radiographic PFS (rPFS), and freedom from prostate-specific antigen (PSA) progression.

OBJECTIVE: The objective of this analysis was to estimate the number needed to treat (NNT), comparing ENZ with BIC, to achieve one additional mCRPC patient with PFS or rPFS, or freedom from PSA progression at 1 year and 2 years.

METHODS: The 1-year and 2-year rates of PFS, rPFS, and freedom from PSA progression in ENZ-treated and BIC-treated mCRPC patients were obtained from the TERRAIN trial results. The NNT was calculated as the reciprocal of the event-rate difference between ENZ and BIC at 1 year or 2 years. The NNT value indicates the number of patients that need to be treated to achieve one additional patient in PFS, rPFS, or freedom from PSA progression comparing ENZ with BIC, with a lower value indicating a greater clinical benefit. The 95% confidence interval (CI) of the NNT was derived based on 95% CI of the event-rate difference.

RESULTS: The NNTs to achieve one additional patient with a PFS outcome, comparing ENZ with BIC at 1 year and 2 years, were 4.3 (95% CI: 2.9, 8.0) and 3.7 (95% CI: 2.6, 6.7), respectively. This indicates that, on average, treating 4.3 patients with ENZ, compared with BIC, would result in one additional patient free of progression or death at the end of 1 year; on average, treating 3.7 patients with ENZ, compared with BIC, would result in one additional patient free of progression or death at the end of 2 years. With respect to rPFS, the 1-year and 2-year NNTs comparing ENZ with BIC were 10.0 (95% CI: 4.4, not reported) and 2.8 (95% CI: 1.9, 3.5), respectively. The 1-year and 2-year NNTs comparing ENZ with BIC to achieve one additional patient with freedom from PSA progression were 2.1 (95% CI: 1.7, 2.9) and 3.2 (95% CI: 2.2, 5.9), respectively.

CONCLUSIONS: The use of ENZ compared with BIC in men with mCRPC leads to more patients with improved clinical outcomes (PFS, rPFS, and freedom from PSA progression). These NNT results should be considered during the management of mCRPC.

SPONSORSHIP: Astellas Pharma; Medivation (Pfizer).

C15  Real-World Economic Outcomes During Time on Treatment Among Patients Who Initiated Pazopanib or Sunitinib as First Targeted Therapy for Advanced Renal Cell Carcinoma: A Retrospective Analysis of Medicare Data

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BACKGROUND: Pazopanib and sunitinib are commonly used first-line targeted therapies (TTs) for aRCC. There is limited real-world evidence on the comparative economic benefits of TTs.

OBJECTIVE: Assess all-cause health care resource use (HRU) and costs during time on first TT among aRCC patients who initiated pazopanib or sunitinib.

SPONSORSHIP: Astellas Pharma; Medivation (Pfizer).
METHODS: Patients aged ≥65 with aRCC (RCC [ICD-9-CM codes: 189.0x, 189.1x] and secondary neoplasm [ICD-9-CM codes: 196.xx-199.xx]) who initiated pazopanib or sunitinib as first TT (index date) were identified from the 100% Medicare data + Part D linkage (1/1/2006-12/31/2014). Characteristics were assessed during the 1 year prior to the index date (baseline period). Patients were followed until first treatment discontinuation (>90 day gap in prescription supply), end of eligibility, end of data, or death, whichever occurred earliest. Patients were stratified by first TT and matched 1:1 using propensity scores based on age, sex, race, year of RCC diagnosis, metastatic sites, and baseline comorbidities and costs. All-cause HRU and costs (2015 USD) were identified using claims incurred during time on first TT and assessed on a per patient per month (PPPM) basis. Outcomes were compared between the matched cohorts using generalized linear models.

RESULTS: Before matching, the cohorts were generally similar in baseline characteristics; however, the pazopanib cohort (N = 526) was associated with higher outpatient visits and costs and lower pharmacy costs than the sunitinib cohort (N = 1,185; all P < 0.05). After matching, all baseline characteristics, including median time on treatment (4.8 vs. 4.1 months, P = 0.169), were balanced (N = 522 for both). First TT with pazopanib was associated with significantly lower total health care costs ($8,527 vs. 10,924, mean difference [MD]: $2,397, P < 0.01), total pharmacy costs ($4,536 vs. $5,043, MD: $506, P < 0.01), total medical costs ($3,991 vs. $5,881, MD: $1,890, P < 0.01), inpatient costs ($2,040 vs. $3,731, MD: $1,692, P < 0.01), inpatient admissions (0.18 vs. 0.29, MD: 0.11, P < 0.01), 30 day inpatient readmissions (0.03 vs. 0.06, MD: 0.03, P < 0.05), and inpatient days (1.1 vs. 1.9, MD: 0.8, P < 0.01) while on treatment compared with the sunitinib cohort.

CONCLUSIONS: In this retrospective analysis of Medicare patients with aRCC, first TT with pazopanib compared to sunitinib was associated with significantly lower all-cause total health care costs, total pharmacy costs, total medical costs, and health care resource use while on treatment, including lower inpatient admissions, readmissions, and shorter length of stay.

SPONSORSHIP: None.

C18 Evaluating Value-Based Frameworks Used for Relapsed or Refractory Multiple Myeloma Regimens: ICER Report, ASCO Value Framework, and NCCN Evidence Blocks

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BACKGROUND: With the continuous rise in costs for oncology drugs, the Institute for Clinical and Economic Review (ICER), the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have developed value-based frameworks (VBFs) to assist stakeholders in formulary and treatment decision-making. While emerging VBFs have the potential to significantly impact therapeutic options for patients, it is important to understand the differences associated with those VBFs within a therapeutic area.

OBJECTIVE: To compare ICER, ASCO, and NCCN VBFs across three therapeutic options for relapsed or refractory multiple myeloma (RRMM).

METHODS: The values of carfilzomib (CFZ), elotuzumab (ELO), and ixazomib (IX) were generated using ICER, ASCO, and NCCN VBFs. Those regimens, used for second or third line treatment of RRMM, were chosen because they share a common comparator in clinical trials, lenalidomide + dexamethasone (LEN + DEX). The ICER 2016 report of treatment options for RRMM was used to obtain results of the comparative clinical effectiveness and the cost effectiveness analysis for those regimens compared to LEN + DEX. ASCO’s 2016 VBF, which incorporates clinical benefit, toxicity and bonus points was used to generate a net health benefit (NHB) score without a scale along with the drug wholesale acquisition cost (WAC) for each regimen compared to LEN + DEX. The NCCN VBF uses a score ranging from 1 to 5, with 1 as the least favorable and 5 as the most favorable, for each of five evidence blocks: efficacy, safety, quality, consistency, and affordability. The 2016 Multiple Myeloma NCCN evidence blocks was used to obtain the value of CFZ, ELO, and IX.

RESULTS: The ICER VBF suggested with moderate certainty that CFZ, ELO, and IX provide a better NHB in patients with RRMM compared to LEN + DEX. Second-line and third-line treatment costs per QALY for CFZ, ELO, and IX were $199,982, $427,607 and $433,794, and $238,560, $481,244, and $484,582, respectively. The ASCO VBF generated a total NHB of 28.8, 23.7 and 23.0 with a monthly WAC of $17,364, $16,032 and $20,607 for CFZ, ELO, and IX, respectively. The monthly cost of LEN + DEX was $11,616. The NCCN VBF had an efficacy score of 5, 3, and 4 for CFZ, ELO, IX, respectively. Safety, quality, consistency, and affordability scores of 3, 4, 4, and 1, respectively, were the same across regimens.

CONCLUSIONS: ICER, ASCO and NCCN VBFs suggest CFZ may be the most valued treatment out of the three regimens. However, their applicability in stakeholder’s decision-making remains unclear due to uncertainty and challenges associated with them.

SPONSORSHIP: None.

C19 Hospitalization for Patients Treated with Inotuzumab Ozogamicin Versus Standard of Care for Relapsed/Refractory Acute Lymphoblastic Leukemia in a Global Phase 3 Randomized Controlled Trial

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BACKGROUND: Inotuzumab Ozogamicin (InO), an anti-CD22 antibody-calicheamicin conjugate, has demonstrated superior clinical activity including clinically meaningful improvement in overall survival, high rate of complete remission, favorable patient-reported outcomes (PRO), and generally manageable safety profile versus standard of care (SOC; intensive chemotherapy) for relapsed/refractory (R/R) acute lymphoblastic leukemia (ALL) in the phase 3 INO-VATE trial. InO has a weekly one-hour infusion schedule over 3-4 week cycle with maximum of 6 cycles.

OBJECTIVE: This analysis aims to determine the impact of InO treatment on patients’ frequency of hospitalization and total hospitalization days per patient in the INO-VATE trial.

METHODS: Patients who received study treatment were included in the analyses. The total number of days hospitalized on study for each patient was calculated. Hospitalization days prior to randomization and those after the end of treatment were excluded. Due to different durations of treatment for InO and SOC (median 8.9 weeks vs. 0.9 weeks), results were reported for the cycle 1 treatment period (randomization to end of cycle 1) and for the entire treatment period (all cycles-randomization to end of treatment period).

RESULTS: A total of 307 patients were available for the analyses. 164 patients received InO and 143 received SOC. Baseline clinical characteristics were comparable between the arms. The percentage of patients requiring hospitalization was lower for InO compared to SOC (76% vs. 94% for cycle 1 and 83% vs. 94% for all cycles). The median
number of hospitalization days was shorter for patients in the InO arm compared to the SOC arm (12 days vs. 26 days for cycle 1 and 17 days vs. 28 days for all cycles). Similar results were seen with mean number of hospitalization days (15 days vs. 25 days for cycle 1 and 26 days vs. 29 days for all cycles).

**CONCLUSIONS:** Treatment with InO for R/R ALL appears to be associated with lower hospital utilization despite longer duration of treatment compared to SOC. Contributing factors likely include high remission rates with limited toxicity, which reduced the need for inpatient management of disease and adverse events, and convenient one-hour weekly dosing schedule that does not require hospitalization. These may also contribute to the better patient reported outcomes, with patients being more ambulatory and reporting significantly less negative impact on their daily lives. Lower hospital utilization is expected to result in favorable budget impact on a health care system.

**SPONSORSHIP:** Pfizer.

### C21 Health and Economic Outcomes in Patients with Newly Diagnosed Multiple Myeloma Treated with RVd Versus CyBord: A U.S. Claims-Based Analysis

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**BACKGROUND:** RVd (lenalidomide, bortezomib, and dexamethasone) and CyBord (cyclophosphamide, bortezomib, and dexamethasone) are 2 common treatment (Tx) options for patients (pts) with newly diagnosed multiple myeloma (NDMM) ineligible for stem cell transplantation (SCT). However, limited data are available on real-world evidence comparing health outcomes and costs in pts who received RVd vs. CyBord for NDMM.

**OBJECTIVE:** In this analysis, duration of Tx (DOT), time to next Tx (TTNT), and health care costs (HC) were evaluated in pts who received first-line (1L) RVd vs. CyBord for NDMM.

**METHODS:** Data from the Truven MarketScan Commercial and Encounters Database (Medicare Supplemental) from January 2008 to May 2015 were evaluated. Pts with NDMM who had ≥ 2 claims of MM diagnosis (ICD-9-CM: 203.0x) ≥ 30-days apart, 12-months (mos) pre- and 3-mos post-index data, and had ≥ 1 full cycle of RVd or CyBord as their 1L Tx (defined as index date) were included. Pts had to be continuously enrolled in the health plan for ≥ 12 mos pre- and post-index, with no evidence of MM diagnosis and MM Tx during pre-index, or SCT during entire study period. DOT was measured as the number of mos between the index date and Tx discontinuation or end of the study period. TTNT was defined as the time from index date to the start of the second-line therapy (addition of a new Tx > 60 days from index, or Tx restart following a > 180 day Tx gap unless the restart was maintenance therapy) and was determined using Kaplan-Meier and Cox proportional hazard models. Adjusted differences (Δ) in HC, measured over 12-mos follow up, were calculated from generalized linear regression models.

**RESULTS:** A total of 464 pts received Tx (RVd: 318; CyBord: 146). Overall baseline characteristics were similar with the exception that comorbidity burden was higher in the CyBord vs. RVd group (mean CCI, 5.2 vs. 4.5; Δ = 0.0215). RVd-treated pts had significantly longer median time on 1L therapy during the study period vs. CyBord-treated pts (14.8 vs. 9.0 mos; Δ = 0.0001). Median TTNT was significantly longer for RVd- vs. CyBord-treated pts (35.7 vs. 22.3 mos, hazard ratio = 0.61; P = 0.0007). RVd-treated pts had significantly higher adjusted pharmacy costs (Δ = $56,494; P < 0.0001) but significantly lower adjusted costs for outpatient and MM & IV chemotherapy-related visits (Δ = $11,378, P = 0.0283; -14,161, P = 0.002, respectively) vs. CyBord-treated pts. No statistically significant difference was observed in total HC over 12 months between the two groups (Δ = $18,422; P = 0.109).

**CONCLUSIONS:** RVd was associated with significantly longer DOT and TTNT than CyBord. Total health care costs between RVd and CyBord were comparable over a 12-month period.

**SPONSORSHIP:** Celgene.
under half of CLL patients receiving first-line oral ibrutinib experienced interruption in ibrutinib therapy. The mean highest number of consecutive days, 40.2% had a gap of 1-7 days, and 12% had no gaps in ibrutinib therapy. 48% of patients had a gap in ibrutinib therapy of ≥ 8 consecutive days has been shown to be related to disease progression events in CLL patients enrolled in a clinical trial.

**OBJECTIVE:** Examine real-world treatment patterns including gaps in therapy and characteristics of CLL patients receiving ibrutinib

**METHODS:** Newly diagnosed CLL patients between November 2013 and December 2014 with at least 1 claim for ibrutinib were identified from MarketScan Commercial Claims and Medicare Supplemental databases. Inclusion criteria were ≥ 18 years of age with continuous enrollment for a minimum of 6 months before and at least 30 days after the index date (i.e., first prescription for ibrutinib). Patients had variable follow-up until either the end of continuous enrollment or the end of the study period. Patient demographics, baseline clinical characteristics, treatment patterns including the total number of days without therapy on hand (gap days) and the total number of consecutive gap days were summarized.

**RESULTS:** CLL patients identified for inclusion in this study (n = 401) had a mean age of 68 years; 65% were male. Over 58% of patients had Medicare insurance; the remainder were commercially insured. The mean National Cancer Institute comorbidity index score at baseline was 0.8. On average, patients were followed for 234 days. In 95.5% of patients, ibrutinib was received as a single agent; ibrutinib was used in combination with rituximab in 4.2%; with ofatumumab in 0.2% and with chlorambucil in 0.2% of patients. Median duration of ibrutinib therapy was 194 days (mean 209; range 33-498). Patients with at least 2 prescriptions for ibrutinib (n = 356) were included in the analysis of gap days. The mean number of total cumulative days off therapy was 24. Forty-eight percent of patients had a gap in ibrutinib therapy of ≥ 8 consecutive days, 40.2% had a gap of 1-7 days, and 12% had no gaps in ibrutinib therapy. The mean highest number of consecutive days off therapy was 16.

**CONCLUSIONS:** Results of this real-world analysis suggest that just under half of CLL patients receiving first-line oral ibrutinib experienced a treatment gap of ≥ 8 consecutive days. Further research is needed to understand the impact that interruptions in ibrutinib therapy have on patient outcomes.

**SPONSORSHIP:** Teva Branded Pharmaceutical Products R & D.

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**C22** Characteristics and Treatment Patterns of Patients Receiving Oral Ibrutinib Therapy for Treatment of Chronic Lymphocytic Leukemia

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**BACKGROUND:** Ibrutinib is an oral therapy for patients with chronic lymphocytic leukemia (CLL). Despite oral therapy being an effective route of administration, studies have shown that nonadherence to treatment occurs. Ibrutinib’s efficacy relies on maintaining the recommended dose. Interruption in ibrutinib treatment of ≥ 8 consecutive days has been shown to be related to disease progression events in CLL patients enrolled in a clinical trial.

**OBJECTIVE:** To describe the setting, duration, and costs associated with induction therapy (tx) and consolidation cycles in the U.S. clinical practice for patients (pts) newly diagnosed with AML who are candidates for standard chemotherapy.

**METHODS:** Adult pts newly diagnosed with AML who received standard (induction) chemotherapy in an inpatient (IP) setting were identified from a U.S. administrative claims database (2006-2015). Pts were observed from induction tx start (index date) to the first event among an HSCT, death, end of health plan enrollment/data, or 180 days after discharge date of the induction episode (observation period). Induction tx and consolidation cycles were identified using DRG codes for chemotherapy with acute leukemia or procedure codes for AML chemotherapy. AML tx episode setting and duration, and costs (USD2015, payers’ perspective) were analyzed.

**RESULTS:** 459 pts (mean age = 54 years; 47% female) were observed. During the 6 months before index date, 16% of pts had MDS, 10% had a non-hematologic malignancy (mainly breast, skin, and lung), and mean Charlson Comorbidity Index score was 1.9. During the observation period, 134 (29%) pts had initial induction and subsequent re-induction tx during the same induction episode; 33 (7%) pts had another re-induction episode. The median duration of IP episodes for pts with 1 cycle of induction tx was 28 days, mean costs were $122,412, and mean costs per day were $4,412. The median duration of OP episodes for pts with induction and re-induction tx (2 cycles) was 47 days, mean costs were $200,430, and mean costs per day were $4,296. Following the induction episode, 20% (64%) pts had ≥ 1 consolidation cycle. 183 (40%) ≥ 2, 117 (25%) ≥ 3, and 60 (13%) ≥ 4. 75% of consolidation cycles were in an IP setting, and 25% in an outpatient (OP) setting. In the IP setting for consolidation, the median duration per cycle was 6 days, mean costs were $28,137, and mean costs per day were $3,823. In the OP setting, the median duration per cycle was 4 days of tx over 5 days, mean costs were $11,271, and mean costs per day of tx were $2,419.

**CONCLUSIONS:** This is the first exploratory study reporting the most recent tx patterns and costs of AML management. While granular information on the type of tx administered is not available in claims data, these findings suggest that, for commercially insured pts newly diagnosed with AML, there is substantial heterogeneity in the consolidation tx setting and costs of AML.

**SPONSORSHIP:** Novartis.

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**C24** Daratumumab Compared to Pomalidomide for Refractory Multiple Myeloma: A Cost-Effectiveness Analysis

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**BACKGROUND:** Options for relapsed/refractory multiple myeloma have been limited. Recently, the FDA approved several new drugs for this population, including daratumumab, elotuzumab, pomalidomide, carfilzomib, panobinostat, and ixazomib.

**OBJECTIVE:** To determine the cost-effectiveness of daratumumab compared to pomalidomide for the treatment of multiple myeloma in patients refractory to both lenalidomide and bortezomib.

**METHODS:** Based on clinical trial data, we developed a Markov model for patients to transition between stable disease, progressed disease, and death. We derived transition probabilities, costs, and utility values from the literature. We calculated the discounted total costs, quality-adjusted life years (QALYs), incremental cost-effectiveness ratios (ICERs) and net monetary benefits (NMBs) of daratumumab relative to pomalidomide, and we assessed the sensitivity of these estimates through a series of one-way sensitivity analyses and a probabilistic sensitivity analysis.
RESULTS: Relative to pomalidomide, and at the current average U.S. willingness-to-pay estimate of $150,000 per QALY gained, dasatinib is approximately cost-effective with a base case ICER of $150,122 per QALY. The ICER remains relatively robust to changes in the parameter values in one-way sensitivity analyses, with results most sensitive to overall survival of dasatinumab and costs of post-progression therapy. Probabilistic sensitivity analyses suggest that dasatinumab is cost-effective more than 50% of the time at a willingness-to-pay threshold of $170,000. Dasatinumab also has higher net monetary benefits at willingness-to-pay thresholds of $150,000 or greater compared to pomalidomide.

CONCLUSIONS: Dasatinumab monotherapy may be a cost-effective option for patients with refractory multiple myeloma compared to pomalidomide.

SPONSORSHIP: None.

C26 Budget Impact Analysis of Treating Patients with Chronic Lymphocytic Leukemia and Rituximab-Refractory Indolent B-Cell Non-Hodgkin Lymphoma with Bendamustine Hydrochloride in the United States

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BACKGROUND: Chronic lymphocytic leukemia (CLL) is a subtype of B-cell non-Hodgkin lymphoma (NHL), and one of the most common leukemias in U.S. adults, with an estimated 18,960 new cases in 2016. Indolent B-cell NHL (iNHL) makes up 30% of all NHL cases in the U.S., with an estimated 72,580 new cases in 2016. Bendamustine hydrochloride is indicated for CLL first-line and iNHL refractory to rituximab. It has been reformulated (2016) with a reduced infusion time of 10 minutes (bendamustine rapid infusion) as compared with 30-60 minutes (bendamustine 30/60) for formulations launched in 2008 and 2014.

OBJECTIVE: Estimate the budget impact associated with the introduction of bendamustine rapid infusion for the treatment of patients with first-line CLL and second-line iNHL from U.S. payer perspectives.

METHODS: A budget impact model was developed to estimate the changes in drug, administration, and adverse event costs associated with projected increases in the market share of bendamustine rapid infusion (80% from bendamustine 30/60 in year 1, 90% in year 2, and 95% in year 3) for a 1-million-member health plan. Ibrutinib was projected to take 5% market share from bendamustine 30/60 in year 1, 8% in year 2, and 11% in year 3. The model included two populations and different competitors, reflecting the approved indications for bendamustine. Total budget impact was calculated annually in years 1, 2, and 3, as well as for the difference in per-member per-month (PMPM) cost between scenarios (with and without bendamustine rapid infusion); one-way sensitivity analyses were conducted.

RESULTS: For CLL, inclusion of bendamustine rapid infusion was associated with total costs decreasing by $10,566 (PMPM = $0.0009), $10,829 (PMPM = $0.0009), and $10,174 (PMPM = $0.0008) in years 1, 2, and 3, respectively. For iNHL, inclusion of bendamustine rapid infusion was associated with total costs decreasing by $8,336, $8,554, and $8,006 in years 1, 2, and 3, respectively (each PMPM = $0.0007). Across both indications, the cumulative 3-year total cost changed from $20,609,358 to $20,552,894, a budget impact of -$56,464. The model was most sensitive to changes in the annual drug cost for bendamustine 30/60 and bendamustine rapid infusion in both indications.

CONCLUSIONS: The average total budget impact of bendamustine rapid infusion over 3 years was -$18,800 and the average PMPM impact was -$0.0016. This decreasing budget impact over time is due to bendamustine rapid infusion’s slightly lower drug and administration costs compared with bendamustine 30/60.

SPONSORSHIP: Teva Branded Pharmaceuticals R & D.

C27 Cost Impact of Elotuzumab in Second-Line+ Versus Third-Line+ Relapsed-Refractory Multiple Myeloma in a Commercial Health Plan

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BACKGROUND: Multiple myeloma (MM) is a rare hematologic malignancy with an expected 30,330 new cases and 12,650 deaths in the United States in 2016. Several new triplet regimens have been...
approved by the Food and Drug Administration for treatment of relapsed-refractory (RR) MM, including the monoclonal antibody elotuzumab (EMPLIDT) in combination with lenalidomide (REVLIMID) and dexamethasone (d)–ERd. Based on the current NCCN guidelines, triplet regimens have become the standard of care in RRMM.

**OBJECTIVE:** This analysis examined the estimated cost impact of utilizing ERd in RRMM as a second-line plus (+) therapy compared to limiting ERd to third-line+ therapy over a 1-year time horizon from a U.S. commercial health care payer perspective.

**METHODS:** An Excel-based treatment cost model was developed. Treatment regimens included ERd, carfilzomib (KYPROLIS) + Rd, ixazomib (NINLARO) + Rd, daratumumab (DARZALEX) + Rd, and daratumumab+bortezomib (VELCADE) and d in RRMM patients. The size of the annually treated patient population was estimated for a hypothetical 1-million member commercial health plan using MM incidence rate data from the National Cancer Institute Surveillance, Epidemiology, and End Results Program. Estimates of the proportion of MM patients by line of therapy were based on a retrospective health care claims analysis. Shifts in market shares of treatment regimens were used to compare a scenario where ERd is utilized second-line+ vs. limited to third-line+. Dosing for the regimens over a 12-month treatment period was based on published clinical trials and package inserts. Drug costs for an average-sized patient (74.5 kg, 1.91 m²) were based on wholesale acquisition costs from Red Book. Administration costs by Current Procedural Terminology code were obtained from the Centers for Medicare & Medicaid Services Physician Fee Schedule. The incremental cost impact of using ERd second-line+ vs. third-line+ was estimated in terms of total cost, cost per-treated-patient-per-month (PTPPM), and cost per-member-per-month (PMPM).

**RESULTS:** The model estimated 10 second-line and 5 third-line MM patients initiating treatment annually in a 1-million member commercial health plan. Utilizing ERd second-line+, as compared to limiting use to third-line+, would cost an incremental $10,628 over a 1-year period. This amounts to a cost of $89 PTPPM and $0.001 PMPM.

**CONCLUSIONS:** Allowing RRMM patients second-line access to ERd would likely have a negligible cost impact on a commercial health plan due to the comparable cost per month of the alternative novel RRMM triplet regimens.

**SPONSORSHIP:** Research funded by Bristol-Myers Squibb.

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**D2**

**Health Care Resource Utilization and Costs in Women with Symptomatic Uterine Fibroids: A Cohort Analysis**

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**BACKGROUND:** Current data on the impact of uterine fibroids (UFs) on health care resource utilization (HCRU) and costs are lacking. Understanding the impact of UFs on HCRU in women with symptomatic UFs is important as contemporary treatment patterns shift towards uterine-sparing modalities.

**OBJECTIVE:** To assess all-cause and UF-related HCRU and costs in women with symptomatic UFs.

**METHODS:** This retrospective cohort study compared outcomes between women with symptomatic UFs to women without UFs. Women with symptomatic UFs were identified with ≥1 medical claim for UFs (I) in the primary position or (2) in the secondary position with UF symptoms in the primary position from 1/1/2008 to 9/30/2014. The comparison cohort had no UF diagnoses. All women were premenopausal, aged 18-50 years and had ≥12 months of continuous enrollment pre- and post-index. The index date was the date of first symptomatic UFs claim or a proximal medical or pharmacy claim for women without UFs. The cohorts were matched 1:1 on key baseline characteristics. All-cause HCRU and total, medical, and pharmacy costs were adjusted for region, race/ethnicity, pre-index HCRU or costs, and UF-related comorbidities and compared using generalized estimating equations. Unadjusted UF-related HCRU and costs were described for women with symptomatic UFs only.

**RESULTS:** After matching, 5,308 women (2,654 per cohort) were included. Median age was 43 years. Significant differences between cohorts were observed for post-index adjusted all-cause HCRU, and by encounter type (P < 0.0001 for all). The adjusted mean (95% confidence interval [CI]) all-cause HCRU visits was 11.71 (10.29-13.32) vs. 8.58 (7.52-9.78) for women with and without UF's (P < 0.0001), respectively. Among women with symptomatic UFs having an inpatient admission(s) or outpatient visit(s), 64.0% or 97.1%, respectively, had a UF-related claim of the same encounter type. The post-index mean (SD) of UF-related HCRU visits was 2.50 (2.29). Significant differences between cohorts were observed for post-index adjusted all-cause total medical costs (95% CI): $7,115 ($5,734-$8,828) vs. $2,177 ($1,740-$2,724) for women with and without symptomatic UF's (P < 0.0001), respectively. Unadjusted UF-related costs accounted for 37.3% of total all-cause medical costs.

**CONCLUSIONS:** All-cause HCRU and total medical costs were significantly greater for women with symptomatic UF's compared to women without UFs. This emphasizes the significant impact of symptomatic UFs on women and health care systems under contemporary treatment approaches.

**SPONSORSHIP:** Allergan, conducted as part of the Allergan-Humana research collaboration.

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**D1**

**Health Care Resource Utilization, Costs, and Health Care Utilization Among Long-Term Cancer Survivors in the United States**

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**BACKGROUND:** Cancer survivors require long-term follow-up care after active cancer treatment and systematic planning for secondary cancer prevention and surveillance. Patient-centered medical homes (PCMHs) may improve outcomes for cancer survivors, however, currently little evidence exists.

**OBJECTIVE:** To evaluate the association between PCMHs and total medical expenditures and health care utilizations among long-term cancer survivors in a nationally representative U.S. sample.

**METHODS:** Using the 2008-2012 longitudinal files from the Medical Expenditure Panel Survey data, adult cancer patients who survived ≥3 years and had a usual care provider were identified. Patients with all PCMH features at baseline year (received comprehensive care, patient-centered care, and accessible care) were categorized as the PCMH group, which was compared with patients without PCMH features. Total medical expenditures as well as office visit, hospitalization, emergency department (ED), and pharmacy related expenditures and utilizations were determined during one year of follow-up. A propensity score methodology was used to balance baseline characteristics between the PCMH and non-PCMH groups. Generalized linear models for the cost analysis, and negative binomial models or logistic regressions were used for the utilization analysis. All analyses considered sampling strata and weights in survey design.

**RESULTS:** A total of 4,288 cancer survivors were identified representing 106 million U.S. population. The mean (SE) age was 65.7 (0.4) years and mean (SE) survival years from the cancer diagnosis was 12.4 (0.3) years. Approximately 43.5% of the patients were categorized as...
the PCMH group at baseline. The crude mean (SE) total expenditures were similar between the PCMH and non-PCMH groups at baseline and follow-up [$11,587 ($903) vs. $11,455 ($434) for PCMH and non-PCMH respectively (P = 0.896) at baseline; $11,728 ($854) vs. $13,883 ($968) for PCMH and non-PCMH respectively (P = 0.092) during follow-up]. Applying propensity score weights, the PCMH was associated with a reduction in health care expenditures ($2,238, P = 0.024). The odds of being admitted to the hospital (odds ratio (95% CI) = 0.82 (0.67, 0.99)) and the number of ED visits were lower in the PCMH group compared to the non-PCMH group (P = 0.049). However, the number of office visits, prescription fills, and related expenditures were similar between the two groups.

CONCLUSIONS: The PCMH features were associated with lower health care expenditures among long-term cancer survivors mainly due to reduction of hospitalizations and ED visits.

SPONSORSHIP: No outside funding supported this study.

D3 U.S. Medical and Pharmacy Director Cancer Concerns

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The JeSTARx Group and National Payor Roundtable

BACKGROUND: Cancer is costly, managed by a variety of treatments that include traditional and robotic surgery, radiation, chemotherapy, and immunotherapy. Diagnostic tests have guided clinicians towards more effective treatments. Treatments are shifting from chemotherapy with limited effectiveness and multiple side-effects to effective targeted immunotherapies with fewer side-effects, multiple treatment pathways/guidelines with indications alone and in combination, and receiving fast-track approvals.

OBJECTIVE: To determine the types of cancers most concerning to U.S. managed care plans.

METHODS: Survey invitations were sent to 210 medical and pharmacy directors (MDs+PDs) of U.S. health plans, insurers, and pharmacy benefit managers. The online interactive survey topics included: advisor+plan information; Ranking (highest = 12-to-1 = lowest) of cancer-types, Copays, benefit-design; and top concerns today and in 5 years from budgetary and medical points of view.

RESULTS: The survey received 61 responses (29%) and 54% of respondents were MDs. Most worked for a health plan (83.6%) and 39.6% of the plans were local, 35.4% national, and 25.0% regional. Most plans cover multiple member types and 91.3% of plans always covered commercial lives, 89.1% Medicaid, 91.3% Medicare MA-PDP and 76.1% Medicare PDP-only lives. Average ranking (out of 12): Breast Cancer = 10.6; Lung Cancer = 10.0; Colon and Rectal Cancer = 9.1; Prostate Cancer = 7.9; Melanoma = 7.5; Leukemia = 7.2; Non-Hodgkins Lymphoma = 6.5; Pancreatic Cancer = 5.2; Kidney Cancer = 4.7; Endometrial Cancer = 3.8; Bladder Cancer = 3.6; Thyroid Cancer = 2.7. In open-ended questions, cancer/ontology was consistently reported the top concern from medical (38.9% today, 51% in 5 years) and budgetary (52% today, 71.1% in 5 years) points of view. Oncology was the 2nd highest ranked Specialty-Pharmacy (SP) condition with 64.3% of plans always managing under the medical-benefit, 5.4% always under the pharmacy-benefit. SP copays are decreasing in fixed (2015 = 15.8%; 2017 = 13.0%) and percentage-based (2015 = 42.1%; 2017 = 37.0%), the rest varied by group and benefit-design. Respondents were concerned about increasing costs of diagnostics, infused/oral treatments and comorbid conditions as survival increases and cancer shifts to a chronic condition. Plans liked pharmacy benefit management for oral therapies.

CONCLUSIONS: The environment for cancer treatment is changing. The shifts towards targeted immunotherapies and chronic maintenance have cost implications requiring P&T committees to adapt and evaluate agents and pathways along the same rapid timelines as they become available.

SPONSORSHIP: TPG-National Payor Roundtable.

D7 Adherence, Persistence, and Dosing Patterns of Eltrombopag for Treatment of Immune Thrombocytopenia

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BACKGROUND: There is limited information on the medication adherence and persistence of eltrombopag, an oral thrombopoietin receptor agonist (TPO-RA) approved for treatment of chronic immune thrombocytopenia (ITP).

OBJECTIVE: Evaluate eltrombopag dosing patterns, medication adherence, and persistence among adults diagnosed with ITP in a real-world study.

METHODS: The study employed a retrospective longitudinal cohort design using integrated health care claims data from July 2008-June 2015. Adults diagnosed with ITP identified by ICD-9 codes, with ≥2 eltrombopag prescription claims from January 2009-July 2014 were included. The index date was the first eltrombopag claim date. Patients not continuously enrolled in medical and pharmacy benefits for 6-months prior or 12-months post the index date and those who received eltrombopag during the pre-index period were excluded. All outcomes were assessed during the 12-month post-index window: initial dose, stable dose, dose escalation and reduction, adherence, persistence (12 and 6-months), and time to discontinuation. Adherence was measured using medication possession ratio (MPR) and assessed between the first and last prescription fill. Patients without a gap of ≥30 days were considered persistent.

RESULTS: Of the 336 patients included, 46.3% (165) were male and the mean age was 58.8 years. During the 6-month pre-index period prior to eltrombopag initiation, patients received the following ITP treatments: 5.9% (21) had a splenectomy, 22.2% (79) corticosteroids, 19.1% (68) intravenous immunoglobulin, 18.3% (65) romiplostim, and 17.1% (61) rituximab. Median initial and stable dose of eltrombopag were 50 mg. Dose escalation and reductions occurred among 29.2% (104) and 30.3% (108) of patients, respectively. Median escalation and reduction in dose were 25 mg. Median time on stable dose was 180 days. Median MPR was 0.9, 78.7% (280) of patients were adherent (MPR ≥ 0.8), and 37.6% (134) were persistent for 12-months (58.9% [210] of patients were persistent over the first 6 months). Among those patients who discontinued, median time to discontinuation (time to gap ≥ 30 days) was 111 days.

CONCLUSIONS: ITP patients on eltrombopag demonstrated good medication adherence, although 1 year persistence was low. Further research is needed to assess the relationship between eltrombopag adherence and persistence and clinical outcomes (e.g., platelet counts and bleeding symptoms), in the real-world setting.

SPONSORSHIP: Novartis.

D8 Trend Analysis of Medicare Hemophilia Drug Utilization, 2011-2015

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BACKGROUND: Hemophilia is a costly, rare disease that requires long-term management and treatment. For Medicare patients, hemophilia is
covered under Medicare Part B. Recently, novel long-acting coagulator factor treatments have been developed that may improve patient care.

**OBJECTIVE:** To understand the trend of hemophilia drug utilization under Medicare from 2011 to 2015.

**METHODS:** We analyzed Medicare Part B drug utilization and costs published by CMS in 2016 (range 2011-2015). All coagulation factors for the treatment of hemophilia A without inhibitors (HA), hemophilia B without inhibitors (HB), hemophilia with inhibitors (inhibitor) and Von Willebrand disease (VWD) were included.

**RESULTS:** From 2011 to 2015, Medicare spending on hemophilia drugs increased from $448,271,249 to $589,153,676, but decreased as part of the overall Medicare Part B spend (2.78% to 2.9%). Among Medicare patients, HA had the highest prevalence (>45%). HA patients had the highest overall spend (~50%), followed by HB, inhibitor and VWD. Over time, the PMPM of treating hemophilia patients increased from $0.83 to $0.88 and the patient’s out of pocket was 15-20% of the CMS spend. The annual spend per inhibitor patient decreased from $539,952 to $405,967 but still remained the highest compared with other hemophilia types. The annual spend per VWD patient was the lowest, but increased from $73,148 to $79,334. For HA patients, PMPM increased from $0.40 to $0.46. Patients using recombinant factors increased from 74% to 85% with the total spending on recombinant factors increasing from 83% to 89%. The annual spend per patient increased from $234,788 to $240,544 using recombinant factor and increased from $131,505 to $171,965 for plasma-derived factor. For HB patients, PMPM increased from $0.11 to $0.16. Alprolix received FDA approval as the first long-acting factor IX in 2014, and JXTG was used from 2015. From 2011 to 2014, the spend on recombinant factors increased from 70% to 75%. In 2015, 10% of HB patients started using Alprolix and cost 29% of the total spend on HB. The annual spend per patient on long-acting factor IX was $482,149 in 2015, higher than that of recombinant factors ($178,608-$204,007) and plasma-derived factors ($61,224-$97,371).

**CONCLUSIONS:** The Medicare spend on hemophilia increased over the period 2011-2015, and there was a decrease compared with overall spend in Medicare Part B. Inhibitor patients cost the highest per patient compared with other hemophilia types. There was an increased spend on recombinant factors and it is expected that long-acting factors will continue to have increased uptake.

**SPONSORSHIP:** WG Group.

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**D10 Improving Payer-Provider Collaboration and Data Reporting for Hemophilia Management: Metric Development for Quality Improvement**

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1Henry Ford Health System/Health Alliance Plan, 2National Hemophilia Foundation

**PROBLEM DESCRIPTION:** Hemophilia represents a significant driver of health care resource utilization and requires expert hematologic and multidisciplinary services to achieve optimal outcomes. Despite serving as federally-recognized centers of excellence in managing this unique patient population for more than 40 years, hemophilia treatment centers (HTCs) may be underused in the current framework of managed care. This is largely due to a lack of communication and information shared between payers and HTC stakeholders.

**GOAL:** Routine information sharing between HTC and payer stakeholders is paramount to improving outcomes in hemophilia; the Comprehensive Care Sustainability Collaborative (CCSC) initiative provides a unique forum for such dialogue and data exchange. The CCSC seeks to develop a set of quality improvement and cost management metrics. These metrics will be used in a first-of-its-kind series of pilot programs that are anticipated to forge innovative collaboration between payers and HTCs.

**PROGRAM DESCRIPTION:** The National Hemophilia Foundation (NHF), in conjunction with Impact Education, developed CCSC: an initiative among 18 leading clinicians and managed care decision-makers. Over the course of consensus meetings, CCSC is developing a framework for quality improvement pilot programs that can be replicated across the United States between payers and HTCs, to facilitate cost-effective hemophilia management integrating the HTC comprehensive care model.

**OBSERVATIONS:** The services delivered by HTCs exceed payer expectations in care delivery, quality, and value. The intensive level of care and oversight provided by HTCs has the potential to result in cost savings for payers through the avoidance of bleeding-related
complications and rigorous management of factor replacement therapy, which may also come at a lower cost due to the 340B discount drug pricing available through many centers.

**FINDINGS/RECOMMENDATIONS:** The following measures will be reported by HTCs and payers via a series of pilot programs (reporting group indicated in parentheses): patient classification by diagnosis (HTC); total cost of clotting factor (payer); prescribed factor dose/dispensed dose/weight (± range) (payer and HTC); emergency department (ED) visits/hospitalizations (payer and HTC); home infusion of clotting factor (%) (HTC); total cost per patient (payer); and patient contacts (clinic visits, follow-ups, telemedicine, e-mail, etc.) (HTC).

**SPONSORSHIP:** The CCSC initiative is jointly sponsored by the National Hemophilia Foundation and Impact Education and supported via a charitable donation from Shire.

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**D13 A Real-World Cost Comparison of IVIG- and SCIG-Treated PIDD Patients**

Noone J, Runken C, Blanchette C, Zacherle E, Howden R. 3rd tier, or requiring prior authorization [PA].

**BACKGROUND:** Primary Immune Deficiency Disorder (PIDD) is a rare, chronic disease limiting a patient's ability to fight off infection due to immune system deficiencies. Acute or recurrent infections often occur, thereby resulting in higher rates of office, emergency department, and inpatient hospital utilization. Compounding these expenses are the high costs of immunoglobulin (IG) therapy which are either nurse-infused intravenous (IV) or self-administered subcutaneous (SC) products.

**OBJECTIVE:** This study's purpose was to compare real-world PIDD-related and total annual costs between PIDD patients receiving IVIG and SCIG treatments.

**METHODS:** The 2010-13 Marketscan commercial dataset was used to identify PIDD patients (ICD-9 code 279 XX) with at least two PIDD claims > 90 days apart who were treatment naïve. Patients who switched administration routes were excluded, with the exception that SC patients could receive up to two IV loading infusions per treatment guidelines. Claims with a primary diagnosis of PIDD and costs related to therapy were identified as “PIDD-related” costs. To adjust for physician treatment preferences and differences in base population characteristics, the two cohorts were matched on age, gender, and all 31 Elixhauser index criteria using propensity score matching. To better represent the spectrum of IV products, the annual costs for patients receiving the three most common IV products were grouped and compared with median annual costs of the SC product using t-tests for means and Wilcoxon Rank-Sum tests.

**RESULTS:** 1,094 PIDD patients met all necessary criteria with 853 being IV infused and 241 SC treated. SC patients were significantly younger (median age 46 vs. 53 for IV), more female (74.3% vs. 61.3%), and had lower Charlson Comorbidity Index scores (CCI 1.4 vs. 2.0) (P≤0.05 for all). Pre-matched PIDD-related and total median annual costs were lower for the IV group ($31,098 vs. $33,609 and $62,571 vs. $64,325, respectively). After matching, there were 178 patients in each group with no demographic differences. Post-matched PIDD-related and total median annual costs remained lower for the IV group ($29,493 vs. $33,267 and $52,278 vs. $63,367, respectively), but with limited sample sizes, differences were not statistically significant.

**CONCLUSIONS:** In this analysis we confirmed previous research that IV patients have higher prevalence of comorbid conditions. Additionally, when comparing matched cohorts of PIDD patients, costs for both groups go down and small differences in costs become larger favoring IV patients.

**SPONSORSHIP:** Grifols SSNA.

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**E00-E90 Endocrine, Nutritional, and Metabolic Diseases (e.g., Growth Hormone, Diabetes, Lipids)**

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**E1 The Impact of Various Clinical Strategies on Achieving 5 Stars for the MTM Program Completion Rate for CMR Star Rating Measure**

Makanji S, Santilli M, Ferro C, Adams J, Braganca E, Dimani M. 3rd tier, or requiring prior authorization [PA].

**BACKGROUND:** As the United States health care system transitions away from fee-for-service models, health insurers are...
placing an increased emphasis on quality of care. To assist AlphaCare in improving the quality of care delivered to their beneficiaries, Magellan Rx Management has collaborated on the development and implementation of a clinical program designed to specifically address the CMS Star Rating measure D15-MTM Program Completion Rate for CMR, which is defined as the percent of Medication Therapy Management (MTM) program enrollees who received a Comprehensive Medication Review (CMR) during the measurement year.

GOAL: To obtain a 5-Star rating for CMS Star Rating measure D15-MTM Program Completion Rate for CMR by leveraging various methods of member engagement and clinical intervention.

PROGRAM DESCRIPTION: A clinical program was implemented to improve the CMR completion rate through various methods of member engagement and clinical intervention, including distribution of quarterly member letters, telephonic outreach, sending outreach materials to prescriber offices and community pharmacies, collaboration with member care management (MCM) teams, scheduling evening shifts (after 5 pm) to reach members with busier schedules, conducting CMRs with long-term care (LTC) facility caregivers or primary care providers, and working with visiting nurses for members unwilling to complete a telephonic CMR or those who were recently discharged from the hospital.

OBSERVATIONS: Between January and November of 2016, a total of 183 members were identified as being MTM-eligible and 132 CMRs were completed, resulting in a CMR completion rate of 72.1%. After applying the 60-day MTM enrollment criteria per the Star Ratings technical notes, the completion rate increased to 77.9%, which is equivalent to a 5-Star rating based on existing thresholds. Of the 132 completed CMRs, 51.5% are attributable to collaboration with the MCM team, 40.2% to direct telephonic outreach, 4.5% to collaboration with visiting nurses/LTC facilities/PCPs, and 3.8% to evening shifts.

FINDINGS/RECOMMENDATIONS: Member engagement is critical in improving the CMR completion rate for Star ratings. Leveraging multiple sources of member engagement helps improve reach rates in a clinically synergistic manner. It has been estimated that a cumulative 1-star improvement across all measurements (from 3 to 4) is worth $50 per member per month. Such results support the efficacy and viability of a clinical program that incorporates care coordination and customized outreach.

SPONSORSHIP: Conducted by AlphaCare and Magellan Rx Management, affiliates of Magellan Health, without external funding.
OBSERVATIONS: Patients working with the CVRS pharmacists for 12 months had improved GA scores compared to those receiving usual care. GA scores are highly correlated to established CMS quality measures. CVRS pharmacists had an 88% acceptance rate for 331 recommendations among 35 PCPs. Discussions with PCPs suggest fewer in-clinic visits needed for uncomplicated disease states managed by the CVRS. The CVRS is a novel, efficient, scalable model that can be adapted to specific needs of various payers, clinics, and patient populations.

FINDINGS/RECOMMENDATIONS: The CVRS was successful in operationalizing selected sets of quality measures, managing chronic diseases, and improving access to care. Findings suggest a rigorous tele-health intervention with EMR access and PCP engagement is a promising way to improve care and can be incorporated into alternative payment structures.

SPONSORSHIP: NIH grant R01HL116311.

E4 Medicare Part D Plan Formulary Coverage, Utilization Management Tools, and Cost Sharing for Insulins and Other Newer Antidiabetic Drugs

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BACKGROUND: Research has shown that persistent use of antidiabetic drugs and effective control of A1c are associated with improved clinical outcomes in diabetes. For the newer antidiabetic drugs, little is known about formulary restrictions and cost sharing under Medicare Part D plans.

OBJECTIVE: To describe the cross-sectional and longitudinal variation across Medicare Part D plans in formulary coverage, utilization management tools, and cost sharing for insulins and newer antidiabetic drugs.

METHODS: Medicare Part D Plan Characteristic and Formulary files were examined during the 2007-2013 period. Descriptive analyses were used to profile the coverage for insulins, GLP-1 agonists, DPP-4 inhibitors, and SGLT-2 inhibitors that were FDA-approved and available during the study period.

RESULTS: Large variations within and between drug classes were identified across Medicare Part D plans pertaining to formulary coverage, utilization management restrictions, and cost-sharing requirements for newer antidiabetic drugs within the same year and across 2007-2013. In 2013, percentage of Medicare Part D plans with off-formulary drugs excluded from the plans ranged from 5-46% for GLP-1 agonists, 3-37% for DPP-4 inhibitors (excluding Nesina, alogliptin, which was 93%), and 7-25% for insulins. In 2013, prior authorization and step therapy policies were seen in 2-7% and 21-34% of plans for GLP-1 agonists, 0% and 0-2% of plans for DPP-4 inhibitors, and 0-2% and 0% of plans for insulins, respectively. For most drugs, approximately 1/3 of the plans required a coinsurance, except for SGLT-2 inhibitor canagliflozin (52% of plans). Among these plans, coinsurance levels ranged from 23 to 43% for GLP-1 agonists, 20 to 30% for DPP-4 inhibitors, and 1 to 25% for SGLT-2 inhibitors, and 20 to 25% for insulins in 2013. In the same year, among the remaining plans using copayments, the mean copayments per 30-day prescription were $39.55 for GLP-1 agonists, $40-78 for DPP-4 inhibitors, $38 for the SGLT-2 inhibitor canagliflozin, and $37-38 for insulins. Intra-brand variations existed, with most variation in the GLP-1 agonist class and least in the insulin class.

CONCLUSIONS: Large variations in formulary restrictions and cost sharing identified across Medicare Part D plans over time suggest that beneficiaries need to carefully select plans during the annual open enrollment period to enable their access to needed antidiabetic drugs. Future research should examine the impact of such restrictions on drug use, adherence, and outcomes in Medicare Part D beneficiaries.

SPONSORSHIP: Sanofi U.S.

E5 Clinical Outcomes of Patients with Type 2 Diabetes Who Switched to Insulin Glargine 300 U/mL from Insulin Glargine 100 U/mL in Real-World U.S. Treatment Settings

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BACKGROUND: In the EDITION 1 and 2 trials, which assessed the efficacy, safety, and dose optimization of insulin glargine 300 U/mL (Gla-300) in patients (pts) with T2D on prior basal insulin, pts randomized to Gla-300 used 10% more basal insulin than pts randomized to insulin glargine 100 U/mL (Gla-100).

OBJECTIVE: To compare insulin dose changes in a real-world setting for adult pts with T2D on prior Gla-100 who either switched to Gla-300 or remained on Gla-100.

METHODS: Retrospective pt-level data were extracted from the Optum Clininformatics database (October 1, 2014 to March 31, 2016). Pts had ≥2 Gla-100 claims at baseline, and either ≥1 Gla-100 or ≥1 Gla-300 claims from April 1 to December 31, 2015. Data were assessed at baseline (≤6 months [mo] prior to inclusion), and follow-up (≤6 mo after the first Gla-300 claim, or a randomly selected Gla-100 claim in the study period). Pts switching to Gla-300 were matched to those continuing Gla-100 based on baseline characteristics via propensity score matching (PSM) at a ratio of 1: to 3. The main endpoint was daily average consumption (DACON) of basal insulin, calculated as the total number of study drug units dispensed from initiation to last refill, divided by the number of days during that period. Average percent change of DACON per pt from baseline to follow-up was also calculated. Pts were considered persistent if they remained on index basal insulin during follow-up.

RESULTS: The PSM yielded 443 pts on Gla-300, and 1,241 pts on Gla-100 with matched baseline characteristics. Within the matched sample, Gla-300 and Gla-100 cohorts had comparable mean A1c at baseline (Gla-300: 9.7%; Gla-100: 7.3%; P=0.0975), corresponding to comparable percent changes in DACON (13.8% vs. 12.6%, respectively; P=0.753). In persistent pts, DACON also increased from baseline to follow-up (Gla-300: 54.6 U/day to 59.2 U/day, n=346; Gla-100: 54.7 U/day to 55.0 U/day, n=1,090), with no statistical difference in percent change in DACON between cohorts (Gla-300: 9.7%; Gla-100: 7.3%; P=0.467). For the subset of pts with available A1c measures, both cohorts showed comparable mean A1c at baseline and follow-up.

CONCLUSIONS: In a real-world clinical setting, switching to Gla-300 from Gla-100 was not associated with a higher basal insulin dose in pts with T2D compared with continuing on Gla-100, and similar changes in DACON and A1c were observed. Despite the increase in DACON, mean A1c remained elevated, possibly reflecting the need for additional therapy intensification and insulin dose optimization.

SPONSORSHIP: Study funding and writing/editorial support was provided by Sanofi U.S.
**E6** Treatment Dosing Patterns and Clinical Outcomes for Patients with Type 2 Diabetes Initiating or Switching to Insulin Glargine 300 Units/mL in a Real-World Setting

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**BACKGROUND:** The usage patterns and effectiveness of a longer-acting formulation of insulin glargine 300 units/mL (Gla-300) have not been studied in a real-world setting after becoming available to eligible patients.

**OBJECTIVE:** This study evaluated changes in dosing and clinical outcomes pre- and post-initiation of Gla-300.

**METHODS:** This was a retrospective observational study using medical-chart data obtained by physician survey for 390 insulin-naive patients who initiated insulin glargine 100 units/mL (Gla-100; n = 92) or Gla-300 (n = 298), and 184 patients who switched to Gla-300 from another basal insulin (BI). Differences in dosing patterns and clinical outcomes during the 6-months pre- vs. a mean of 4-months post-initiation or switching were examined by generalized linear mixed-effect models adjusting for demographics and clinical characteristics.

**RESULTS:** Among patients switching to Gla-300, 65.9% switched from Gla-100 and 25.1% from insulin detemir. On their previous insulin regimen, 43.2% of patients injected twice daily (b.i.d.). After switching to Gla-300, only 9.8% of patients required b.i.d. dosing. Units per injection was similar for patients on the same dosing frequencies: patients on once-daily dosing had least-squares (LS) means of 0.53 units/kg and 0.56 units/kg pre- and post-switch, respectively (adjusted difference [95% CI] 0.03 [-0.12, 0.18]; P = 0.684); patients with b.i.d. dosing had LS means of 0.94 units/kg and 0.76 units/kg pre- and post-switch, respectively (adjusted difference [95% CI] -0.18 [-0.48, 0.12]; P = 0.230). Post-switching, compared with pre-switching, mean A1c (LS means: 7.61% vs. 8.57%; adjusted difference: -0.96 [95% CI -1.14, -0.77], P < 0.0001) and hypoglycemic events per patient-year (LS means: 0.17 vs. 0.79; relative risk: 0.23 [95% CI 0.16, 0.32], P < 0.0001) were lower. In insulin-naive patients who initiated BI, no difference in dose (units/kg) was seen in titrated Gla-300 vs. Gla-100 initiators (LS means: 0.42 vs. 0.44, P = 0.77). Both groups had reductions in A1c (LS means: 1.21% vs. 1.12%; P < 0.001) with no between-group difference (P = 0.62). Initiation of Gla-300 was associated with lower hypoglycemic risk vs. Gla-100 (relative risk: 0.31, 95% CI 0.12, 0.81, P = 0.018) at similar daily doses.

**CONCLUSIONS:** Switching to Gla-300 resulted in lower frequency of hypoglycemic events and without compromising A1c reduction. In insulin-naive patients, initiation of Gla-300 vs. Gla-100 resulted in fewer hypoglycemic events and a similar A1c reduction, with no difference in insulin dose.

**SPONSORSHIP:** Study funding provided by Sanofi U.S.

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**E7** Pharmacist-Led Diabetes Wellness Clinical Outreach Program Significantly Decreases Hemoglobin A1c

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WellDyneRx

**BACKGROUND:** Diabetes affects approximately 29.1 million people in the U.S., with an estimated total medical cost of $245 billion annually. Approximately $1 out of every $10 health care dollars is spent on diabetes medications with an overall trend of 14% increase in drug spend annually. Better disease management through improved medication use and ongoing self-management education and support is needed to reduce health care costs. For optimal outcomes, diabetes care must be individualized for each patient.

**OBJECTIVE:** To evaluate the effectiveness of a pharmacist-led diabetes wellness clinical outreach program administered by a pharmacy benefits manager (PBM).

**METHODS:** A random sample of 50 patients who participated in a pharmacist-led diabetes wellness clinical outreach program was compared to a random sample of 50 patients who did not participate in the program. The patients in both sample sets were continuously enrolled in the same PBM-administered plan between October 1, 2015 and September 30, 2016. Recent hemoglobin A1c levels of both sample groups were compared using a student’s t-test. The proportion of members receiving a statin, an ACE inhibitor/ARB, and adherence to diabetes medication was also recorded and differences were analyzed using a chi-square analysis.

**RESULTS:** Out of 702 clinic records of members within the plan continuously enrolled with at least one A1c during the study period, 298 were enrolled in the program and met at least once with the pharmacist. The average A1c level among the sample pharmacist-led program group was significantly lower at 6.4% ± 1.2% whereas the average A1c level for the sample group that did not meet with a pharmacist was 7.6% ± 1.4% (P < 0.001). There were no statistically significant differences among members in terms of statin use, ACEIs/ARBs, or adherence rates.

**CONCLUSIONS:** Members enrolled in the pharmacist-led diabetes wellness program showed a significant decrease in hemoglobin A1c levels compared to members not enrolled in the program, despite similar diabetic mediation adherence rates. Implementing a pharmacist-led multi-factorial diabetes wellness program that addresses appropriate medication, diet, and weight management results in significant decreases in A1c levels.

**SPONSORSHIP:** WellDyneRx

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**E8** Real-World Analysis of Patient Characteristics in Patients Who Received an Eye Exam Within the First Year of Type 2 Diabetes Mellitus Diagnosis Compared with Patients Who Did Not Receive an Exam

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**BACKGROUND:** Diabetes is the leading cause of new cases of blindness, but patients with diabetic retinopathy are often asymptomatic until significant damage occurs. Prevention and early detection are crucial, but only about 62% of adults with type 2 diabetes mellitus (T2DM) had dilated eye exams in 2010. At risk patients may benefit from eye exams, which may increase early detection and patient engagement, potentially improving health care resource utilization.

**OBJECTIVE:** To analyze real world health plan claims data to assess differences in characteristics between those receiving an eye exam in the first year of T2DM diagnosis compared to those who did not and to assess screening rates over time.

**METHODS:** A retrospective study of real-world medical and pharmacy claims from regional health plans in Magellan’s medical and pharmacy claims database. Qualifying patients were 18-75 years old at start of study period (1/1/2011 and 12/31/2015), had a T2DM diagnosis in the baseline period (either 2 outpatient claims or one inpatient claim with appropriate diagnosis code), and eligible for the entire calendar year of interest for annual screening calculations. Patients were segmented into 2 cohorts based on evidence of an eye exam within the first year of
T2DM diagnosis and a multivariate logistic model was used to assess the characteristics.

RESULTS: Of 142,086 patients, 99,776 (70%) did not receive an eye exam during the first year of T2DM diagnosis. Patients receiving an eye exam in the first year were more likely to be female and older than those who did not (odds ratio = 1.029, 95% CI = 1.028, 1.030). Female patients were more likely than males to receive an eye exam in the first year (odds ratio = 1.22, 95% CI = 1.196, 1.255). Comorbidity assessment showed patients receiving an eye screen in year one had greater comorbidities than those who did not: 45.3% of screened patients had a comorbidity score > 1, vs. 27.1% of those not screened. In general, eye exams over time increased from 37% in 2011 to 61% in 2015 (P = 0.003).

CONCLUSIONS: This analysis suggests patients receiving an eye exam within one year of T2DM diagnosis are more likely to be female and older than those who do not. When comparing screening rates over time, eye exams rates improved. The rate of eye exams observed in this study is lower than rate observed by the CDC in 2010. This discrepancy may be due in part to payers having little incentive to collect this data until member retention was influenced by and financial rewards were attached to the STAR rating program.

SPONSORSHIP: Research funded by Regeneron Health Care Solutions.

**E9** Any Statin Use Among Commercially Insured Members with Diabetes Age 40-64 Without History of Atherosclerotic Cardiovascular Disease and Association Between Adherence to Statin Therapy in 2014 and Adverse Cardiovascular Events in 2015

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BACKGROUND: The 2013 updated guidelines from American College of Cardiology (ACC) and American Heart Association (AHA) recommend primary prevention with statins for nearly all adults with diabetes mellitus (DM) age 40 to 74. However, there remains uncertainty of the real world value statins provide.

OBJECTIVE: To determine the proportion of commercially insured members with diabetes (MwDM) age 40 to 64 without history of atherosclerotic cardiovascular disease (ASCVD); percent of 2015 adverse cardiovascular events (CV events) in MwDM that occurred in this subset; percentages of this subset that had any pharmacy claim (Rx) for a statin and were adherent to statin therapy in 2014; and the association between statin therapy in 2014 and 2015 CV events.

METHODS: All 15 million members from 10 clients were queried to identify those continuously enrolled 2014-2015, younger than 65 years, and resided in the client's primary service area. First, members with any DM Rx or 1 inpatient or 2 outpatient medical claims for evaluation and management (E&M) with DM diagnosis code (Dx) were categorized as MwDM and all others as MnotDM. Second, a random sample of 250,000 MwDM was selected along with 1,000,000 MnotDM matched 4:1 by sex, one year age group, insurer, expense disproportionately associated with diabetes (DM).

OBJECTIVE: To compare all pharmacy (Rx) and medical claims expenses for commercially insured MwDM with that for matched members without diabetes (MnotDM) to quantify major categories of expense disproportionately associated with diabetes (DM).

METHODS: We identified all members from 5 Midwest and 5 Southern Blue Cross Blue Shield clients who were continuously enrolled 2014-2015, younger than 65 years, and resided in the client's primary service area. First, members with any DM Rx or 1 inpatient or 2 outpatient medical claims for evaluation and management (E&M) with DM diagnosis code (Dx) were categorized as MwDM and all others as MnotDM. Second, a random sample of 250,000 MwDM was selected along with 1,000,000 MnotDM matched 4:1 by sex, one year age group, insurer, and state of residence. All medical claims were categorized by first Dx and subcategorized by procedure codes and all Rx by national drug codes. Expense described is the sum of insurer and member payments without adjustment for rebates or coupons.

RESULTS: Out of an average of about 13.8 million member-years per year, there were 5.5 million continuously enrolled members who met stated criteria, of whom 281,221 (5.1%) were categorized as MwDM. Mean total cost per member per year (PMPY) in 2014 for all MnotDM was $4,322 vs. $4,198 for MwDM (3.28× higher) and in 2015 $4,849 vs. $17,345 (3.58× higher). However, PMPY for matched MnotDM was $9,938 in 2014 (DM 2.39× higher) and $6,832 in 2015 (DM 2.54× higher), showing that about 16% of the difference from MnotDM was due just to the older age distribution of MwDM. Of the remaining difference in PMPY for 2014 + 2015 combined: Rx accounted for 35% with DM drugs and supplies accounting for 25.3% and lipid regulators and antihypertensives 4.5%, medical claims accounted for 64.8% (28.2% inpatient + 36.6% outpatient) with atherothrombotic cardiovascular disease (ASCVD) and conditions usually due to ASCVD (E9). The proportion of 2014 PMPY accounted for by FDM was 2.54× higher, showing a substantial difference between MnotDM and MwDM.

CONCLUSIONS: This recent real world data quantifies the substantial value statin therapy imparts to commercially insured individuals with diabetes, allowing for estimated program clinical event rate avoidance calculations. In 2014, the year following the latest ACC/AHA guidelines update, only 55% of these members had a statin claim and only 28% were adherent to statin therapy. Those adherent to statin therapy had about 25% lower incidence of adverse cardiovascular events.

SPONSORSHIP: Prime Therapeutics.

**E10** Total 2014 and 2015 Claims Expense by Drug, Diagnosis, and Procedure Codes: 250,000 Commercially Insured Members with Diabetes Compared with 1,000,000 Matched Members Without Diabetes

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BACKGROUND: Health plans need to understand which categories of claims expense occur in excess for members with diabetes mellitus (MwDM) and, of these, which are potentially modifiable by improved drug therapy.

OBJECTIVE: To compare all pharmacy (Rx) and medical claims expenses for commercially insured MwDM with that for matched members without diabetes (MnotDM) to quantify major categories of expense disproportionately associated with diabetes (DM).

METHODS: We identified all members from 5 Midwest and 5 Southern Blue Cross Blue Shield clients who were continuously enrolled 2014-2015, younger than 65 years, and resided in the client's primary service area. First, members with any DM Rx or 1 inpatient or 2 outpatient medical claims for evaluation and management (E&M) with DM diagnosis code (Dx) were categorized as MwDM and all others as MnotDM. Second, a random sample of 250,000 MwDM was selected along with 1,000,000 MnotDM matched 4:1 by sex, one year age group, insurer, and state of residence. All medical claims were categorized by first Dx and subcategorized by procedure codes and all Rx by national drug codes. Expense described is the sum of insurer and member payments without adjustment for rebates or coupons.

RESULTS: Out of an average of about 13.8 million member-years per year, there were 5.5 million continuously enrolled members who met stated criteria, of whom 281,221 (5.1%) were categorized as MwDM. Mean total cost per member per year (PMPY) in 2014 for all MnotDM was $4,322 vs. $4,198 for MwDM (3.28× higher) and in 2015 $4,849 vs. $17,345 (3.58× higher). However, PMPY for matched MnotDM was $9,938 in 2014 (DM 2.39× higher) and $6,832 in 2015 (DM 2.54× higher), showing that about 16% of the difference from MnotDM was due just to the older age distribution of MwDM. Of the remaining difference in PMPY for 2014 + 2015 combined: Rx accounted for 35% with DM drugs and supplies accounting for 25.3% and lipid regulators and antihypertensives 4.5%, medical claims accounted for 64.8% (28.2% inpatient + 36.6% outpatient) with atherothrombotic cardiovascular disease (ASCVD) and conditions usually due to ASCVD (E9). The proportion of 2014 PMPY accounted for by FDM was 2.54× higher, showing a substantial difference between MnotDM and MwDM.

CONCLUSIONS: This recent real world data quantifies the substantial value statin therapy imparts to commercially insured individuals with diabetes, allowing for estimated program clinical event rate avoidance calculations. In 2014, the year following the latest ACC/AHA guidelines update, only 55% of these members had a statin claim and only 28% were adherent to statin therapy. Those adherent to statin therapy had about 25% lower incidence of adverse cardiovascular events.

SPONSORSHIP: Prime Therapeutics.
E11 Real-World Basal Insulin Intensification Patterns in the United States

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Compare pre/post annual diabetes drug utilization, generics and branded formulary products has not been assessed. However, the impact of zero dollar diabetes drug coverage for both has been associated with improved diabetes medication adherence. Providing zero dollar generic diabetes drug coverage into 2017.

RESULTS: 816 intervention group members were matched to 8,160 control members. The change Pppy in diabetes drug claims was 4.2 (15.5 in 2014 to 19.7 in 2015) for the intervention group and 2.2 (14.9 to 17.1) for the control group. Member cost share (i.e., out of pocket expense) for diabetes drugs decreased $253 Pppy ($327 in 2014 to $74 in 2015) for the intervention group and increased $42 Pppy ($367 to $409) in the control group. Total cost for diabetes drugs increased $1,010 Pppy ($1,694 in 2014 to $2,704 in 2015) for the intervention group and increased $855 Pppy ($2,082 to $2,937) for the control group. Intervention group 2014 to 2015 adherence increased 4.4 percentage points, 71.6% to 76.0%, with the control group increasing 2.5 percentage points, 69.8% to 72.3%.

CONCLUSIONS: A zero dollar cost share for both generic and branded formulary diabetes drugs was associated with increased diabetes drug utilization, improved diabetes drug adherence, a substantial $253 Pppy member cost share savings, and an incremental additional $155 Pppy increase in total diabetes drug cost compared to the matched control group. The self-insured employer continues to provide zero dollar diabetes coverage into 2017.

SPONSORSHIP: No external sponsorship.

E12 Zero Dollar Diabetes Drug Coverage: Impact on Utilization, Costs, and Adherence

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BACKGROUND: Providing zero dollar generic diabetes drug coverage has been associated with improved diabetes medication adherence. However, the impact of zero dollar diabetes drug coverage for both generics and branded formulary products has not been assessed.

OBJECTIVE: Compare pre/post annual diabetes drug utilization, costs, and adherence from a matched control group to the intervention group that implemented a zero dollar formulary brand and generic diabetes drug coverage benefit.

METHODS: The intervention group was a large national self-insured employer, with 20,000 insured lives. On 1/1/2015 a zero dollar formulary brand and generic diabetes drug coverage began and non-formulary diabetes drugs cost share remained at $70 per month or a 20% coinsurance. The control group consisting of continuously enrolled members during 2014 and 2015 who met HEDIS diabetes diagnosis criteria. All analyzable continuously enrolled intervention members were each matched to 10 control members on age, gender, and state from Prime Therapeutics national commercially insured database of 15 million members. Analyzable members diabetes drug claims total cost, defined as member plus plan paid, were obtained to calculate a per patient per year (Pppy) diabetes drug cost. Diabetes drug adherence was calculated annually using the CMS Star rating proportion of days covered (PDC) methodology of percentage with ≥80% PDC.

RESULTS: Of 427 eligible patients with A1c available at 6 months, 59% were male, mean age was 53.9 years, mean follow-up was 29.4 months and mean dose at initiation was 29.6 (median 24). Six months after initiating basal insulin, 81% of patients (n = 346) remained in poor glycemic control and mean basal insulin dose was 31.0 insulin units (U; median 25U). Most (88%; n = 306) of these uncontrolled patients subsequently intensified treatment over the available (minimum ≥ 12 months) follow-up. Kaplan-Meier (KM) analysis evaluated time to treatment intensification and time to A1c goal.

RESULTS: 816 intervention group members were matched to 8,160 control members. The change Pppy in diabetes drug claims was 4.2 (15.5 in 2014 to 19.7 in 2015) for the intervention group and 2.2 (14.9 to 17.1) for the control group. Member cost share (i.e., out of pocket expense) for diabetes drugs decreased $253 Pppy ($327 in 2014 to $74 in 2015) for the intervention group and increased $42 Pppy ($367 to $409) in the control group. Total cost for diabetes drugs increased $1,010 Pppy ($1,694 in 2014 to $2,704 in 2015) for the intervention group and increased $855 Pppy ($2,082 to $2,937) for the control group. Intervention group 2014 to 2015 adherence increased 4.4 percentage points, 71.6% to 76.0%, with the control group increasing 2.5 percentage points, 69.8% to 72.3%.

CONCLUSIONS: A zero dollar cost share for both generic and branded formulary diabetes drugs was associated with increased diabetes drug utilization, improved diabetes drug adherence, a substantial $253 Pppy member cost share savings, and an incremental additional $155 Pppy increase in total diabetes drug cost compared to the matched control group. The self-insured employer continues to provide zero dollar diabetes coverage into 2017.

SPONSORSHIP: No external sponsorship.
A total of 80 surveys were distributed and 80 surveys were received back. 70% of PCPs reported awareness of DEEP (n = 56). There was a significantly lower awareness in PCPs located in South Texas (35.6%), compared to PCPs located in El Paso (100%), (P = 0.03). Among those aware, the majority of the responses were positive, displaying perceptions of moderately/extremely improved patient outcomes. There were no statistically significant differences in responses with PCP and practice characteristics.

CONCLUSIONS: Awareness of DEEP was significantly lower in the South Texas region compared to El Paso, indicating the need to educate PCPs in this area. Overall, DEEP was well received, and results indicated positive perception amongst PCPs that referred patients to the program. Future research should focus on evaluating patient perceptions of DSME programs like DEEP, as this feedback is crucial to program improvement coupled with the enhancement of patient care.

SPONSORSHIP: Center Point Clinical Services sponsored this project.

E14 Evaluating the Impact of Pharmacist Support for Medication Adherence and Patient Compliance in Clinical Trials for 2 NIGLMs in Suboptimally Controlled Patients with Diabetes

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BACKGROUND: New medications are constantly being developed to improve the health of patients. The average drug requires $2.56 billion in R&D costs to receive FDA approval. The likelihood of approval (LOA) from the FDA is only 1 out of 10 for drugs from phase 1 on. Therefore, it is important for patients to remain adherent to medication and compliant with protocols for a clinical trial to produce reliable and high-quality data. It is estimated that mean adherence rates for short- and long-term medication adherence within clinical trials is 78% and 59% respectively.

OBJECTIVE: Studies demonstrate numerous positive impacts that pharmacists have made on medication adherence and patient compliance when engaging patients. Pharmacists can provide clinical trial support by establishing a relationship with the patient, promoting appropriate medication adherence and addressing patient questions regarding medication therapy in a real-time. The impact of pharmacist interventions in clinical trials with patients with diabetes has not been studied to date. The objective of this research is to quantify the frequency and level of pharmacist interventions in pre-approval clinical trials.

METHODS: Pharmacists called study participants at specific time points during 11 clinical trials of 2 non-insulin glucose lowering medications (NIGLM) according to protocol. This was in addition to regular site monitoring interactions provided by the clinical trial site staff. The number and amounts of interventions were documented during each call. Retrospective and descriptive analysis (frequency and type) were performed.

RESULTS: Mean number of patients and calls per trial were 292 and 845.6. A total of 3,212 patients received a total of 9,302 pharmacist calls. Total 1st, 2nd, 3rd, 4th and 5th+ calls were 3212, 3,138, 1,701, 407, and 729, respectively. Total 1st, 2nd, 3rd, 4th and 5th+ calls with interventions were 444 (12.3%, P = 0.001), 374 (11.9%), 184 (10.8%), 36 (8.8%), and 93 (12.8%), respectively. 140 (4.4%) patients with 1st call intervention required a second call.

CONCLUSIONS: The use of the clinical trial research pharmacist calls can be used to improve patient education and adherence when utilized in addition to the normal clinical site monitoring. These pharmacist interventions identified and addressed patient compliance and adherence issues that would have gone unchecked, would have negatively impacted the trial results and outcomes. Larger controlled studies are needed to evaluate the use and impact of clinical trial research pharmacist support in clinical trials.

SPONSORSHIP: Sponsored by Humana Lilly Research Collaboration.
E16 **Assessment of New Onset Diabetes and Statin Medication Utilization**

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**BACKGROUND:** HydroxyMethyl Glutaryl Coenzyme A (HMG-CoA) Reductase Inhibitors (also called statins) and the development of new onset diabetes has been recently confirmed in the literature. A 2012 warning letter from the Food and Drug Administration (FDA) providing caution on statin drug use in diabetes patients merits research on management of diabetes as well as concomitant statin utilization in newly diagnosed patients.

**OBJECTIVE:** This study retrospectively examines medical records of patients newly diagnosed with type 2 diabetes mellitus. We assess potential contributing factors and statin use, while evaluating patients’ current diabetes control compared to national standards.

**METHODS:** A United States retrospective medical chart review of 1,000 randomly selected adult patients with new onset diabetes, identified from 5 Accountable Care Organizations (ACOs), was conducted. Patients had a current diagnosis of diabetes (ICD-9 codes 250.00-250.93) in the study timeframe of January 1st 2013–December 31st 2014, and had at least one recorded follow-up visit after diagnosis. Patient demographics, comorbidities, blood pressure control, LDL screening and A1c level data were collected from the medical record and analyzed using t-tests or chi-square tests where appropriate. Analyses were stratified by statin use and A1c levels. A two-sided alpha level of 0.05 determined statistical significance.

**RESULTS:** The sample was 51% male and 49% Caucasian with a mean age of 66 ± 12.7 years. A total of 501 (50.1%) diabetes patients were on a statin by the end of the study period. Patients on a statin were significantly more likely to have blood pressure below 130/80 (P = 0.032) and LDL below 100 mg/dl (P = 0.018) than patients not on a statin. No significant difference in age, gender or A1c level was present between statin and non-statin use patients. Out of 978 total patients that had a recorded A1c level in their medical chart, 794 (81%) patients had a recent A1c level at 8% or less. Statin usage was comparable between ≤8% and >8% A1c groups of patients, with Atorvastatin and Simvastatin being the most common statins used.

**CONCLUSIONS:** In this real-world observational study, only 50% of diabetes patients were on a statin. Diabetes patients taking a statin were more likely to have their blood pressure and LDL levels within national controls, compared to diabetes patients not on a statin.

**SPONSORSHIP:** Boehringer-Ingelheim Pharmaceuticals.

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E17 **Cost Offsets Predicted with Empagliflozin in Patients with Type 2 Diabetes and Established Cardiovascular Disease**

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1RTI Health Solutions; 2Boehringer Ingelheim Pharmaceuticals

**BACKGROUND:** The randomized EMPA-REG OUTCOME trial demonstrated that the addition of empagliflozin (empa) to standard-of-care (SoC) therapy reduced the risk of cardiovascular (CV) outcomes in patients with type 2 diabetes (T2DM) who have established CV disease.

**OBJECTIVE:** To model the health-plan cost offsets of empagliflozin plus SoC versus SoC only in patients with T2DM and established CV disease.

**METHODS:** We created an economic model to compare the cost offsets associated with treating adult T2DM patients with established CV disease with empagliflozin plus SoC versus treating the same patients with SoC only. Patients incurred annual risks for CV outcomes (nonfatal myocardial infarction, nonfatal stroke, or CV death), renal outcomes (continuous renal replacement therapy, acute renal failure, and chronic kidney disease) and adverse events observed in the EMPA-REG OUTCOME trial. Annual costs associated with these outcomes were taken from the published literature. Annual drug costs were estimated based on resource use in the trial and wholesale acquisition costs from Redbook. We modeled a 5-year time horizon to estimate the annual, per-member per-month (PMPM) and per-treatment-member per-month (PTMPM) costs and outcomes for patients receiving empagliflozin plus SoC and SoC only. Results were reported as incremental PMPM and PTMPM.

**RESULTS:** When compared with SoC only, treating a starting population of all 23,220 adult T2DM patients with established CV disease with empagliflozin plus SoC was found to have incremental PTMPM total costs of $379.00, $20.25, $40.13, $83.51, and $130.22 in years 1 through 5, respectively. Incremental PMPM total costs were estimated to be $0.88, $0.54, $0.11, $0.43, and $1.08 in years 1 through 5, respectively. Over the 5-year period, treating all adult T2DM patients with established CV disease with empagliflozin plus SoC was associated with the avoidance of 2,089 CV outcomes (including 966 avoided CV deaths) compared with SoC only.

**CONCLUSIONS:** In adult T2DM patients with established CV disease, use of empagliflozin plus SoC was associated with overall health care cost savings over a 5-year time horizon, driven by reductions in fewer CV outcomes including CV death.

**SPONSORSHIP:** Boehringer-Ingelheim Pharmaceuticals.
E19 Health Care Resource Costs and Utilization for Type 2 Diabetes Patients on New Antidiabetic Classes Compared to Traditional Classes in Central Texas

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BACKGROUND: According to 2016 AACE/ACE Comprehensive Type 2 Diabetes (T2D) Management Algorithm, new anti-diabetes classes (NAC): SGLT2i, GLP1-Ra, or DPP4i, are preferred over more traditional anti-diabetes classes (TAC: SU, TZD, Meglitinide) for dual therapy after initiation of metformin. This is due, in part, to the association of NAA with lower risk of hypoglycemia and greater reduction in body weight. This study evaluates the validity of this recommendation and whether there is a difference in health care costs and utilization between patients on the NAC and TAC.

OBJECTIVE: To estimate and compare all-cause and diabetes-related health care resource utilization and costs associated with NAC and TAC in patients with T2D.

METHODS: This was a retrospective analysis of medical and pharmacy claims from the Scott and White Health Plan. Patients were required to be > 18 years old, with ICD9 diagnosis of T2D and use of TAC at least one year prior to first claim for a NAC on the index date, or matched claim for a TAC for the index date. Differences in inpatient, emergency department, and outpatient utilization from baseline period (one year prior to index date) compared with follow-up period (one year post index date) were evaluated between the NAC vs. TAC groups.

RESULTS: A total of 126 NAC and 397 TAC eligible patients were included in the final analytical dataset. There were no statistically significant differences between age-sex matched NAC and TAC cohorts in prevalence of baseline microvascular (43.8% vs. 37.3%, P = 0.19), macrovascular (20.7% vs. 19.1%, P = 0.688), and other cardiovascular disease (95.9% vs. 95.2%, P = 1.00) and Diabetes Complication Severity Index results (1.21 vs. 1.22, P = 0.97). Outpatient utilization between NAC and TAC groups were comparable (P = 1.00). There was a greater proportion of TAC patients with an increase in inpatient hospitalizations compared to those on NAC (14.7% vs. 5.6%, P = 0.001). Patients on NAC had an unadjusted mean [standard deviation] annual difference in pre and post all-cause inpatient cost of -$14 [$261] (P = 0.94). Patients on TAC had an annual difference in pre and post difference in all-cause hospitalization cost of $32 [$274] (P = 0.01). The unadjusted mean [standard deviation] annual emergency department costs post-index was not significant between NAC and TAC [$31 [$64] vs. $34 [$66], P = 0.55).

CONCLUSIONS: The results of this real-world study demonstrate that patients newly started on an NAC experienced a significantly greater reduction all-cause inpatient utilization compared to those on a TAC.

SPONSORSHIP: Funded by Novo Nordisk.

E20 The Burden of Severe Hypoglycemia in Type 2 Diabetes

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BACKGROUND: More than 27 million people in the United States have type 2 diabetes mellitus (T2DM), a chronic metabolic disease that develops from insulin resistance and may ultimately require insulin therapy. Incorrect dosing that delivers excess amounts of insulin can cause severe hypoglycemia (SH), a condition that requires immediate medical attention and that could result in seizures, coma, and death.

OBJECTIVE: To identify patients with T2DM who have been hospitalized, and without an accompanying emergency department (ED) admission, for SH; to estimate the prevalence and costs of SH-related hospitalizations; and to estimate the long-term costs of those SH-related hospitalizations.

METHODS: Using Truven MarketScan claims we identified adult T2DM patients basal (without bolus) insulin who were hospitalized for SH (index patients) from 2010-2015. We estimated lengths of stay (LOS) and costs for SH-related hospitalizations. We defined two T2DM comparison groups: those with SH-related outpatient encounters only, including ED admissions not resulting in hospitalization (SH comparison) and those without any SH- (or acute hyperglycemia [AH]) related events (non-SH/AH comparison). Propensity scores and inverse probability weighting methods were used to adjust for baseline differences across the groups.

RESULTS: About 1.1% of T2DM patients were hospitalized for SH (712 index vs. 1,909 SH comparison and 63,558 non-SH/AH comparison patients); most (67%) index patients were admitted to the hospital through the ED. Index patients spent on average 2.81 (SD: 3.40) days in the hospital and incurred an average of $6,898 during their stay. Index patients incurred $1,222 (52%) more per month following their SH hospitalization than SH comparison patients ($3,586 vs. $2,364) and $1,316 (82%) more per month than non-SH/AH comparison patients ($2,928 vs. $1,612). About 40% of index patients were hospitalized again for SH.

CONCLUSIONS: The immediate and long-term impacts of SH in patients with T2DM are substantial. Patients with T2DM who were hospitalized for SH not only incurred the costs of their SH hospitalization, but also at least $1,222 more per month after their hospitalization than comparison patients. Limitations include: not all SH events may have been captured or coded, we do not know of patients used insulin as directed, clinical information may be incorrectly coded or not captured at all, and these results may be biased due to confounding factors we cannot measure using administrative data.

SPONSORSHIP: Funded by Novo Nordisk.

E29 Evaluating Physician-Perceived Benefit of Lumacaftor/ Ivacaftor in Patients with Cystic Fibrosis

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BACKGROUND: Lumacaftor/ivacaftor is indicated for treatment of cystic fibrosis (CF) in patients 12 and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene, which affects nearly 8,500 patients in the United States. Medical directors of certified Cystic Fibrosis Foundation centers in Michigan challenge if pulmonary function tests (PFTs) are appropriate for coverage determinations of lumacaftor/ivacaftor since not solely used in practice, although used to assess efficacy in its...
pivotal trials. Therefore, physicians were surveyed to assess clinical benefit of lumacaftor/ivacaftor.

**OBJECTIVE:** Evaluate physician reported outcomes in members on lumacaftor/ivacaftor therapy.

**METHODS:** Commercially insured members with Blue Cross Blue Shield of Michigan pharmacy coverage on lumacaftor/ivacaftor therapy were identified using pharmacy claims data and prior authorization (PA) requests from July 2015 to March 2016. Surveys were faxed to physicians with renewal requests after six months of therapy were faxed a survey identifying their perceived benefit in CF with respect to exacerbations, pulmonary function, weight and quality of life. Discontinued therapy was defined as at least 3 months without a paid claim and lack of renewal request. Surveys were faxed to the discontinued group to identify rationale for discontinuation: adverse drug reaction, lack of benefit, cost and non-adherence.

**RESULTS:** A total of 45 unique members were continuously enrolled with an approved PA and initial paid claim for lumacaftor/ivacaftor from July 2015 to March 2016. Twenty-five (55.6%) members had complete renewal requests and 8 (17.8%) discontinued therapy, 12 (26.7%) with incomplete renewal requests were excluded. Renewal group had a 48.0% response rate (n=25) and clinical benefit was observed among the majority of respondents: reduction in antibiotic use (88.9%, n=9), pulmonary exacerbations (88.9%, n=9), hospitalizations (77.8%, n=9) and improvements in quality of life (75.0%, n=8), PFTs (60.0%, n=10) and weight gain (55.6%, n=9). Discontinued group had a 23.0% response rate (n=8), citing respiratory events (100.0%, n=2) as rationale for discontinuation. Lack of benefit, cost and non-adherence were not identified as reasons for discontinuation.

**CONCLUSIONS:** Respondents cite top benefits of lumacaftor/ivacaftor as reductions in antibiotic use and pulmonary exacerbations. Physicians discontinued lumacaftor/ivacaftor treatment due to respiratory adverse reactions.

**SPONSORSHIP:** Blue Cross Blue Shield of Michigan.

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**BACKGROUND:** Gout is an inflammatory condition that arises with the formation and deposition of urate crystals as a consequence of chronic hyperuricemia.

**OBJECTIVE:** To estimate the budget impact on U.S. payers adopting lesinurad as an add-on to allopurinol treatment for second-line urate-lowering therapy in gout patients for whom allopurinol monotherapy has failed to reduce serum uric acid (sUA) below the American College of Rheumatology recommended target (<6.0 mg/dL).

**METHODS:** A budget impact model was developed for a U.S. payer perspective, using a Markov model to estimate costs, survival, and discontinuation in a 1-million-member health plan. The model population included patients failing first-line gout therapy, patients were followed for 5 years. A scenario based on allopurinol and febuxostat use was compared with a future scenario in which lesions inurad is added to a portion of allopurinol patients not meeting sUA goal. The proportion of patients using lesinurad was assumed to increase from 1.2% to 5.2% over 3 years. The model inputs were primarily derived from the CLEAR1 and CLEAR2 phase III trials of lesinurad. Indirect comparison methods were used to estimate febuxostat parameters. Annual and cumulative incremental costs between the 2 scenarios were reported as total cost, per-member per-month (PMPM) cost, and cost per treated patient per year. One-way sensitivity analysis was conducted to evaluate uncertainty using approximate 95% confidence intervals.

**RESULTS:** A total of 8,205 or 8,228 patients would be treated with a second-line therapy in treatment mixes with and without lesinurad, respectively. The incremental costs of adding lesinurad compared with no lesinurad were $241,907 in the first year and $1,098,220 in the fifth year, for a cumulative 5-year incremental cost of $3,633,440. Cumulative 5-year cost per treated gout patient per year was $112 and cumulative incremental 5-year PMPM was estimated at $0.06. Sensitivity analysis indicated the model was most sensitive to the proportion of patients receiving lesinurad, male gout prevalence, and lesinurad + allopurinol cost, each with a range of total incremental costs exceeding $750,000 or PMPM $0.01. Allopurinol discontinuation rate and cost, female gout prevalence, and annual gout prevalence increase were the only other inputs tested with a 5-year incremental cost range exceeding $100,000.

**CONCLUSIONS:** Initiating the use of lesinurad would result in a cumulative total incremental PMPM cost of approximately $0.06 over 5 years.

**SPONSORSHIP:** Sponsored by AstraZeneca.

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**E31 Cost-Effectiveness of Adding Lesinurad to Allopurinol for Second-Line Urate-Lowering Therapy in Gout Patients: A U.S. Payer Perspective**

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1Medical Decision Modeling; 2AstraZeneca; 3University of Michigan; 4Ironwood Pharmaceuticals; 5YourCareChoice

**BACKGROUND:** Gout is a painful inflammatory condition that arises as a consequence of chronic hyperuricemia and is characterized by sudden, severe attacks of pain, redness, and tenderness in joints. Long term, tophi may form. Many patients do not achieve target serum uric acid (sUA) (< 6.0 mg/dL) using allopurinol monotherapy. Febuxostat inputs were based on comparisons to allopurinol. Key epidemiology, tophi changes over time based on sUA were also reported.

**OBJECTIVE:** To determine the cost effectiveness of adding lesinurad to allopurinol, for second-line treatment in gout patients for whom allopurinol monotherapy has failed to reduce sUA levels below the American College of Rheumatology recommended target.

**METHODS:** A Markov cohort model with a U.S. private-payer perspective and life time horizon was developed. The modeled patient population was based on pooled data from the CLEAR 1 and CLEAR 2 phase III trials of lesinurad and adjusted for the U.S. gout prevalence by gender. Epidemiology, flare prophylaxis and treatment, utility, safety, efficacy, and treatment costs data were combined to estimate the costs and cost-effectiveness of sUA-lowering treatment using allopurinol alone or in combination with lesinurad or febuxostat. Data were obtained from clinical trials, published literature, government resources, and augmented with assumptions where necessary. Febuxostat inputs were based on comparisons to allopurinol. Key outputs include estimates of mean costs and quality-adjusted life years (QALYs) per patient for each treatment, and incremental cost effectiveness ratios (ICER). Clinical components such as number of flares and tophi changes over time based on sUA were also reported.

**RESULTS:** When compared to allopurinol monotherapy, lesinurad in combination with allopurinol had an estimated ICER of $132,000 per QALY (rounded to $1,000s). Febuxostat was dominated by allopurinol, for second-line treatment in gout patients for whom allopurinol monotherapy has failed to reduce sUA levels below the American College of Rheumatology recommended target. The discontinuation of treatment results in high sUA levels. Over the
average lifetimes of about 25 years, the mean number of flares per patient year were 10.1 for allopurinol in combination with lesinurad, 11.2 for allopurinol monotherapy, and 12.9 for febuxostat. Mean patient years with tophi were 5.6, 7.3, and 7.0 for allopurinol in combination with lesinurad, allopurinol monotherapy, and febuxostat, respectively.

CONCLUSIONS: In a U.S. commercial health care plan, cost-effectiveness analysis demonstrated that compared with febuxostat and allopurinol monotherapy, lesinurad in combination with allopurinol increases QALYs and result in ICERs that may be considered cost effective.

SPONSORSHIP: This study was sponsored by AstraZeneca.

Osteoarthritis and Gout: Real-World Evidence Evaluating Patient Characteristics, Treatment Patterns, and Health Care Utilization

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BACKGROUND: Gout and osteoarthritis (OA) are common in the U.S., but little is known about potential associations of OA and hyperuricemia/gout with clinical outcomes.

OBJECTIVE: This study examined variations in gout severity, management, and health care utilization among gout patients with and without OA.

METHODS: Data were assessed from a survey of U.S. physicians and patient chart audits. Participating physicians managed the care of ≥ 50 patients with gout annually; chart audits were of their last 5 consecutive adult patients with confirmed gout. Gout severity was measured by physician global assessment, flares, organ/joint damage, and tophi. Treatment characteristics, presence of clinician-confirmed OA, and sociodemographics were identified. Descriptive and multivariate (stepwise logistic regression) statistics analyzed the differences among gout patients with and without clinician-confirmed comorbid OA, and assessed urate-lowering therapy (ULT) use and gout control.

RESULTS: Overall, 1,159 charts of gout patients were abstracted (230 w/OA, 929 w/o; 81% male; 71% white); the proportion of patients age ≥ 61 with gout was greater for those with OA than without OA (61% vs. 32%; P < 0.001). Patients with gout and OA had longer mean duration of gout (63 vs. 41 months), were more likely to have tophi (44% vs. 19%), joint damage (31% vs. 11%), and clinician-rated severe gout (31% vs. 12%) than those without OA (all P < 0.01). Patients with gout and OA were also more likely to receive ULT (89% vs. 70%; P < 0.01), and among those receiving ULT, OA patients treated with allopurinol received a higher average daily dose (325 mg vs. 295 mg; P = 0.031). Gout patients with OA were more likely to have additional comorbidities (cardiovascular disease, kidney disease, COPD, depression, diabetes, hyperlipidemia, hypertension, obesity, prostate problems [men]) and have chronic pain than those without OA (all P < 0.05). Gout patients with OA reported more office visits (4.0 vs. 3.5), were more likely to have an emergency department visit (17% vs. 9%), and were more likely to require surgery for gout in the past 12 months (3% vs. 0.3%) (all P < 0.01). In both groups, ULT use was associated with better gout control, but the specific factors predictive of ULT use and disease control varied between those with and without OA.

CONCLUSIONS: Gout patients with OA were more likely to have a greater impact on health system spending, with additional comorbidities and more severe gout than those without OA. These data suggest that gout patients with OA constitute a less healthy group in need of careful monitoring and more aggressive gout management.

SPONSORSHIP: AstraZeneca.

Utilization and Cost of Diabetic Medications Among U.S. Medicare Part D Beneficiaries

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BACKGROUND: The total cost of diabetes in the United States in 2012 has been estimated at $245 billion with the second largest expenditure being prescription medications to treat the complications of diabetes (18% or about $64 billion). Medications are a key element in diabetes management.

OBJECTIVE: This study evaluates the diabetes medication prescribing patterns of U.S. health care providers.

METHODS: The 2013 Medicare Part D Prescriber Public Use File was used for analysis. Diabetes medications were identified using drug name and the chemical ingredient information available in the data file. Diabetes-related brand-generic medication prescribing patterns were determined for providers by specialty type, diabetes drug class, and geographic region. Multivariate logistic regression models examined the association between geographic regions and generic prescribing patterns.

RESULTS: In 2013 the total cost paid for all prescriptions in Medicare Part D program was $80.9 billion; diabetes-related medications accounted for 11% ($8.6 billion) of the total cost. Insulin products accounted for 63% of the total diabetes drug cost; other brand name hypoglycemic drugs accounted for 27% of the total diabetes drug cost. Generic drugs accounted for 10% of diabetes drug cost. The most prescribed generic medication was metformin, accounting for 4% of the total diabetes drug costs. The brand drug Januvia (sitagliptin) accounted for $1.3 billion or 15% of all diabetes drug claim expenditures. Practitioners identified as primary care providers (e.g. family practice, pediatrics, nurse practitioner) accounted for 89% of the total diabetes drug claim counts; 11% of the total diabetes drug claims were attributable to specialists. A small number of claims were attributed to unknown providers. A significant difference in the proportion of generic prescribing was noted by geographic region-highest in the West (mean 73% ± 0.05%) and lowest in the Midwest (68% ± 0.05%). In the multivariate model, the odds of prescribing generic drugs were higher in the West region (adjusted odds ratio (AOR) = 1.18, 95% CI = 1.16-1.19), compared with the South region. Primary care providers have higher odds of prescribing generic drugs (AOR = 1.50, 95% CI = 1.52-1.49) compared to Specialists.

CONCLUSIONS: Diabetes care, as evidenced by prescription medication prescribing, is largely provided by family practice physicians. Generic medications contribute only 10% of all diabetes drug costs. Insulin and brand name product prescribing have a dramatic effect on total costs of diabetes medications.

SPONSORSHIP: None.

Health Care Resource Utilization Among School-Aged Children with Cystic Fibrosis

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BACKGROUND: CF is a rare, progressive genetic disease affecting patients (pts) from birth. The pattern of health care resource utilization (HCRU) by age among school-aged pts with CF using administrative claims data is not well described.

METHODS: The 2013 Medicare Part D Prescriber Public Use File was used for analysis. Diabetes medications were identified using drug name and the chemical ingredient information available in the data file. Diabetes-related brand-generic medication prescribing patterns were determined for providers by specialty type, diabetes drug class, and geographic region. Multivariate logistic regression models examined the association between geographic regions and generic prescribing patterns.

RESULTS: In 2013 the total cost paid for all prescriptions in Medicare Part D program was $80.9 billion; diabetes-related medications accounted for 11% ($8.6 billion) of the total cost. Insulin products accounted for 63% of the total diabetes drug cost; other brand name hypoglycemic drugs accounted for 27% of the total diabetes drug cost. Generic drugs accounted for 10% of diabetes drug cost. The most prescribed generic medication was metformin, accounting for 4% of the total diabetes drug costs. The brand drug Januvia (sitagliptin) accounted for $1.3 billion or 15% of all diabetes drug claim expenditures. Practitioners identified as primary care providers (e.g. family practice, pediatrics, nurse practitioner) accounted for 89% of the total diabetes drug claim counts; 11% of the total diabetes drug claims were attributable to specialists. A small number of claims were attributed to unknown providers. A significant difference in the proportion of generic prescribing was noted by geographic region-highest in the West (mean 73% ± 0.05%) and lowest in the Midwest (68% ± 0.05%). In the multivariate model, the odds of prescribing generic drugs were higher in the West region (adjusted odds ratio (AOR) = 1.18, 95% CI = 1.16-1.19), compared with the South region. Primary care providers have higher odds of prescribing generic drugs (AOR = 1.50, 95% CI = 1.52-1.49) compared to Specialists.

CONCLUSIONS: Diabetes care, as evidenced by prescription medication prescribing, is largely provided by family practice physicians. Generic medications contribute only 10% of all diabetes drug costs. Insulin and brand name product prescribing have a dramatic effect on total costs of diabetes medications.

SPONSORSHIP: None.
OBJECTIVE: To evaluate the frequency of inpatient (IP) admissions, outpatient (OP) office visits, medication utilization, and pulmonary exacerbations (PEx) by age in a cohort of school-aged pts with CF.

METHODS: This retrospective study used administrative claims from the Truven Health MarketScan Commercial (COMM) and Medicaid Multi-State (CAID) databases. Pts with CF aged 6-17 years were identified as having ≥1 IP or ≥2 OP claims ≥30 days apart with a primary diagnosis of CF (ICD-9-CM: 277.0x) between 2010-2015 and ≥12 months of continuous health plan coverage. Study outcomes included IP admissions, OP office visits, and PEx events requiring IP admission and/or intravenous (IV) antibiotics, evaluated by 1-year age groups using pts’ most recent year of data. Multivariate logistic regression analyses were conducted to determine impact of age on outcomes after controlling for other demographics, common comorbidities, and medications.

RESULTS: The COMM cohort included 2,400 pts with CF (mean [SD] age: 11.9 [3.5] years) and the CAID cohort 1,264 (mean [SD] age, 11.4 [3.5] years). Proportions of pts with IP admissions increased with age: 20.7% (COMM) and 29.6% (CAID) at age 6 and 46.7% (COMM) and 49.6% (CAID) at age 17. Based on logistic regression analysis the odds of an IP admission were 1.048 and 1.063 times greater with each 1-year increase in age for COMM and CAID pts, respectively (P<0.01 for both). OP office visits remained stable with age (range in COMM, 8.8-11.2 visits; CAID, 8.4-12.6 visits). Proportions of pts with ≥1 PEx requiring IP admission/IV antibiotics were higher in older age groups: 21.9% (COMM) and 28.7% (CAID) at age 6 and 45.9% (COMM) and 50.4% (CAID) at age 17 (maximum 47.4% [COMM] and 64.8% [CAID] at age 16). PEx event rates were 0.3 and 1.1 (COMM) and 0.4 and 1.3 (CAID) per person per year at ages 6 and 17 (maximum 1.4 [COMM] and 1.6 [CAID] at age 16). Based on logistic regression analysis the odds of PEx events were 1.041 and 1.048 times greater with each 1-year increase in age for COMM and CAID pts, respectively (P<0.05 for both).

CONCLUSIONS: School-aged pts with CF incur significant HCRU at all ages. The risk of hospitalizations and PEx events increases with age, highlighting the need for treatments that slow disease progression throughout school-aged years.

SPONSORSHIP: Sponsored by Vertex Pharmaceuticals.

F00-F99 Mental and Behavioral Disorders
(e.g., Depression, Antipsychotics, Schizophrenia, Bipolar Disorder)

A Multichannel Prescriber-Directed Program Including Case Management to Reconcile Potential Opioid Overutilization
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MedImpact Health Care Systems

PROBLEM DESCRIPTION: The 2013 CMS Call Letter introduced the Overutilization Monitoring System (OMS) and directed Part D plans to employ retrospective drug utilization review and case management approaches to address potential opioid overutilization. CMS is currently considering high opioid use as quality measure for the 2019 Display Ratings and started reporting concurrent benzodiazepine (BZD) to encourage management for both drug classes.

GOAL: Two national prescription drug plans, Medicare GenerationRx and Transamerica MedicareRx, implemented a case management program, operated by MedImpact, to coordinate care and survey prescribers to limit potential opioid overuse.

PROGRAM DESCRIPTION: Starting April 2013, monthly claims analysis identified members with cumulative daily morphine equivalent dose (MED) exceeding 120 mg for at least 90 consecutive days and with ≥3 prescribers and ≥3 pharmacies. Prescribers were sent a questionnaire to attest that prescribed opioid medication(s) and current cumulative opioid dosages were appropriate, medically necessary, and safe. Prescribers were also given options to manage opiate use by limiting coverage. Available survey responses included: appropriate therapy, not aware my patient was on high doses, will refer to pain clinic, not my patient, did not prescribe these medications and/or limit quantity or type of opiate. Prescribers not responding by fax were contacted within 10 days of identification. A case management pharmacist reviewed all cases. To measure program effectiveness prescriber responses were clinically evaluated to reconcile final case outcomes.
OBSERVATIONS: A total of 617 patients were identified between April 13th and October 16th. The average daily MED was 276 mg. All prescribers responded and the most common outcome based on case management calls was ‘appropriate pain treatment’ (52%) followed by ‘overutilization resolved’ (31%) and appropriate use for cancer treatment (7%). Opioid summary rates per 1,000 members (January-October) for high dose (HD), multiple provider (MP) and HDMP were lower (27.9, 5.7, 0.3) than national Prescription Drug Plan rates (45.3, 14.1, 1.3).

FINDINGS/RECOMMENDATIONS: This program offers a solution to the OMS recommendations, supports efforts to reconcile opioid use and coordinates care with multiple prescribers. Future program components include detecting concurrent BZD-high opiate use (Phase 2), messaging prescribers of patients with 30-day overlap of opioid and BZD (Phase 3), and flexible identification techniques to address current and future opioid-related quality measures.

SPONSORSHIP: MedImpact Health Care Systems.

F2 Impact of a Managed Care Pharmacist Consultation Program on Controlled Substance Drug Cost, Emergency Room Visits, and Hospitalizations

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PROBLEM DESCRIPTION: The Comprehensive Addiction and Recovery Act of 2016 (CARA) focuses on opioid abuse prevention, including the role of a pharmacist. There is a paucity of data evaluating the impact of managed care (MC) pharmacist controlled substance (CS) programs.

GOAL: To evaluate the impact of an MC pharmacist consultation program on CS use, CS spend, emergency room (ER) visits, and hospitalizations.

PROGRAM DESCRIPTION: The intervention group was from a 1 million member commercial health plan that began MC pharmacist (75% effort) outreach in January 2015. Following a prescriber letter, the MC Pharmacist did prescriber outreach via call/fax to discuss CS regimens and suggest changes. A member’s index date was defined as the earliest outreach date in 2015. Members were required to be continuously enrolled from 6 months before (pre period) through 6 months after the index date (post period). Control members were identified as CS users among 2 commercial health plans with 3.3 million members where no outreach was performed. A generalized linear regression model was used to measure the pre to post period change between intervention and control members, with adjustment for member characteristics, pharmacy risk group score severity of illness, zip code derived sociodemographic factors and baseline CS use.

OBSERVATIONS: The intervention had 213 members with MC Pharmacist to prescriber outreach performed. The control was 1,387 members. The unadjusted intervention group CS cost per member decreased from $5,802 (pre) to $5,148 (post) and increased in the controls from $3,511 per member (pre) to $3,627 (post). The unadjusted average number of CS claims per member was 31 (pre) and 28 (post) for the intervention group compared to 30 (pre) and 27 (post) for the control group (P=0.18). Regression model adjusted results showed the intervention group had 64% fewer ER visits compared to the control group from the pre to post period. (P=0.02). The number of hospitalizations was not statistically different. Intervention group members had a significantly larger decrease in CS costs following MC pharmacist outreach compared to a control group. Post period CS drug costs were $920 lower than the pre period relative to the control group (P<0.01). The lower CS drug costs translated to an overall savings of $193,960 over the 6 month post period ($0.03 PMPM) and annualized savings of $301,920.

FINDINGS/RECOMMENDATIONS: A 75% time MC pharmacist consultation program intervening upon a small number of members resulted in a significant $0.03 PMPM CS drug cost savings. Further research across other health plans is needed to validate the findings.

SPONSORSHIP: Prime Therapeutics.

F3 Employing Bayesian-Calibrated Microsimulation to Assess the Cost-Effectiveness of Long-Acting Injectable Buprenorphine Versus Sublingual Buprenorphine to Treat Opioid Use Disorder

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ECONOMIC ANALYSIS OF BUPRENORPHINE SUBDERMAL IMPLANT VERSUS STANDARDS OF CARE FOR PRIMARYLY TREATMENT-NAIVE PRIMARILY HEROIN-ADDICTED PATIENTS WITH OPIOID USE DISORDER

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BACKGROUND: Responding to an opioid epidemic due partly to misuse of orally-administered opioids, the FDA granted fast-track status to long-acting, injectable buprenorphine (LA-BPN) for opioid use disorder (OUD). A recent 24-week Phase 3 clinical trial demonstrated that LA-BPN was non-inferior and superior to sublingual BPN (SL-BPN) in primary and key secondary endpoints, respectively.

OBJECTIVE: Given the high economic burden of opioid misuse in the United States we sought to assess the health-economic implications of an effective alternative to SL-BPN that cannot be diverted or misused.

METHODS: We developed a patient-level microsimulation to assess the incremental cost of LA-BPN per overdose avoided versus SL-BPN. Transitions occurred weekly through the following 4 health states for 24 weeks: on treatment (1) without or (2) with illicit opioid use, (3) off treatment with illicit opioid use, and (4) death. Between-state transition probabilities were derived from the pivotal Phase 3 clinical trial and were calibrated by Bayesian Monte Carlo methods to address the influence of patient characteristics. Within-state event probabilities were literature-based and included diversion/misuse, infection, hospital and rehabilitation services utilization, productivity loss, and accidental pediatric exposure. With a societal perspective, literature-based costs of within-state events, adverse events, and local reference costs for drug acquisition, administration, and monitoring were included (2016 USD). Uncertainty was assessed by deterministic and probabilistic sensitivity analysis (PSA).

RESULTS: Consistent with trial outcomes, treatment retention over 24 weeks was similar between the two groups (~58%). SL-BPN patients encountered 3% higher rates of serious adverse events, 11% more relapses, and approximately 400% greater risk of non-fatal overdose. In the majority of model simulations, LA-BPN patients incurred fewer total costs and fewer drug overdoses versus SL-BPN in the base case analysis. Deterministic sensitivity analysis identified LA-BPN drug acquisition cost and relapse-associated hospital / emergency room utilization rates as key drivers of modeled outcomes. PSA confirmed a strong likelihood of cost-savings and fewer overdoses with LA-BPN depending on initial assumptions.

CONCLUSIONS: LA-BPN may be a cost-effective alternative to SL-BPN. These findings should be interpreted carefully as they are not based on direct observation. Nevertheless, LA-BPN offers an opportunity to improve OUD clinical outcomes and reduce the societal economic burden of OUD.

SPONSORSHIP: This study was sponsored by Braeburn and Camurus AB.
BACKGROUND: Recent analyses have reported that buprenorphine subdermal implant (BSI) is pharmacoeconomically superior to sublingual buprenorphine (SL-BPN), extended-release naltrexone (XR-NTX), and methadone (MTD) for opioid use disorder (OUD). These analyses considered patients who were clinically-stable and primarily abused prescription opioids. However, a large proportion of OUD patients are treatment-naïve and primarily abuse heroin, and are traditionally more difficult to treat owing to higher rates of relapse and treatment discontinuation.

OBJECTIVE: Herein, we report an economic model comparing BSI versus SL-BPN, XR-NTX, and MTD for OUD among this more difficult to treat subgroup.

METHODS: Outcomes from OUD clinical trials populated a Bayesian network meta-analysis (NMA) to derive odds abstinence on therapy. This included 8 trials of SL-BPN, MTD, and XR-NTX and 2 BSI trials that enrolled cohorts who were primarily treatment-naïve and primarily abused heroin. NMA outcomes were used in a Markov model simulating cohort progression for 12 months (cycled monthly) through four mutually-exclusive health states: on therapy (1) with or (2) without illicit opioid use, (3) off therapy with illicit opioid use, and (4) death. In each health state, cohorts accumulated direct medical costs associated with drug acquisition, administration, diversion/misuse, and relapse; and indirect costs associated with death, lost productivity, and accidental pediatric exposure. Event risks and costs not derived from the NMA were literature based. The impact of underlying model uncertainty on outcomes was assessed by deterministic, probabilistic, and scenario sensitivity analyses.

RESULTS: BSI was also the economically advantageous therapy at a total annual cost of $23,917 versus SL-BPN ($25,723), MTD ($27,384), and XR-NTX ($35,878). Sensitivity analysis indicated that the primary driver of total annual cost—other than efficacy—was drug acquisition cost, which was the second largest contributor of costs following relapse-related hospitalizations and emergency room visits.

CONCLUSIONS: BSI was more effective and less costly than SL-BPN, MTD, and XR-NTX to treat OUD among higher risk patients. The outcomes should be interpreted somewhat cautiously given that they were based on an economic model and not entirely on direct observation in a real-world treatment setting. Nevertheless, these findings have important implications for budget-constrained providers and policymakers seeking to ameliorate the intensifying opioid abuse epidemic.

SPONSORSHIP: This study was sponsored by Braeburn Pharmaceuticals.

OBJECTIVE: To determine the impact of physician communication on the utilization of opioid medications.

METHODS: This retrospective review of de-identified pharmacy claims data was conducted at a large managed care organization in Western Pennsylvania. The study included members of the Commercial, Exchange, Medicaid, and Medicare lines of business that were continuously enrolled during the pre-intervention, suppression, and post-intervention periods. To measure the effectiveness of the DUR, the study looked at the percent of members who continued to meet the DUR criteria at nine months post-intervention. Additionally, the study compared the average daily MED each member was prescribed pre- and post-intervention and the median average daily MED pre- and post-intervention.

RESULTS: The percentage of members that continued to meet DUR criteria post-intervention was 38.5% between all intervention periods and all lines of business. 43.4% of members had a decrease in average daily MED pre- to post-intervention. The median average daily MED in the study population also decreased pre- to post-intervention.

CONCLUSIONS: The intervention resulted in a decrease of members qualifying for DUR criteria post-intervention. Also, a higher percentage of members had a decrease in the average daily MED versus an increase or no change in average daily MED from pre- to post-intervention period. Further studies should evaluate the long-term cost effectiveness of the appropriate pain management DUR, long term sustainability of decreased opioid utilization, and the impact of additional provider communication strategies.

SPONSORSHIP: None.

F5 Predictors of Opioid Use in the United States Using the National Ambulatory Medical Care Survey Data

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BACKGROUND: Addiction to prescription opioids is a major public health issue in the U.S. To our knowledge, very few studies have assessed the recent trends and predictors of opioid prescriptions in recent years. Understanding opioids prescribing patterns will contribute in strategizing provision of interventions for opioid over-prescribing and abuse.

OBJECTIVE: To investigate factors associated with the prescription of opioid analgesics among patients who have visited ambulatory care settings (2009-2013).

METHODS: This is a pooled cross sectional study using 2009-2013 National Ambulatory Medical Care Survey (NAMCS) data. Opioid prescriptions were identified through drug codes for narcotic and narcotics combination. Disease states were categorized based on ICD-9 codes. We conducted descriptive analyses using t-test, Wilcoxon Mann Whitney and chi-square tests where appropriate to assess differences in the distribution of various patient characteristics among opioid, disease states, and other prescription records. We used the multivariate logistic regression model to evaluate the association between the following factors and opioid prescriptions: demographics, number of yearly visits, total prescribed medications, reasons for visits, average physicians visit time, insurance types, physician specialties, having mental disorders, nervous system and musculoskeletal system/connective tissue diseases (statistical significance: P<0.05; 95% confidence interval).

RESULTS: A total of 15,882 from 225,234 visits included opioid prescriptions (7.05%). Statistical significant differences were observed
Among the opioid prescribed and opioid non-prescribed groups in year of visit, race, insurance types, geographic regions, physician specialty and visit reasons (P<0.0001). Opioid group was older, had more diseases, higher number of yearly visits, higher number of prescription medications and longer visit time than non-prescribed narcotic group (P<0.0001). Associated characteristics with receiving an opioid prescription included being American Indian/Alaska Natives (AIAN), male, self-paid, from Southern U.S., younger than 60 years old, having surgical care prescribers, receiving multiple medications, having at least 4 visits yearly, pre/post-surgery visit, having nervous system and musculoskeletal system/connective tissue diseases (P<0.0001).

CONCLUSIONS: Caution is advised before prescribing opioids to the population with high rate of substance abuse such as AIAN. Future studies must focus on the exact causes of the high rate of prescribing opioids in Southern U.S., young population and those who self-paid for opioids.

SPONSORSHIP: None.

F7 Prevalence of Concurrent Opioid and Benzodiazepine Use Among 19 Million Commercial Members
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BACKGROUND: Several organizations/agencies (e.g., CMS, CDC, FDA) have reported concerns about the concurrent use of opioids and benzodiazepines (BZD). Advanced knowledge around prevalence of concurrent use can help insurers plan for potential quality measures or other prescribing restrictions.

OBJECTIVE: To describe the prevalence of concurrent opioid and BZD use in a commercial population.

METHODS: Pharmacy claims data from ~19 million commercial members was queried to identify members 18 or older with 2 or more opioid claims filled on 2 or more separate days with a 15 days supply or more. Buprenorphine/naloxone combination products were excluded and opioid containing cough/cold products were included. Members were also required to have 2 or more BZD claims on 2 or more separate days. Members were assigned an index date based on the earliest opioid or BZD claim. The measurement period for examining concurrent use was defined as 30 or more cumulative days of overlap based on days supply found on the claims. Using medical claims data, concurrent use was also examined after excluding members with one or more medical claim cancer diagnosis code in 2015.

RESULTS: 3,992,900 members out of ~19 million (21.0%) had at least one opioid or BZD claim in 2015. 2,668,934 (67.8%) had only opioid claims, 674,880 (16.9%) had only BZD and 649,086 (16.3%) had both opioids and BZD. 93.2% (3,723,372) of the members were 18 or older and 884,407 (23.8%) had 2 or more opioid claims on separate days with 15 days supply or more. 234,966 (26.6%) of the 884,407 also had 2 or more BZD on separate days in 2015 with 25% (221,264) having at least 1 day of overlapping supply and 152,083 (17.2%) having 30 or more cumulative overlapping days of opioids and BZD. 107,372 (12.1%) of the 884,407 members had one or more medical claim cancer diagnosis codes. After excluding the cancer members, the rate of concurrent opioid and BZD use for 30 or more days did not change, 132,308 (17.0%) of 777,435.

CONCLUSIONS: One of every 6 commercial opioid users without cancer and 7 per 1,000 overall commercial members had evidence of concurrent opioid and BZD for 30 or more days in 2015. Combination opioids and BZD use has been shown to increase risk of overdose and death. Health insurers should consider identifying at risk members and developing clinical programs to help reduce the rate of combination use.

SPONSORSHIP: Prime Therapeutics.

F12 Budget Impact Analysis Comparing Aripiprazole and Aripiprazole Lauroxil Based on Real-World Dosage Patterns
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BACKGROUND: Aripiprazole and aripiprazole lauroxil are two long-acting injectable antipsychotics (LAIs) approved for the treatment of schizophrenia. Aripiprazole lauroxil is a prodrug of aripiprazole.

OBJECTIVE: The objective of this analysis was to evaluate the cost of utilizing aripiprazole and aripiprazole lauroxil in patients with schizophrenia based on real-world dose mix, timing, and market share information.

METHODS: An economic model based on a hypothetical health plan of 1,000,000 members was developed. The proportion of members with schizophrenia and the subset taking an LAI were based on prior research. The model estimated costs of treatment based on IMS Health market share data and wholesale average costs of the two drugs. Market share and dose mix for each LAI was based on IMS Health National Sales Perspectives™ data from October 2015 to September 2016. The dose mix for aripiprazole lauroxil 882 mg 4 weeks and 6 weeks was adjusted to match national utilization patterns based on IMS Health anonymized patient-level data from October 2015 to March 2016.

RESULTS: In a hypothetical cohort of 1,000,000 patients, 1.1% were assumed to have schizophrenia and of those, 13% would be taking an LAI. Based on market share data, 187 patients were assigned to treatment with aripiprazole while 14 were assigned to treatment with aripiprazole lauroxil. Dose mix for aripiprazole indicated that 83.9% of patients were taking the 400 mg dose while 16.1% were taking the 300 mg dose, both every 4 weeks. Both doses were taken every 4 weeks. Dose mix for aripiprazole lauroxil shown that 15.4% of patients were taking the 441 mg dose every 4 weeks, 32.4% were taking the 662 mg dose every 4 weeks, 21.2% were taking the 882 dose every 6 weeks, and 50.1% were taking the 882 mg dose every 4 weeks. The weighted average cost of treatment per patient per month was $1,784 with aripiprazole and $1,894 with aripiprazole lauroxil.

CONCLUSIONS: Use of aripiprazole lauroxil resulted in higher drug costs compared to aripiprazole in this model based on real-world dose utilization patterns.

SPONSORSHIP: This study was funded by Otsuka Pharmaceutical Development & Commercialization, and Lundbeck.
OBJECTIVE: To compare two-year hospitalization and emergency department (ED) use and costs between Medicaid schizophrenia patients after a switch in antipsychotic therapy to PP vs. OA.

METHODS: Adult patients with a diagnosis of schizophrenia (ICD-9 295.xx) and ≥ 2 claims for PP or OA from 1/1/2010 to 12/30/2014 were selected from the Truven Health MarketScan Medicaid database. Index date was assigned as the date of 2nd observed claim of PP or OAT. Patients were required to have continuous enrollment in Medicaid for ≥ 12 months prior to and ≥ 24 months after the index date and ≥ 1 pre-index OA claim. PP patients were matched 1:1 to OA patients based on propensity scores calculated from 6 month baseline demographic, clinical, resource utilization and cost variables. Quarterly, annual, and two-year antipsychotic utilization, health care resource use and costs (in 2015 dollars) were compared using t-tests for continuous variables and chi-square tests for categorical variables.

RESULTS: A total of 7,430 patients met study criteria. In the two years post-index, 51.4% were hospitalized and 74.0% had an ED visit. The study population had 6,439 OA patients and 991 PP patients, of which 55.9% were still on PP during the last 3 months of the 2-year follow-up. After matching, two cohorts of 954 each were well-balanced on baseline characteristics. Among the matched cohorts, a significantly lower proportion of PP patients relative to OA were hospitalized over two years (42.5% vs. 49.4%, P = 0.002), in year 1 (31.2% vs. 37.0%, P = 0.008) and in year 2 (26.8% vs. 31.0%, P = 0.043). Significantly lower proportions of PP vs. OA patients had ≥ 1 ED visit in two years (66.1% vs. 72.5%, P = 0.002), in year 1 (52.6% vs. 59.2%, P = 0.004) and in year 2 (48.8% vs. 54.2%, P = 0.019). Compared to two year costs for OA, PP medical costs (i.e., inpatient + outpatient + ED) were significantly lower ($43,023 vs. $48,936, P = 0.044) and PP pharmacy costs (not including rebates) were significantly higher ($32,367 vs. $21,346, P < 0.001), with no significant difference in total cost.

CONCLUSIONS: Medicaid schizophrenia patients on OA therapy who switched to PP had significantly lower two-year hospitalization and ED usage rates with no difference in total health care costs compared to matched patients switching among OA agents.

SPONSORSHIP: Research funded by Janssen Scientific Affairs.

F15 Relationship Between EMR Utilization, Health Care Quality, and Patient Outcomes: Analysis from a Nationally Representative Sample of Schizophrenia Physicians

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BACKGROUND: Use of electronic medical records (EMR) has been on the rise, but their impact on health care quality and patient outcomes remain unclear. Effective schizophrenia treatment relies on seamless care coordination between patients and physicians that may be improved through EMR use.

OBJECTIVE: The present study assessed the relationship between EMR use among a sample of schizophrenia physicians and its relationship with schizophrenia outcomes.

METHODS: Patients with schizophrenia were identified in the More2 Registry Database during calendar year 2014 via ICD-9-CM codes (295.x). Four total Health Care Effectiveness Data and Information Set (HEDIS) measures assessing various aspects of care were calculated, along with the following patient outcomes: presence of a schizophrenia inpatient admission, presence of a psychiatric ER visit, HbA1c lab values for diabetic patients, and LDL-C lab values for cardiovascular disease (CVD) patients. All outcomes were aggregated at the physician level, and physicians were flagged as EMR users or non-users. Physicians were also classified as providing high quality health care,
defined as ≥90% of their eligible patient panel meeting HEDIS measures. Relationships between EMR use, health care quality, and patient outcomes were examined at the physician level.

**RESULTS:** Within the sample of 32,178 physicians, 24.3% used EMR. Physicians using EMR systems were significantly more likely to provide high quality health care compared to physicians who did not use EMR, as evidenced by HEDIS measure performance (28.7% vs. 20.9%, P < 0.001). Further, physician provision of high quality health care was associated with improved patient outcomes including a lower mean proportion of patients with a schizophrenia hospitalization (21% vs. 28%) and psychiatric ER visit (43% vs. 53%), HbA1c values for diabetics (6.8% vs. 7.2%), and LDL-C values for patients with CVD (88.3 mg/dL vs. 92.3 mg/dL, all P < 0.01). Physicians utilizing EMR who provided high quality health care had the healthiest patient panels of all groups, with the lowest hospitalization (19.8%) and ER visit (38.3%) rates, mean diabetic HbA1c of 6.8%, and mean CVD patient LCL-C of 83.0 mg/dL.

**CONCLUSIONS:** EMR utilization by schizophrenia physicians is associated with higher quality health care and improved patient outcomes. Payers who encourage utilization of EMR systems may be able to simultaneously improve patient outcomes and HEDIS ratings and increase the quality of care received by their members.

**SPONSORSHIP:** Sunovion sponsored this study.

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**F16 Projection-Based Methods to Assess the Population Effectiveness of Once-Monthly and Once-Every-3-Months Formulations of Paliperidone Palmitate Versus Oral Antipsychotics in a Medicaid Population**

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**BACKGROUND:** Population effectiveness of long-acting injectable (LAIs) antipsychotics is unknown vs. oral antipsychotics (OA). Projection-based methods are useful for assessment of population effectiveness.

**OBJECTIVE:** This study projects impact of using paliperidone palmitate (PP) once-monthly (PP1M) and once-every-3-mos (PP3M) LAIs on all-cause (AC) and psychiatric (PSYCH) hospitalizations over 18 mos in a Medicaid population of patients with schizophrenia currently treated with OA.

**METHODS:** Decision model compared 3 treatment strategies: (1) initiating with OA and continuing on OA; (2) initiating with PP1M and continuing on PP1M if stable at 6 mos or to OA otherwise; (3) initiating with PP1M and switching to PP3M if stable at 6 mos or to OA otherwise. Data from 2 different clinical trials were used to inform the first 6-mo outcomes vs. outcomes in stable patients over the next 12 mos. Primary outcome was PSYCH hospitalizations. We also studied AC hospitalizations and time to discontinuation. Outcomes from each arm and time spent within an arm were reweighted to reflect distribution of patient characteristics found in the multi-state Medicaid claims database against inclusion/exclusion criteria similar to those of the PRIDE trial, a randomized, pragmatically oriented study of PP1M vs. OA. Several validation exercises were carried out to ensure that reweighted results could reproduce observed outcomes in the Medicaid population.

**RESULTS:** In the real-world population (N = 4609), the PP1M to PP1M strategy is projected to produce a per-patient decrease of 0.28 (95% confidence interval [CI]: -0.28, 0.84) and 0.27 (95% CI: -0.43, 0.97) in AC- and PSYCH-related hospitalizations, respectively, compared to initiating treatments with OA. Similarly, PP1M to PP3M is projected to produce per-patient decreases of 0.31 (95% CI: -0.27, 0.87) in both AC- and PSYCH-related hospitalizations over initiating with OA. Validation exercises support the reweighting methodology used to replicate observed outcomes in the Medicaid population. These incremental estimates could translate into potential savings of ~$1.2 billion for the 4M Medicaid patients diagnosed with schizophrenia and treated with OA over an 18-mo period, based on a 100% conversion rate from OA to LAIs.

**CONCLUSIONS:** Using PP1M and PP3M to treat schizophrenia patients in the Medicaid population could lead to large savings through reduced hospitalizations. These savings plus improvements in patients’ health should be accounted for in order to properly assess the value of LAIs.

**SPONSORSHIP:** This study was funded by Janssen Scientific Affairs.
CMC-related utilization of inpatient and long-term care services were lower in patients on PP1M.

SPONSORSHIP: Supported by Janssen Scientific Affairs.

**F18 Economic Utility: Combinatorial Pharmacogenomics and Medication Cost Savings for Mental Health Care in a Primary Care Setting**

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**BACKGROUND:** Major depressive disorder affects 6.8% of the U.S. population and has direct costs of $98.9 billion a year. Psychiatric medications alone cost $30.3 billion per year. Half of patients who seek treatment for depression are expected to respond to their first antidepressant, and the rest often experience many medication failures. Because of medication challenges, some clinicians now use pharmacogenomics to guide treatment and help avoid genetically discordant medications. Combinatorial pharmacogenomic testing has been shown clinically to predict medication response better than single gene testing. The only psychiatric combinatorial pharmacogenomic testing platform with multiple prospective clinical trials supporting its clinical validity and utility over treatment as usual is the GeneSight Psychotropic test powered by CPGx technology (Assurex Health, Mason, OH). A study by the pharmacy benefits manager Medco reviewed over 13,000 patients, and prospectively yielded a medication cost savings of $1,036 per member per year when treatment was guided by GeneSight. This study presents subanalysis data on medication cost savings for patients and payors based on treatment by psychiatrists and non-psychiatrists.

**OBJECTIVE:** To evaluate direct health care costs, indirect workloss-related costs, and employment status change in TRD.

**METHODS:** A U.S. health care claims database of privately-insured employees was used to identify adults diagnosed with major depressive disorder (MDD; ICD-9-CM: 296.2-296.3) between 1/2010-3/2015. Using a claims-based algorithm, TRD patients were required to have changed their antidepressant treatment regimen at least twice at an adequate dosage and duration (≥6 weeks). TRD patients were matched 1:1 to two control cohorts (employees with MDD and without MDD) based on demographics and workloss data availability. Outcomes were measured up to 2 years post-index date (i.e., defined as the 1st antidepressant claim [TRD and MDD cohorts] or randomly imputed [non-MDD]). Costs, health care resource utilization (HRU), and employment status change (i.e., termination or COBRA) were compared using ordinary least squares (P-value obtained using a nonparametric bootstrap), negative binomial, and Cox regression, respectively. Cost and HRU comparisons were adjusted for comorbidity index and baseline health care costs.

**RESULTS:** A total of 2,800 employees with TRD (1,908 with workless data) were selected. Employees with TRD had more direct HRU than either control cohort (e.g., 1.8 and 4.7-times the rate of inpatient visits vs. employees with MDD and without MDD, respectively; all P < 0.001). Furthermore, employees with TRD had higher per patient per year (PPPY) direct health care costs: $5,817 more than employees with MDD and $8,931 more than employees without MDD (all P < 0.001). Employees with TRD had 35.8 workloss days PPPY on average (25.8 disability and 10.0 medical-related absenteeism days), which was 1.7 and 6.2-times the rate of workloss days in employees with and without MDD, respectively. Consequently, TRD was associated with higher PPPY workloss-related costs: $1,811 more than employees with MDD and $3,460 more than employees without MDD (all P < 0.001). Lastly, employees with TRD were more likely to change employment status than employees with MDD (hazard ratio [HR]: 1.28, P = 0.019) or without MDD (HR: 1.37, P = 0.004).

**CONCLUSIONS:** TRD poses a significant direct and indirect cost burden to U.S. employers even when compared to MDD, and may also be associated with higher rates of employment status change.

**SPONSORSHIP:** Supported by Janssen Scientific Affairs.

**F19 Direct and Indirect Cost Burden and Change of Employment Status Among Employees with Treatment-Resistant Depression in the United States**

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**BACKGROUND:** Treatment-resistant depression (TRD) poses a substantial burden to health care payers including employers, costing an estimated $29–48B yearly in the U.S. However, the impact of TRD on employment status remains unexplored.

**OBJECTIVE:** To evaluate direct health care costs, indirect workloss-related costs, and employment status change in TRD.

**METHODS:** A U.S. health care claims database of privately-insured employees was used to identify adults diagnosed with major depressive disorder (MDD; ICD-9-CM: 296.2-296.3) between 1/2010-3/2015. Using a claims-based algorithm, TRD patients were required to have changed their antidepressant treatment regimen at least twice at an adequate dosage and duration (≥6 weeks). TRD patients were matched 1:1 to two control cohorts (employees with MDD and without MDD) based on demographics and workloss data availability. Outcomes were measured up to 2 years post-index date (i.e., defined as the 1st antidepressant claim [TRD and MDD cohorts] or randomly imputed [non-MDD]). Costs, health care resource utilization (HRU), and employment status change (i.e., termination or COBRA) were compared using ordinary least squares (P-value obtained using a nonparametric bootstrap), negative binomial, and Cox regression, respectively. Cost and HRU comparisons were adjusted for comorbidity index and baseline health care costs.

**RESULTS:** A total of 2,800 employees with TRD (1,908 with workless data) were selected. Employees with TRD had more direct HRU than either control cohort (e.g., 1.8 and 4.7-times the rate of inpatient visits vs. employees with MDD and without MDD, respectively; all P < 0.001). Furthermore, employees with TRD had higher per patient per year (PPPY) direct health care costs: $5,817 more than employees with MDD and $8,931 more than employees without MDD (all P < 0.001). Employees with TRD had 35.8 workloss days PPPY on average (25.8 disability and 10.0 medical-related absenteeism days), which was 1.7 and 6.2-times the rate of workloss days in employees with and without MDD, respectively. Consequently, TRD was associated with higher PPPY workloss-related costs: $1,811 more than employees with MDD and $3,460 more than employees without MDD (all P < 0.001). Lastly, employees with TRD were more likely to change employment status than employees with MDD (hazard ratio [HR]: 1.28, P = 0.019) or without MDD (HR: 1.37, P = 0.004).

**CONCLUSIONS:** TRD poses a significant direct and indirect cost burden to U.S. employers even when compared to MDD, and may also be associated with higher rates of employment status change.

**SPONSORSHIP:** Supported by Janssen Scientific Affairs.
considered depression, remission and recovery, and disease progression through 3 phases: acute (2 months), maintenance (6-8 months), and recovery (2-4 months). Patients were followed for up to 3 treatment lines after switching ADs. Published data were used for comparative efficacy (2-month remission and withdrawal due to adverse events), tolerability, and relapse information. A societal perspective was adopted. Direct costs and indirect costs due to absenteeism were considered in 2015 U.S. dollars. Utilities associated with health states and disutilities related to short- and long-term adverse events were included. The main outcome was the incremental cost-effectiveness ratio (ICER). Sensitivity analyses were conducted.

RESULTS: The total costs of managing patients with MDD switching from their first AD were highest in patients treated with levomilnacipran ($6,763), followed by vortioxetine ($6,615) and vilazodone ($6,294). Direct costs were >60% of total costs. The percentage of patients in recovery after the initial line of treatment was highest for vortioxetine (34.1%) followed by vilazodone (28.8%) and levomilnacipran (28.3%). Vortioxetine was the most cost-effective AD based on quality-adjusted life year (QALY) analyses (additional QALY: 0.0083 vs. vilazodone and 0.0070 vs. levomilnacipran). Vortioxetine was more cost-effective than levomilnacipran and comparable to vilazodone (ICER: $38,608/QALY). Similar results were found when only direct costs were considered. Sensitivity analyses found that the cost-effectiveness probability was 75% at a $50,000 willingness-to-pay threshold (lower limit of the recommended U.S.-based threshold).

CONCLUSIONS: In these U.S.-setting analyses, vortioxetine was comparable in efficacy and cost to levomilnacipran and was cost-effective vs. vilazodone for treating patients with MDD after switching from a first AD. Vortioxetine may be beneficial for patients with MDD who switch from their current generic AD treatment.

SPONSORSHIP: Lundbeck/Takeda.

F25 Comparing the Medication-Specific Child Core Set Among Commercial Health Plans, Managed Medicaid, and Marketplace Children in 2015

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BACKGROUND: As a central component of the overall DHHS strategy for implementing Children's Health Insurance Program Reauthorization (CHIPRA), the Agency for Health Care Research and Quality (AHRQ) recently announced a new initiative called the AHRQ-CHS Pediatric Quality Measures Program, which supported State Medicaid/CHIP agencies in collecting and reporting data on a core set of standardized child health quality measures. In order to better monitor the quality of medication management among young population, quality measures should be validated by multiple data sources.

OBJECTIVE: To compare the quality of children's health care, especially on medication management, among Commercial, managed Medicaid and Marketplace populations.

METHODS: Data were extracted from a large nationally representative and statistically de-identified administrative database, Inovalon’s MORE2 Registry. We assessed the following quality measures for the 2015 measurement year: (1) APC, the percentage of children ages 1-17 who were on ≥2 concurrent antipsychotic medications; (2) MMA, the percentage of children ages 5-20 who were identified as having persistent asthma and remained on an asthma controller medication for ≥50% percent or ≥75% of their treatment period; (3) ADD, the percentage of children ages 6-12 newly prescribed ADHD medication who had one follow-up visit with practitioner during the 30-day initiation phase and who had at least two follow-up visits within 9 months after the initiation phase ended.

RESULTS: A total of 3,662 children met the selection criteria for APC-50% with commercial insurance; 46% managed Medicaid; and 4% Marketplace members. Respectively, 2%, 3% and 6% had 2 or more concurrent antipsychotic medications. For the MMA measure, we identified 8,150 children with persistent asthma; the percent of children that remained on the medication at least 75% of the treatment period were 27%, 25% and 27% respectively. Out of 7,091 children identified for the ADD measure, the percent of children with 1 follow-up visit during the initiation phase was 19% and 28% of children had at least 2 follow-up visits during the continuation phase.

CONCLUSIONS: Our results demonstrate the feasibility of using the MORE2 Registry to investigate plan performance on the Medication-Specific Child Core Set measures released by DHHS. The performance of plans varied by payer (whether Commercial, Medicaid, or Marketplace), suggesting that there are differences in health service delivery, although the source of the variation has to be investigated.

SPONSORSHIP: Inovalon.

F28 Association Between Physician Care Coordination and the Use of Psychotropic Polypharmacy in the Management of Pediatric Mental Disorders

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BACKGROUND: Psychotropic polypharmacy has been a main safety concern in the management of pediatric mental disorders. Although seeing multiple providers has been identified as an important predictor for the receipt of polypharmacy, no study has yet assessed the impact of care-coordination between providers.

OBJECTIVE: To examine the association between the intensity of care-coordination within a patient’s care team and the likelihood of the patient receiving psychotropic polypharmacy.

METHODS: A retrospective cross-sectional study was conducted using the 2013-2015 administrative claims data from a Medicaid Managed Care Organization (Texas Children’s Health Plan). The study included individuals: (a) ≥ 18 years of age, (b) diagnosed with a mental disorder, and (c) received psychotropic prescriptions from multiple prescribers. Psychotropic polypharmacy (PP) was defined as the receipt of ≥2 psychotropic medications from different drug classes concurrently for 60 days or more. Care coordination was measured using Care-density (CD), a surrogate included in the AHRQ Care Coordination Measures Atlas, calculated as the ratio of the sum of patients shared by physician pairs within a patient’s care team to the total number of physician pairs. Guided by Andersen behavioral model, multivariate logistic regression analyses were conducted to assess the association between CD and patients’ likelihood of receiving PP after controlling for predisposing and need factors.

RESULTS: A total of 24,147 children and adolescents diagnosed with a mental disorder were identified. Nearly half (n = 11,102; 45.98%) of these individuals received medications prescribed by multiple providers. Logistic regression analysis showed a significant association between care density and the use of psychotropic polypharmacy. However, the direction of this relationship varied depending on the composition of the patient’s care team. Among patients with only PCPs involved in their care team, patients in the higher CD group were 84% less likely to receive PP (OR=0.136, 95% CI 0.056-0.432) than those in low CD group. In contrast, among patients who had both PCPs and specialists involved in their care team, those in the higher CD group were 2.4 times more likely to experience PP (OR=2.44; 95%
BACKGROUND: The average delay in ALS diagnosis is one year after the appearance of the first symptom. This prolonged diagnostic time is detrimental as it delays initiating approved treatments and may preclude patients from enrolling in clinical trials.

OBJECTIVE: Big data analytics of a large claims database may identify early predictors of ALS and potentially shorten the diagnosis timeline.

METHODS: The Truven MarketScan database, containing patient-level claims for 170+ million patients, was used without any code pre-selection for this analysis. A mutual information (MI) measure was used to quantify the statistical relevance of every code in MarketScan as a future ALS diagnosis in four U.S. states. Codes considered include patient demographics, labs, diagnosis codes, procedure codes, medications, standard provider types, and standard care facility types. An ensemble suite of classifiers developed employing machine learning techniques were applied to the MarketScan claims database to optimize the selection and ranking of ALS diagnosis predictors. We specifically looked for predictors within the following time brackets: 3, 6, 9, 12, 18, 24, 36, 48, and 60 months before the initial ALS diagnosis.

RESULTS: The ALS ICD-9 diagnosis code identified 12,332 ALS patients with an average of 4.4 years of claims history in the national dataset. Average age was 60 years ± 14 years; male gender represented 58% of ALS patients, and 25% had a prescription claim for riluzole. The top differentiating diagnoses that are more common in the ALS group compared to the overall population were: non-traumatic joint disorders (-60 months), connective tissue diseases (-60 months), skin disorders (-48 months), fatigue (-36 months), lower respiratory diseases (-24 months), gastrointestinal disorders (-18 months) and other nervous system disorders (-12 months).

CONCLUSIONS: This study suggests that 5 years before ALS is diagnosed, patients may be presenting with symptoms suggestive of connective tissue disorders, skin disorders, and nonspecific neurological complaints. Based on claims data review, features that differentiate potential ALS patients before diagnosis may allow clinicians to diagnose ALS. The next steps of this project are to validate these findings in the national dataset, optimize the algorithm differentiating ALS patients prior to diagnosis, and further characterize early predictors of ALS.

SPONSORSHIP: MTPA provided support for the analyses and abstract development.
RESULTS: 2,047 HDAC patients were identified, with 14% currently treated with TBZ (n = 295 TBZ, n = 1,752 other medications). Over 50% of HDAC patients taking TBZ were covered by federal insurance. For the dosing analysis, the data set yielded 126 patients with ≥ 1 TBZ prescription record and signature information. The average daily dose was ≤ 50 mg in 80% and ≤ 37.5 mg in 63% of patients; 72% were instructed to take their medication once or twice a day. The most common daily dose in patients initiated on TBZ was 25 mg. For the antidepressant dosing analysis, 180 patients with nonmissing information were identified, 93 (52%) of whom had evidence of antidepressant use. Of these, 47 (51%) initiated antidepressants only after TBZ initiation. A total of 122 patients (67.8%) either discontinued TBZ or switched to another therapy during the study period (start of each patient’s medical record to 10/7/2016). The most frequent neurological- or psychiatric-related diagnoses in these 122 patients were depression (39%), dysphagia (36%), major depressive disorder (one episode) (29%), insomnia (23%), mood disorder (20%), and psychotic disorder (19%).

CONCLUSIONS: This descriptive study using EMR data provides insights into the real-world use of TBZ in HDAC patients. The findings of low use of TBZ treatments, high rates of discontinuation or switching of TBZ, and lower-than-expected mean daily doses highlight an unmet need for alternative chorea treatment options with improved risk–benefit profiles in these HD patients.

SPONSORSHIP: This study was supported by Teva Pharmaceuticals Industries.

### G9 Health Care Utilization and Costs for Patients with Tardive Dyskinesia

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BACKGROUND: Tardive dyskinesia (TD), an often-irreversible movement disorder, can affect any part of the body and is often debilitating. TD is caused by prolonged use of the neuroleptic (antipsychotic) drugs that are frequently prescribed for psychiatric disorders. The estimated prevalence of TD is 15-30% among patients on antipsychotics, and the reported incidence of TD in this same patient population ranges from < 1% to 24% depending on the antipsychotics under study. Furthermore, patients with TD are known to have lower quality of life. To date, very few studies on the economic burden of TD have used real-world data.

OBJECTIVE: To assess health care utilization and costs pre- and post-TD diagnosis in a sample of patients from the commercially insured and Medicare Supplemental U.S. populations.

METHODS: A retrospective cohort analysis was conducted using Truven MarketScan Commercial and Medicare administrative claims data. For each patient included in the analysis, the index date was set as the first TD diagnosis between 1/1/2008 and 9/30/2014. Patients included must have had ≥ 12 months of both pre- and post-index medical and pharmacy continuous enrollment, ≥ 1 inpatient (IP) or ≥ 2 outpatient (OP) non-diagnostic claims for TD (ICD-9 CM 333.85), and no evidence of TD claims during the pre-index period. Descriptive statistics on the incidence of resource utilization and costs of health care were reported.

RESULTS: Of 1,020 patients (mean age of 63.7 years) included in the analysis, 301 (49.1%) patients had commercial insurance and 519 (50.9%) had Medicare. Patients generally had significantly greater utilization during the 12 months after TD diagnosis as compared with the 12 months before TD diagnosis. During the post-TD-diagnosis time, IP admissions occurred for more patients (54.9% vs. 37.3%, P < 0.001) and more frequently for individual patients (mean 1.8 visits vs. 0.7 visits; P < 0.001), and had longer lengths of stay (mean 4.7 days vs. 3.0 days; P < 0.001) than in the pre-TD-diagnosis time. Emergency room visits also occurred for more patients (59.6% vs. 51.8%, P < 0.001) and more frequently for individual patients (mean 1.8 visits vs. 1.5 visits; P = 0.023) during the post-TD-diagnosis time versus the pre-TD-diagnosis time. Total health care costs were significantly greater ($55,980 vs. $40,418; P < 0.001) during the post-TD-diagnosis time than in the pre-TD-diagnosis time.

CONCLUSIONS: Patients identified as being diagnosed with TD demonstrate significantly higher health care utilization and costs in the 12 months after diagnosis compared with the 12 months before diagnosis.

SPONSORSHIP: Supported by Teva Pharmaceutical Industries.
**G10**

**ADS-5102 (Amantadine Hydrochloride) Extended-Release Capsules Improve Clinician’s Global Impression of Change in Activities of Daily Living by Reducing Levodopa-Induced Dyskinesia in Parkinson’s Disease (EASE LID Study)**

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**BACKGROUND:** Dyskinesia is a complication of levodopa therapy marked by involuntary non-rhythmic, purposeless, unpredictable movements during waking hours. It is associated with negative impacts on QoL, burden of care and health care costs. No FDA-approved drug exists to treat it. ADS-5102 is in development for treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson’s disease (PD).

**OBJECTIVE:** Investigate 340 mg of ADS-5102 taken once daily at bedtime to reduce LID and evaluate its effect on activities of daily living (ADLs) and Clinician’s Global Impression of Change (CGI-C).

**METHODS:** A 25-week, double-blind, placebo-controlled study of 126 PD subjects with LID randomized 1:1 to placebo or ADS-5102 (NCT02136914). Primary outcome measure was the Unified Dyskinesia Rating Scale (UDysRS). Key secondary outcome measures included ON time without troublesome dyskinesia and OFF time based on 24-hour PD home diaries. Pre-specified secondary measure included CGI-C in overall PD symptoms, including but not limited to LID. A post-hoc analysis to evaluate the effect of ADS-5102 on ADLs (as reported in UDysRS Part 1B) was also performed.

**RESULTS:** MITT population included 121 subjects—63 treated with ADS-5102, 58 with placebo. The study met its primary endpoint. Least squares (LS) mean treatment difference of change from baseline to Week 12 in UDysRS total score was -7.9 (P = 0.0009). The Week 12 placebo-adjusted outcomes in diary states were: ON time without troublesome dyskinesia increased by 2.8 hours (P < 0.0001); OFF time decreased by 0.9 hours (P = 0.017); ON time with troublesome dyskinesia decreased by 1.6 hours (P = 0.003). ADS-5102 improved ADLs compared to placebo by reducing the UDysRS Part 1B total score at Week 12—LS mean treatment difference: -3.0, P < 0.012. An approximate 25% improvement was shown in ADS-5102 treated patients vs. placebo in the following ADLs: public and social settings, walking and balance, exciting and emotional settings, and chewing and swallowing. CGI-C results showed that 51 patients (81%) in the ADS-5102 group and 21 patients (36%) in the placebo group were assessed as improved in overall PD symptoms including dyskinesia at week 12. The most frequent AEs were hallucinations, peripheral edema, dizzyness, dry mouth, constipation, and falls. Treatment discontinuations due to AEs occurred in 21% of ADS-5102 patients vs. 7% with placebo.

**CONCLUSIONS:** The reduction in LID in patients with PD was demonstrated by patient diaries along with improvement in CGI-C and ADLs. These results warrant further evaluation of the effect of ADS-5102 on QoL, caregiver burden and health care costs in PD patients with LID.

**SPONSORSHIP:** Supported by Adamas Pharmaceuticals.

**G11**

**Systematic Review of Valbenazine and Tetrabenazine for Treatment of Tardive Dyskinesia**

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**BACKGROUND:** Tardive dyskinesia (TD) is a persistent movement disorder associated with antipsychotic therapy for which there is no approved treatment. Tetrabenazine (TBZ), a vesicular monoamine transporter 2 (VMAT2) inhibitor, is prescribed off-label for TD, but a novel, highly selective VMAT2 inhibitor, valbenazine (VBZ), has shown promising efficacy and tolerability.

**OBJECTIVE:** Systematically review the safety and efficacy of VBZ and TBZ for the treatment of TD.

**METHODS:** A systematic literature search for clinical trials of VBZ and TBZ in the treatment of TD was performed using Pubmed, Embase, OVID, and Google Scholar (1980 to September 2016). Data were collected for study design, sample size, study sites, comparators, efficacy and safety measures.

**RESULTS:** Of 479 search results, 10 studies met the criteria for systematic review. In 7 open-label, observational studies with mixed designs and outcome measures (total N = 473), moderate or marked clinical improvement was reported in 42% to 89% of TD patients treated with TBZ (mean dose range, 39–175 mg/day [ thrice-daily dosage]). One uncontrolled, single-blind trial with standardized Abnormal Involuntary Movement Scale (AIMS) video scoring reported a 54.2% decrease in AIMS mean score from 17.9 (SD = 4.4) to 8.2 (SD = 5.3) (P < 0.001) in 19 TD patients receiving TBZ (mean dose, 58 mg/day TID; mean duration, 20 weeks). Two studies of once-daily VBZ (KINET 2 and KINET 3, total N = 325) were multi-site, randomized, placebo (PBO)-controlled trials using the AIMS (assessed by blinded centralized videotape raters) as the primary efficacy measure. After 6 weeks, treatment with VBZ led to a mean AIMS score change of -3.6 vs. -1.1 for PBO (KINET 2), and -3.2 (80 mg) and -1.9 (40 mg) vs. -0.1 for PBO (KINET 3; P < 0.01, both trials). 6-week treatment with VBZ also led to higher AIMS 50% responder rates (≥ 50% score decrease from baseline): 48.9% vs. 18.2% for PBO (KINET 2); 40.0% (80 mg) and 23.8% (40 mg) vs. PBO (8.7%; KINET 3; P < 0.05, both trials). The most common adverse events (AEs) reported with TBZ were parkinsonism, akathisia, sedation, insomnia, and worsening of mood (depression, anxiety). The most common AEs reported with VBZ were fatigue, headache, and decreased appetite, with no significant differences in extrapyramidal or psychiatric measures compared to PBO.

**CONCLUSIONS:** Two randomized PBO-controlled trials support the efficacy of VBZ in reducing TD severity. No direct comparisons can be made between VBZ and TBZ trial results, but VBZ may have fewer side effects in addition to a more favorable once-daily dosing regimen for the treatment of TD.

**SPONSORSHIP:** Neurocrine Biosciences.

**G12**

**Hospitalizations and Emergency Department Visits in Patients with Parkinson’s Disease in the United States: A National Perspective**

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**BACKGROUND:** Parkinson’s disease (PD) is the second most common neurodegenerative disorder affecting as many as one million Americans. Previous studies reported that patients with PD have high rates of ED visits and hospitalizations, but few recent national estimates are available.

**OBJECTIVE:** To study the utilization of emergency department (ED) and hospitalization visits in patients with PD in the U.S.

**METHODS:** We examined the prevalence and characteristics of all ED visits and hospitalizations with diagnosis of Parkinson’s disease (ICD-9 code 332.0) in the U.S. community population in 2013 using
the Nationwide Emergency Department Sample (NEDS) and the National Inpatient Sample (NIS) databases. NEDS is a 20-percent stratified sample of all U.S. hospital-based EDs and is the largest all-payer emergency department database in the United States. NIS is a stratified random sample of all U.S. community hospitals. It is the largest inpatient care database with information on all inpatient care regardless of insurance status. Prevalence of ED visits and hospitalizations was calculated using population statistics of U.S. taken from U.S. Census Bureau (2013 estimates).

RESULTS: In 2013, there were 134.8 million all-cause ED visits in the U.S., with a prevalence of 42,662 visits per 100,000 population. PD patients accounted for 408,830 ED visits (129 visits/100,000 population/year). One-half of these ED visits resulted in hospitalization. Men accounted for 55.2% of the ED visits (prevalence 149/100,000/year vs. 114/100,000/year in women). Although prevalence increased with age, over 14% of ED visits were in patients younger than 65 years of age. Medicare paid for 85.7% of these visits while Medicaid paid for 3.5% of these visits. There were 271,520 hospitalizations in patients with PD. Approximately 10% of these were directly related to a primary diagnosis of PD. Men accounted for 55.8% of hospitalizations (prevalence 97/100,000/year vs. 75/100,000/year in women). Medicare paid for 87.2% of hospitalizations.

CONCLUSIONS: In this study, PD patients had a substantial number of ED visits and hospitalizations in the U.S. Nearly 14% of ED visits and 12% of hospitalizations were among patients younger than 65 years of age, suggesting a potential impact on work-loss and productivity.

SPONSORSHIP: Funding for this sponsored research was provided by Acorda Therapeutics.

G18 Cost-Effectiveness of Alemtuzumab in the Treatment of Relapsing Forms of Multiple Sclerosis in the United States

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BACKGROUND: Relapsing multiple sclerosis (RMS) is a neuro-degenerative disease associated with significant clinical, economic, and humanistic burden. Several disease modifying treatment options are available for RMS but evidence is lacking regarding the cost-effectiveness (CE) of new high efficacy therapies such as alemtuzumab.

OBJECTIVE: To evaluate PROs by prior use of DMDs in patients with MS.

METHODS: A Markov CE model with annual cycles and 20-year time horizon was run from a U.S. managed care perspective. The modeled RMS population represented the demographics and clinical characteristics of pooled treatment-naive and -experienced patients from the CARE-MS I and CARE-MS II trials. The comparative efficacy of therapies at reducing relapses and slowing disability worsening was obtained from a published network meta-analysis. Relative treatment safety information was extracted from package inserts. Published studies and clinical expert opinion were used to derive withdrawal rates, treatment waning, resource use, and utility inputs. To project the natural history of disease progression, data from the British Columbia Multiple Sclerosis (BCMS) longitudinal observational cohort was used.

RESULTS: Alemtuzumab dominated comparators by accumulating higher total QALYs (8.851) and lower total costs ($421,996) compared to NAT (8.456; $1,048,599) and FIN (7.955; $1,085,814). Patients on alemtuzumab had the lowest total number of relapses. The CE dominance of alemtuzumab was mostly driven by savings in treatment acquisition costs as alemtuzumab has long-term durable effect and is administered over only 2 annual courses while other comparators need to be used daily or monthly on a chronic basis. In conservative model scenarios where the long-term durable effect of alemtuzumab is assumed not to hold and the therapy has to be administered annually, probabilistic sensitivity analyses showed that alemtuzumab remained cost-effective versus NAT at a CE threshold of $100,000/QALY in 92%-100% of all model runs.

CONCLUSIONS: Patients on alemtuzumab accrued lower incremental total costs and higher incremental number of QALYs than other comparators over a time-horizon of 20 years. Model results should be used to optimize clinical and managed care decisions for the patients with RMS.

SPONSORSHIP: Sanofi Genzyme.

G19 Prior Disease-Modifying Drug Use and the Relationship with Patient-Reported Outcomes

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BACKGROUND: Patient-reported outcome (PRO) measurement in multiple sclerosis (MS) can provide valuable information as it captures the patient perspective, complementing and supporting the meaningfulness of clinical or economic outcomes. Understanding the relationship between PROs and prior disease-modifying drug (DMD) use may provide insights into treatment patterns and patient characteristics.

OBJECTIVE: To evaluate PROs by prior use of DMDs in patients with MS.

METHODS: Data were obtained from patients with MS from the U.S. National Health and Wellness Survey or Lightspeed Research panel and its affiliates who completed a 30-minute Internet survey from April to October 2015. Questions about demographics, disease severity, prior and current DMD use, symptoms, comorbidities, quality of life (QoL), and life satisfaction were included. The Patient-Determined Disease Steps (PDDS) scale assessed MS disease status/disability; the Multiple Sclerosis Rating Scale, Revised (MSRS-R) assessed self-reported functional disability; and the MS Quality of Life questionnaire (MSQoL) assessed disease-specific patient QoL. Patients were grouped based on prior DMD use: no prior use, use of 1, 2, or ≥3 prior DMDs.

RESULTS: A total of 902 survey respondents reported currently using DMDs: 311 (34.5%) reported no DMD use prior to the current DMD; 296 (32.8%) reported prior use of 1 DMD; 154 (17.1%) reported prior use of 2 DMDs; and 141 (15.6%) reported prior use of ≥3 DMDs. Compared to patients without prior DMD use, those with prior DMD use were younger when their symptoms started, younger at the time of MS diagnosis, and younger when first treated (P < 0.05). A higher number of prior DMDs was associated with self-reported prior relapse, presence of MS symptoms, greater functional disability, and worse QoL (P < 0.05). Life satisfaction did not differ significantly between patients with and without prior DMD use. A greater proportion of patients with no prior DMD use reported treatment with a self-injectable (66.6%, P < 0.01), while a greater proportion with prior DMD treatment were currently receiving treatment with oral DMDs or infusion therapies (55.7%, P < 0.001).

CONCLUSIONS: Many patients with MS report prior DMD use, with almost one-third reporting ≥2 DMDs. Those with prior DMD use had greater disability and worse QoL, yet no difference in life satisfaction vs. patients with no prior DMD use.

SPONSORSHIP: EMD Serono.
Impact of Multiple Sclerosis Relapse Severity on Health Care Costs

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BACKGROUND: A multiple sclerosis (MS) relapse is a new neurologic symptom which lasts greater than 24 hours in the absence of fever or infection. Relapses are the clinical hallmark of relapsing remitting multiple sclerosis (RRMS) and contribute to neurologic disability as recovery is variable. Relapses often require additional medical visits and treatment based on severity, which implies differential health care costs.

OBJECTIVE: To estimate the medical care costs associated with MS relapse severity, under the perspective of private payers in the U.S.

METHODS: Newly diagnosed adult MS patients (ICD-9-CM: 340.x) from a large U.S. insurance claims database between 2011 and 2015 were included in the analysis. These patients were stratified into three cohorts: no relapse, low/moderate relapse, and severe relapse, according to the Chastek validated claims-based algorithm. A severe relapse is characterized by a hospitalization with a principal diagnosis of MS. A low/moderate relapse is characterized by an outpatient or emergency room visit with a diagnosis of MS followed by a corticosteroid pharmacy or medical claim within 7 days. The incremental all-cause and MS-related medical costs between the year prior to and the year post relapse for each cohort were estimated, adjusted for age, gender, region, insurance type and year of identification. Costs included inpatient, outpatient, emergency room and pharmacy spending.

RESULTS: Among the 9,597 MS patients identified, the mean age was 48.3, 75.6% were women, 84.8% had a fee-for-service insurance. Geographically, 34.5% lived in the South, 30.6% in the North Central, 17% in the Northeast and 17% in the West. In terms of severity of relapses, 7,054 (73.5%) had no relapses, 2,013 (21%) had low/moderate relapses, and 330 (3.5%) had severe relapses. Compared to the no relapse cohort, the mean and standard deviation of incremental all-cause and MS related costs were $8,680 ($909) and $7,587 ($1,185) higher for the low/moderate relapse cohort and $36,938 ($1,758) and $32,731 ($2,103) higher for severe relapse cohort, respectively.

CONCLUSIONS: In a large retrospective analysis of insurance claims across 3.5 years, relapse severity was significantly and positively associated with higher medical costs. Providing MS patients with access to disease-modifying treatments that are effective in decreasing the number and severity of relapses is likely to lower medical costs.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.

The Burden of Relapsing-Remitting Multiple Sclerosis on Workers in the United States: A Cross-Sectional Analysis of Survey Data

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BACKGROUND: Real-world studies that assess the impact of Relapsing Remitting Multiple Sclerosis (RRMS) on individuals’ ability to maintain employment and performance at work are limited.

OBJECTIVE: To assess the burden of RRMS on the work productivity and health resource utilization of persons with MS (pwMS).

METHODS: Data were drawn from the 2015-2016 U.S. National Health and Wellness Surveys (NHWS). Individuals who reported a diagnosis of RRMS were propensity matched to individuals without a diagnosis of MS at a 1:1 comparison to target ratio on: year of survey, age, gender, household income, marital status, education, health insurance, body mass index, experience of anxiety, sleep problems, and depression (past 12 months), alcohol use, smoking status, exercise status, and comorbidity burden as assessed by the Charlson Comorbidity Index. A separate match was conducted with employed RRMS respondents as the target group. Respondents in each match were then compared on chronic conditions for which there are multiple established therapies. Here, the cost-effectiveness of fingolimod as an oral therapy for relapsing-remitting multiple sclerosis (RRMS) versus intramuscularly-administered interferon beta-1a (Avonex) has been explored, with and without the inclusion of price reductions following a potential loss of exclusivity (LOE).

OBJECTIVE: To investigate the impact of including price reductions following LOE into health economic models, using disease-modifying therapies for RRMS as an example.

METHODS: The model was adopted from a previously published model and was conducted from a U.S. payer’s perspective over a 10-year time horizon. Outcomes included per-patient total direct costs (medication, administration and monitoring, disease-related costs including relapses) and quality-adjusted life years (QALYs), and the incremental cost per QALY. Price reductions on LOE were based on published, historical estimates for oral medicines (fingolimod) and the relative prices of branded and generic injectables already available for use in RRMS (Avonex). Scenario analyses were conducted to test assumptions regarding LOE, including the proportion of patients switching to generic versions.

RESULTS: Assuming no price reductions following LOE, fingolimod was considered cost-effective versus Avonex (QALYs: 4.99 fingolimod vs. 4.77 Avonex; incremental: $139,219 per QALY, fingolimod vs. Avonex), despite having higher total direct costs than Avonex over 10 years (costs: $485,820 fingolimod vs. $454,628 Avonex). Including future price reductions following LOE, total direct costs were reduced with fingolimod and were lower than those accrued with Avonex over the model time horizon ($327,536 fingolimod vs. $451,583 Avonex).

CONCLUSIONS: These analyses demonstrate the importance of including future price reductions following LOE into health economic models and show how the costs associated with established therapies may be overestimated if LOE is not considered. In some cases, the inclusion of LOE may determine whether or not an intervention is considered cost-effective and as such may influence reimbursement decisions based on cost-effectiveness analyses.

SPONSORSHIP: Novartis Pharmaceuticals.
a number of health outcomes including health care utilization (physician visits, emergency room [ER] visits, and hospitalizations), work productivity and activity impairment (WPAI: 6-item validated scale that assesses work and activity impairment).

**RESULTS:** Individuals with RRMS (n = 543) compared to matched controls (n = 2,172) were more likely to use health care resources (% used past 6 months: ER = 21.4% vs. 15.1%, Hospitalized = 13.1% vs. 8.7%, HCP = 95.9% vs. 87.0%; P < 0.05) and to use them more often than non-RRMS patients (average # of HCP visits in past 6 months = 6.29 vs. 4.83, P < 0.05). They were also more likely to report time lost work time and being more unproductive while at work (% lost in last 7 days: absenteeism = 12.3% vs. 6.0%, presenteeism = 33.4% vs. 19.7%, P < 0.05). Moreover, they also reported more impairment in their day-to-day activities (% lost in last 7 days: 50.2% vs. 28.7%; P < 0.05). Results of the separate match within employed RRMS respondents showed a similar pattern of results-increased health care resource use and activity impairment among the employed RRMS group (n = 196) relative to employed controls (n = 784).

**CONCLUSIONS:** This research suggests that RRMS has a substantial impact on work productivity and increased health care resource utilization.

**SPONSORSHIP:** Novartis provided funding for this analysis.

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**G23 The Burden of Relapsing-Remitting Multiple Sclerosis on Individuals in the Labor Force**

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**BACKGROUND:** Real-world studies that assess the impact of Relapsing Remitting Multiple Sclerosis (RRMS) on persons with MS (pwMS) in the labor force are limited.

**OBJECTIVE:** To assess the burden of RRMS on individuals in the labor force, especially among those who are employed and experience varying levels of impairment.

**METHODS:** Data were drawn from the 2015-2016 U.S. National Health and Wellness Surveys (NHWS). PwMS who reported a diagnosis of RRMS were divided into two groups, labor force participant (LFP=employed full time, part time, self-employed, or not employed but looking for work) and not labor force participant (non-LFP), and were compared on health outcomes. A second analysis focused on tertiles of work impairment in the past 7 days (no impairment, tertile1 = 1-30%, tertile2 = 31-68%, tertile3 = 69-100% impairment) among employed participants (LFP minus “not employed but looking for work”). Outcomes examined included health care utilization (physician visits, emergency room [ER] visits, and hospitalizations), activity impairment (WPAI: validated scale assessing work and activity impairment), and health-related quality of life (SF-36).

**RESULTS:** LFP pwMS (n = 211) were younger (mean age: 45.6 vs. 52.7 years), had higher incomes (% < $50k/yr: 62.1 vs. 39.8%), and were more likely to have a college degree (50.2 vs. 29.5%; P < 0.05) than non-LFP pwMS (n = 332). LFP pwMS had higher mental quality of life (44.8 vs. 43.7) and less activity impairment (P = 0.001) than non-LFP pwMS. LFP pwMS rated their RRMS as less severe than non-LFP respondents. Impairment of employed respondents showed clear negative trends for mental (no impairment = 54.0, tertile1 = 47.8, tertile2 = 38.5, tertile3 = 38.0) and physical component summary scores (no impairment = 50.4, tertile1 = 45.7, tertile2 = 41.8, tertile3 = 37.3) and positive trends for activity impairment (no impairment = 5.1%, tertile1 = 24.4%, tertile2 = 54.8%, tertile3 = 75.7%), and resource use (% of HCP visits: no impairment = 3.2, tertile1 = 3.9, tertile2 = 6.6, tertile3 = 8.4).

**CONCLUSIONS:** This research suggests that individuals with RRMS in the labor force have better outcomes than those not in the labor force, however this association may be because those respondents in the labor force have less severe RRMS than those not in the labor force. Within employed respondents there appears to be an association between increased impairment and humanistic burden.

**SPONSORSHIP:** Novartis provided funding for this analysis.

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**G24 Multiple Sclerosis Medication Adherence Within Walgreens Local Specialty Pharmacies Is Significantly Higher Compared to Other Class-of-Trade Pharmacies**

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**BACKGROUND:** Walgreens local specialty pharmacies (LSPs) are on health system campuses and located in select communities that focus on managing complex chronic health conditions such as cancer, HIV/AIDS, hepatitis C, multiple sclerosis, CID, transplant and cystic fibrosis in addition to others. For multiple sclerosis (MS) patients, LSPs provide personalized, comprehensive pharmacy care, copay assistance and have access to therapies, even those with a limited distribution label.

**OBJECTIVE:** To compare patient adherence for MS medication therapies for patients treated at Walgreens LSPs to patients treated at food stores, mass merchandisers, independent pharmacies, traditional Walgreens pharmacies or other chain stores (i.e., Class of Trade, CoT). A second objective compared the same cohort of MS patients’ adherence to non-specialty drug treatment groups of oral antidiabetics, antihypertensives, and antihyperlipidemics from LSPs to the other pharmacies (i.e., CoT).

**METHODS:** QuintilesIMS conducted a retrospective cohort design using their longitudinal retail prescription database (LRx) that includes pharmacy claims information across CoT. Inclusion criteria required patients to be exclusive to the Walgreens cohorts and compared to exclusive CoT patients from January 2015 through December 2015. Additional requirements included patient having at least two sold MS medications and being least 18 years of age. MS medications included were glatiramer acetate, interferon beta-1a, interferon beta-1b, peginterferon beta-1a, teriflunomide, alemtuzumab, natalizumab, dimethyl fumarate, dalfampridine, and fingolimod HCl. Proportion of days covered (PDC) was calculated at the drug subclass level and then overall as either a weighted average or average level of adherence. For the three comorbid conditions, PDCs were calculated at the same subclass level, but reported at the drug group level, using the weighted average approach.

**RESULTS:** For MS medications, mean PDC in Walgreens LSPs (M = 78.5) was significantly higher than the CoT cohorts (P < 0.0001; mean CoT PDC ranged from 75.0 to 72.1). Also the adherence rate (percent of patients with PDC ≥ 80%) was significantly higher in Walgreens LSP compared to CoT cohorts (P < 0.0001). Mean PDC levels indicated no significant differences between cohorts for antihypertensives or antihyperlipidemics.

**CONCLUSIONS:** Patients utilizing Walgreens LSPs for their MS medications were significantly more adherent to these medications than other Class of Trade pharmacies and similar to CoT pharmacies in levels of adherence to antihypertensives or antihyperlipidemics.

**SPONSORSHIP:** Walgreen Co and QuintilesIMS.
**G25 Subcutaneous Immunoglobulin to Treat Chronic Inflammatory Demyelinating Polyneuropathy: The Costs to Payers**

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**SPONSORSHIP:** This study was funded by Grifols SSNA, a manufacturer of Gamunex-C.

**BACKGROUND:** The intravenous (IV) forms of Gamunex-C/Gammaked (GAM) are the only immunoglobulin (IG) formulations approved in the U.S. for the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

**OBJECTIVE:** Subcutaneous (SC) IG has been gaining popularity in PIDD as an alternative route of administration based on its claims of convenience and cost savings from self-administration. However, recent analyses have shown that these cost savings do not exist in the U.S. Therefore, we wanted to investigate what costs would look like for payers if SCIG were used to treat CIDP.

**METHODS:** A basic cost calculator was developed from the PATH study protocol to assess the economic impact of SCIG (Hizentra) use in the treatment of CIDP, comparing the two PATH study Hizentra maintenance treatment arms to a GAM regimen. For all calculations, patient weight was set at 80 kg. The 3 treatment regimens were: 0.2 g/kg (SC2) and 0.4 g/kg (SC4) of Hizentra administered weekly and 1 g/kg (IV1) of GAM administered every 3 weeks. Since SC was administered every week and IV every 3 weeks, all comparisons were set to a 3 week cost period. PATH SCIG infusion rates were 35 mL/h with maximum site volumes of 50 mL. IV1 rate was 250 mL/h. WAC costs per gram on December 1, 2016 were used: GAM ($105) and Hizentra ($168) for economic calculations. Customary and common infusion reimbursement costs used (supplies) for SC were $20 and for IV $300 (supplies and nursing) per infusion.

**RESULTS:** Three-week period doses for each product were 0.6 for SC2, 1.2 for SC4, and 1.0 g/kg for IV1. Total product volumes infused for each IG product were computed to be 240, 480, and 800 mL for SC2, SC4 and IV1, respectively. These volumes resulted in 3-week period IG product costs of $8,064 for SC2, $16,128 for SC4 and $8,400 for IV1. When the costs of administration were added to each route of administration, total costs increased to $8,124 for SC2, $16,188 for SC4, and $8,700 for IV1.

**CONCLUSIONS:** This economic calculator of SC versus IV at current WAC pricing uncovers the plausible cost impact of SC in the treatment of CIDP; demonstrating that if low doses of Hizentra are utilized in a CIDP population, costs would most likely be at price parity with current Gamunex-C therapy. However, if the larger dose of Hizentra is required, costs to a payer could nearly double.

**SPONSORSHIP:** This study was funded by Grifols SSNA, a manufacturer of Gamunex-C.

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**G26 Implementing a Pharmacist-Led Multiple Sclerosis Specialty Pharmacy Clinical Outreach Program**

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**SPONSORSHIP:** U.S. Specialty Care.

**PROBLEM DESCRIPTION:** Multiple sclerosis (MS) is a chronic and complicated disease that requires a multi-factorial treatment approach to achieve the best clinical outcomes. Improved communication among pharmacy providers, patients, and providers is necessary to achieve the best clinical outcomes.

**GOAL:** To improve the overall care of patients living with MS through a pharmacist-led clinical outreach program.

**PROGRAM DESCRIPTION:** The program focuses on improving patient education, enhancing care coordination, facilitating provider communication, and enabling more robust reporting of patients’ responses to treatment. Clinical pharmacists review patient care plans, collect clinical data, and evaluate medication adherence during monthly refill calls. They also perform quarterly assessments and compile quarterly reports based on all the information collected during calls with patients and share their findings with the prescribing provider. Providers also receive an annual report that includes the patient’s medication adherence history, MS exacerbations, hospitalizations, missed work days, risk factors, and quality of life measures. Throughout treatment, the provider is alerted if a patient falls below an 80% medication adherence rate or whenever a patient is 30 or 60 days late refilling their medication.

**OBSERVATIONS:** Quarterly assessments have been completed on approximately one-half of our MS population. Most patients participating in this program were diagnosed with MS at least eight years ago and had experienced one to three lifetime relapses. The majority of participants had an expanded disability status scale (EDSS) score of 6 or less. The most common symptoms experienced were fatigue, difficulty with balance, and muscle weakness. Only one patient reported missing work due to MS. About 40% of the patients reported that MS slightly affects their daily living activities, and over 95% of patients report not experiencing an exacerbation. To date, the average PDC for MS patients increased from 89% to 91%. Since the program began, the adherence rate has not fallen below 80% for any of the MS patients.

**FINDINGS/RECOMMENDATIONS:** Patient and provider feedback regarding the program has been positive. Several providers expressed that the information provided in the reports is useful in guiding discussions with their patients during visits. Outcomes reporting of the effects of the program on newly diagnosed patients will be a focus in the coming year, as well as tailoring provider reports based on their feedback.

**G27 Comparative Effectiveness of Delayed-Release Dimethyl Fumarate Versus Fingolimod and Teriflunomide on Risk of Relapse**

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**BACKGROUND:** Comparative effectiveness research on disease modifying therapies (DMTs) using real-world data can better reflect the value of a therapy in routine clinical practice; however, such data are still limited due to the only recent availability of oral DMTs.

**OBJECTIVE:** To compare the risk of relapse after initiation of oral delayed-release dimethyl fumarate (DMF), fingolimod (FTY), or teriflunomide (TER) using real world data.

**METHODS:** Adult MS patients (18-64 years) who initiated an oral DMT between January 1, 2013, and September 30, 2015, were identified in MarketScan, a U.S. commercial insurance claims database. Patients were followed until disenrollment from the health plan or September 30, 2015. Kaplan-Meier curves were plotted to compare the risk of relapses over the follow-up period. In addition, a Cox proportional hazard model was built to estimate the relative risk of relapse among patients initiating FTY or TER vs. DMF after adjusting for demographics, baseline comorbidities, MS symptoms, prior DMT use, and pre-index annualized relapse rate (ARR). The analysis included all eligible patients and was stratified by receipt of DMTs in the prior year.
RESULTS: A total of 5,600, 1,110, and 795 patients, respectively, initiated DMF, FTY, and TER. Differences were observed in mean age at initiation, proportion receiving an alternate DMT in the prior year and average follow-up (years) after initiation. In the overall study cohort, no difference in risk of relapse was observed between FTY vs. DMF following initiation of treatment (HR: 0.995; \(P = 0.94\)), whereas TER was associated with a 30% (HR: 1.302; \(P < 0.01\)) increased risk relative to DMF. Similar findings were observed in the subgroups stratified by receipt of DMT in the prior year (newly-treated or switching patients).

CONCLUSIONS: In this retrospective study, no difference in risk of relapse between FTY and DMF was evident, whereas TER was associated with a significantly higher risk of relapse, relative to DMF. Results were consistent among newly-treated and switching patient subgroups.

SPONSORSHIP: Biogen.

G29 Hospital Readmissions in Epilepsy Patients: A U.S. National Perspective
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BACKGROUND: Readmission rates are an indicator of the quality of care that patients receive during a hospital admission and after discharge. There is little data on hospital readmission rates in patients with uncontrolled seizures.

OBJECTIVE: To examine hospital readmissions in patients 18 years and older after an index hospitalization for primary diagnosis of epilepsy.

METHODS: We examined all hospitalizations in the State of California from 2005-2011 in patients 18 years or older, using California State Inpatient Database. Index hospitalizations with primary diagnosis of epilepsy (ICD-9 code 345 and 780.39) were identified. Readmission was calculated as the first subsequent unscheduled hospital admission for any cause within 30, 60 and 90 days following an index stay.

RESULTS: There were 27 million all-cause hospitalizations and 160,249 hospitalizations for primary diagnosis of epilepsy from January 2005-December 2011. Of these, 15,910 (15.6%), 22,626 (22.5%), and 26,830 (27%), resulted in readmissions in 30, 60 and 90 days, respectively. Readmission rates were highest in 45-64 years age group, in Native Americans and African-Americans (P < 0.001 for all comparisons). White Caucasian populations had lowest readmission rates. Patients covered by Medicaid had higher readmission rates (18%, 27% and 32% at 30, 60 and 90 days, respectively) as compared to those with Medicare (17%, 25% and 30%) and Private Insurance (11%, 15% and 18%). Patients in the poorest income quartile had higher readmission rates than the richest income quartile (P < 0.001).

CONCLUSIONS: Hospital readmission rates are high in patients with epilepsy, indicating a need for better in-patient management and post discharge care. We identified specific population groups at greater risk for readmissions (ages 45-64, Native Americans and African Americans, persons in lower income quartiles and those on Medicaid).

More effective education regarding their disease management and better follow up care after hospitalization is needed to reduce the health care disparity in these populations.

SPONSORSHIP: This study was supported by a research grant from Acorda Therapeutics.

G30 Burden of Epilepsy in the Medicare Population
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BACKGROUND: One out of every three epilepsy patients have been shown to have uncontrolled seizures and may incur significant health care costs. Recent demographic trends in epilepsy also suggest that patients aged ≥ 60 represent the fastest growing segment, which may potentially impose a disproportionate economic burden on Medicare. However, the economic burden of epilepsy among Medicare beneficiaries is currently not fully known.

OBJECTIVE: To estimate the prevalence of epilepsy, and to assess clinical and economic burden of epilepsy among Medicare beneficiaries.

METHODS: The Medicare 5% sample claims data from 2013-2014 were used for this retrospective study. Medicare fee-for-service beneficiaries having > 1 month of eligibility in 2014 (index year) and 12 months of eligibility in 2013, and continuously enrolled in Part A and B were included. Identification of epilepsy required > 1 claim with an epilepsy diagnosis (ICD-9: 345.00-345.51, 345.70-345.91) or ≥ 2 claims at least 30 days apart with a primary or secondary convolution diagnosis (ICD-9: 780.33 or 780.39) during 2014. Comorbid conditions, annual inpatient admission rate, 30-day readmission rate, and per-patient-per-month (PPPM) costs were compared between the epilepsy and non-epilepsy populations, CMS Hierarchical Condition Category (HCC) scoring was used to compare cost on a risk adjusted basis at the population level. Differences between epilepsy vs. non-epilepsy groups were evaluated using T-tests.

RESULTS: From a total of 1,435,275 eligible Medicare beneficiaries, 37,418 patients with epilepsy were identified (prevalence: 2.6%). Patients with epilepsy were younger (63.3 vs. 71.8 years) with a higher proportion of males (47.5% vs. 44.6%), compared to non-epilepsy patients. The epilepsy population had a higher prevalence of schizophrenia/bipolar/major depressive disorder (23.3% vs. 8.0%), cognitive impairment (28.0% vs. 9.8%), cerebrovascular disease (36.7% vs. 14.0%), and falls and fractures (28.2% vs. 13.5%). The annual all-cause, medical and psychiatric inpatient admission rates were 3.3, 3.6, and 6.7 times higher, respectively, among epilepsy vs. non-epilepsy patients. Thirty-day readmission rates were higher among epilepsy patients (31.4% vs. 19.4%). The incremental risk adjusted cost of epilepsy was $909 PPPM. All comparisons \(P < 0.001\).

CONCLUSIONS: In this retrospective claims analysis of Medicare beneficiaries, patients with epilepsy had a higher burden of medical and psychiatric comorbidities, inpatient admissions, readmissions, and costs, compared with beneficiaries without epilepsy.

SPONSORSHIP: Sunovion Pharmaceuticals.

G31 Dosage Titration of AED Treatments and Related Health Care Resource Use and Costs: A Retrospective Chart Review in the United States
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BACKGROUND: Little is known about the real-world impact of anti-epileptic drug (AED) titration on health care resource use (HRU) and costs.

OBJECTIVE: To explore the relationship between AEDs and HRU and costs during AED titration and maintenance.
OBJECTIVE: To determine whether titration vs. maintenance periods are associated with increased health care costs in patients with epilepsy. Health care spending was measured as the difference between outpatient, specialty medication, and total health care spending in each 90-day period following index. PDC was measured using standard methods.

RESULTS: A total of 187,421 beneficiaries across 5,159 plans met the eligibility criteria; 54% were female; 42% of beneficiaries were 45-65 years of age. The most common plan type was PPO (66%). Across all post-index 90-day periods, the mean (SD) PDC was 0.85 (0.26), mean (SD) epilepsy-specific hospitalizations, outpatient visits, and ED visits were 0.02 (0.13), 0.54 (0.47), and 0.05 (0.22), respectively. Median (IQR) overall spending in a 90-day period was $1,848 ($597-$5,569); median overall epilepsy-specific spending was $140 ($84-$559). In multivariable linear regression models without health plan fixed effects, higher OOP spending was associated with a decrease in PDC (coefficient -0.008 [95% CI -0.009, -0.006]; P < 0.001), and increases in overall plan (coefficient 194.5 [0.8, 388.1], P < 0.05) and epilepsy-specific spending (coefficient 93.9 [54.1, 133.7], P = 0.0001). Health plan fixed effects model estimates were similar though confidence intervals were wider.

CONCLUSIONS: Increased co-insurance costs shifted to epilepsy patients leads to higher overall spending and lower PDC.

SPONSORSHIP: Sponsored by UCB Pharma.

G33 Utilization Patterns of Topiramate Formulations in Epilepsy and Migraine: Analysis of Administrative Claims Comparing Trokendi XR (Extended-Release Topiramate) and Immediate-Release Topiramate

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BACKGROUND: Successful therapy in chronic disorders such as epilepsy and migraine depends on adherence and persistence with treatment, which can be influenced by tolerability and dosing frequency. Several studies suggested the potential for better tolerability, including fewer cognitive effects, and greater adherence with once-daily (OD) Trokendi XR (extended-release topiramate) vs. its immediate-release topiramate (TPM-IR) counterpart dosed BID.

OBJECTIVE: Use national administrative claims database to compare adherence and persistence patterns associated with use of Trokendi XR vs. TPM-IR in epilepsy and migraine populations.

METHODS: Medical and pharmacy claims data were retrieved from HealthCore Integrated Research Database. Key inclusion criteria were initial prescription (index claim) between 8/1/2013 and 10/31/2014, patients ≥ 6 yrs old, continuous health plan enrollment ≥ 12 months pre-index and ≥ 6 months post-index, and epilepsy or migraine diagnosis. Adherence was measured as medication possession ratio (MPR). Persistence was assessed with Kaplan-Meier survival analysis. Claims for potential drug-related complications served as proxies for adverse events (AEs).

RESULTS: Analysis populations: 9,064 migraineurs (Trokendi XR, 468, TPM-IR, 8956); 1,463 epilepsy patients (Trokendi XR, 99, TPM-IR, 1364). Migraine: Persistence significantly (P < 0.001) favored Trokendi XR. Mean (SD) time to discontinuation was 7.7 (0.36) months with Trokendi XR vs. 6.4 (0.08) months for TPM-IR. Average MPR was significantly greater (P < 0.001) with Trokendi XR (52%) vs. TPM-IR (43%) in epilepsy. Persistence significantly (P = 0.005) favored Trokendi XR. Mean (SD) time to discontinuation was 9.7 (0.82) months with
Trokedni XR vs. 7.5 (0.22) months for TPM-IR. Average MPR was significantly greater (P<0.001) with Trokedni XR (65%) vs. TPM-IR (50%). In both populations, the difference in persistence emerged within first 2 months; claims for potential drug-related complications (AEs) tended to be lower with Trokedni XR vs. TPM-IR.

CONCLUSIONS: In this retrospective claims-based study, initiation of Trokedni XR was associated with greater persistence and adherence vs. TPM-IR in migraineurs and epilepsy patients. Better overall tolerability and adherence with Trokedni XR may have influenced the improved persistence observed early on since the peak period of CNS and cognitive AE occurrence with TPM-IR has historically been the first several months of treatment. Analyses of larger datasets and prospective studies are needed to confirm these observations.

SPONSORSHIP: Supernus Pharmaceuticals.

G37 Utilizing Electronic Health Records to Assess the Severity and Impact of Chronic Pain

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BACKGROUND: The management of chronic noncancer pain can be improved by the systematic, consistent use of multidimensional assessment tools. Measurement of several dimensions of pain may alert busy clinicians to significant comorbid disorders before poor outcomes and treatment failures disappoint and frustrate both patients and providers. The use of technology may facilitate data capture.

OBJECTIVE: To describe common pain conditions and their impact on patient general well-being, function, and resource utilization through use of a multidimensional assessment tool administered via electronic health record (EHR).

METHODS: A multidimensional chronic pain assessment tool (CPAT) was devised for use in this retrospective, cross-sectional study. The CPAT consisted of separately validated questions to assess pain severity, function interference, pain duration, anxiety/depression, and risk for opioid abuse. The CPAT was built into a multispecialty medical group’s EHR and administered by pain specialists to adult patients with noncancer pain who were currently receiving, or being considered for opioid therapy.

RESULTS: The CPAT was administered to a total of 216 patients between January and July, 2016. 198 patients were included in the final analysis. Of those, the average pain intensity score was 6.7 (0-10), average function interference due to pain was 6.1 (0-10), and the average composite CPAT score was 18.8 (0-58). The patient population as a whole reported a low likelihood of depression, anxiety, and risk for opioid abuse as measured by the PHQ-4 (avg. anxiety 2.1, avg. depression 1.9) and ORT (avg. 2.1). Lower back pain (81%), back pain (71%), joint pain (44%), and fibromyalgia (43%) were the most frequently identified chronic pain conditions. Three or more co-morbid chronic pain conditions were noted in 86% of patients. Analysis comparing the average # of encounters/month for 12 months prior to CPAT administration to 6 months post administration demonstrated a significant decrease from 1.96/pt/month to 1.67/pt/month (P=0.013).

CONCLUSIONS: The treatment of chronic pain can be improved through multidimensional assessment. The inclusion of the CPAT into an EHR facilitated the capture and tracking of pain attributes such as severity, function, anxiety, depression, and opioid abuse risk potential. This tool provides valuable information at the point of care that can assist with pain management strategies as well as provide broader chronic pain type and prevalence information. Important next steps include discussions to further the relevance, effectiveness and validity of this research.

SPONSORSHIP: Pfizer.

H00-H95 Diseases of the Eye and Adnexa

(e.g., Macular Degeneration)

H1 Burden of Noninfectious Inflammatory Eye Diseases: A Systematic Literature Review

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BACKGROUND: Non-infectious inflammatory eye diseases (IEDs), although rare, can have detrimental effects. Treatment goals are to prevent vision loss, reduce inflammation, and minimize complications.

OBJECTIVE: To conduct a systematic literature review on the burden of IED, focusing on clinical and economic outcomes across all treatment options.

METHODS: Scientific literature databases accessed via the Ovid search platform (Wolters Kluwer) included MEDLINE, Embase, Cochrane libraries, Health Technology Assessment, and the NHS Economic Evaluation database. The search strategy targeted clinical and economic outcomes research in 2009-2016, and excluded conference abstracts and papers assessing pediatrics. Titles and abstracts resulting from inclusion criteria were screened, and two reviewers independently extracted relevant information from the selected full-text articles.

RESULTS: The review included 39 studies (21 clinical trials, 7 database analyses, 6 systematic literature reviews, 3 chart reviews, and 2 patient surveys), assessing steroids, immunosuppressants, implants, and biologics. Mainstay therapy was corticosteroids delivered via topical, oral, intravitreal, or peri-bulbar routes. Prevalence of treatment related adverse events is notable: glaucoma (3%-65%), cataracts (2%-91%), retinal detachment (11%), hyperglycemia (25%), and ocular hypertension (12-28%). In particular, patients treated with corticosteroids had significantly higher rates of glaucoma, cataracts, cytokoid macular degeneration, and retinal detachments than other treatment options. The average annual cost of IED patients was between $13,728 to $32,268 in 2009 dollars, or 3.1 to 8.3 times the cost of patients without IED. Inpatient admissions were 83% higher for patients receiving corticosteroid treatment than those receiving biologics: 24 vs. 44 admissions per month per 1,000 patients. Implants, as compared to systemic therapies, are associated with higher up-front costs ($43,100 vs. $8,100 during first 6 months), requirements of close monitoring, potential need for implant removal, and increased rates of adverse ocular events, including cataract surgery (80% vs. 31%) and IOP-lowering surgery (26% vs. 4%).

CONCLUSIONS: IEDs are rare conditions that impact quality of life, and threaten a patient’s vision; however, the treatment can be ineffective, with many of the same adverse ocular outcomes that treatments are supposed to prevent. Further research is needed to more fully explore the burden of IED and treatment-related adverse events, and that more proactive treatment intensification may be warranted.

SPONSORSHIP: Sponsored by Mallinckrodt Pharmaceuticals.

I00-I99 Diseases of the Circulatory System

(e.g., Atrial Fibrillation, ACS, Pulmonary Hypertension)

H10 Statins Are Differentially Sensitive to the Medication Possession Ratio

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BACKGROUND: Examination of the medication possession ratio (MPR) is a common method of assessing patient adherence to a prescribed drug regimen. When defining adherence in a binary manner, an MPR of 0.8 is often used as the threshold between adherence and non-adherence. However, this threshold for adherence is somewhat arbitrary, and dosing regimens corresponding to MPR 0.8 may not provide a satisfactory clinical effect for all drugs.

OBJECTIVE: The objective of this study was to demonstrate that the MPR corresponding to adherence may differ between drugs within the same class.

METHODS: We used pharmacokinetic/pharmacodynamic (PK/PD) modeling to predict serum levels of low-density lipoprotein cholesterol (LDL-C) in patients taking simvastatin 20 mg or atorvastatin 5 mg once daily for 30 days. Model parameters were derived from published sources. Real-world dosing regimens corresponding to MPR values of 1.0, 0.8, 0.6, 0.4, and 0.2 were obtained from an online database of medication event monitoring system data. The effect of MPR on LDL-C reduction was assessed within a cardiovascular prevention scenario in which a patient with an initial LDL-C level of 100 mg/dL took simvastatin or atorvastatin to achieve an LDL-C goal of <70 mg/dL. The results were expressed as the percentage of time spent at the LDL-C goal. Adherence was defined as any dosing regimen that facilitated attainment of the LDL-C goal for the same amount of time as perfect adherence (i.e., MPR 1.0), subject to a z-test of proportions.

RESULTS: For simvastatin 20 mg, the dosing regimen corresponding to MPR 0.8 resulted in a significant loss of time at the LDL-C goal compared to MPR 1.0 (54.8% versus 85.1%; P < 0.001), and MPRs < 0.8 resulted in progressively less time at goal (21.1%, 8.3%, and 0.0%, for MPRs 0.6, 0.4, and 0.2, respectively). For atorvastatin 5 mg, MPRs 0.8 and 0.6 allowed attainment of the LDL goal for essentially the same amount of time as MPR 1.0 (87.8% and 87.7%, respectively, versus 88.1%; P > 0.05 for both), with a reduction of time at goal only occurring at MPRs < 0.4 (63.5% for MPR 0.4 and 22.4% for MPR 0.2; P < 0.001 for both).

CONCLUSIONS: In PK/PD simulations, statins exhibited differential sensitivity to the MPR, with simvastatin requiring an MPR > 0.8 to maintain clinical effectiveness, while atorvastatin did so with MPR values ≥ 0.6. These findings suggest that an MPR of 0.8 cannot be applied as a universal threshold for adherence and demonstrate the usefulness of PK/PD modeling for determining the correct MPR threshold.

SPONSORSHIP: None.

13 A Systematic Review of Cost-Effectiveness Analyses of Antihypertensive Medications

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BACKGROUND: Many cost-effectiveness analyses (CEA) of antihypertensives have been published, but a systematic review has not been available.

OBJECTIVE: To conduct a systematic review of the CEA of antihypertensives.

METHODS: Based on the PRISMA guidelines, we searched Pubmed, Embase, Cochrane library, and Health Technology Assessment to identify original CEA published in 1990-2016. Results were summarized by drug class and antihypertensive class (ACEIs, angiotensin receptor blockers (ARBs), calcium channel blockers (CCBs), thiazide-type diuretics, beta-blockers, and others). The incremental cost-effectiveness ratio (ICER) was adjusted to the 2016 U.S. dollar.

RESULTS: Among 76 studies reviewed, 26 studies compared the cost-effectiveness of medications with no treatment, 29 studies compared between drug classes, 13 studies compared within drug class, and eight studies compared combination therapies. All antihypertensives were cost-effective compared to no treatment (ICERs: dominant to $35,670/quality-adjusted life year [QALY]). Between drug classes, nine studies compared ARBs and CCBs; ARBs were more cost-effective than CCBs (ICERs: dominant to $43,714/QALY) (e.g., eprosartan vs. amlodipine) in seven studies, while CCBs were more cost-effective than ARBs (ICERs: dominant to $1,606/QALY) (e.g., amlodipine vs. valsartan) in two studies. When comparing ARBs with ACEIs or beta-blockers, ARBs were more cost-effective than ACEIs (ICERs: dominant to $43,715/QALY) (e.g., eprosartan vs. enalapril) and beta-blockers (ICERs: dominant to $5,774/QALY) (e.g., losartan vs. atenolol) in all nine studies.

CONCLUSIONS: Although all antihypertensives were cost-effective compared to no treatment, ARBs appeared to be more cost-effective.
than ACEIs and beta-blockers. However, caution should be taken due to publication bias and the heterogeneity of study setting.

**SPONSORSHIP:** None.

### 14 A Motivational Interviewing Intervention by Pharmacy Students to Improve Medication Adherence

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**BACKGROUND:** Patients with comorbid Diabetes (DM) and hypertension (HTN) are at high risk for developing micro and macrovascular complications. Angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) are recommended for these patients, having shown to reduce such complications. However, adherence remains suboptimal, compromising the potential benefit. Interventions to improve adherence are greatly needed. Motivational interviewing (MI) is a patient-centered collaborative communication style utilized to strengthen internal motivation for change that may prove effective in enhancing adherence.

**OBJECTIVE:** To demonstrate the benefit of an MI telephonic intervention conducted by pharmacy students to improve adherence to ACEIs/ARBs among Medicare Advantage Plan (MAP) patients with DM and HTN.

**METHODS:** A randomized trial was conducted among patients enrolled in a Texas MAP. Patients with DM and HTN who filled a prescription for an ACEI/ARB during June, 2014 were included. Patients with a 6-month proportion of days covered (PDC)<0.80 in the previous 6 months were determined to be non-adherent and randomized to an intervention or control group. The intervention was a phone call by pharmacy students on rotation at the MAP followed by 5 monthly follow-up calls. Prior to implementing calls, 11 participating students attended a 3-day MI training. Patients receiving calls were randomly selected from those randomized to intervention until 250 was reached; 500 controls were randomly selected from controls. Refill data during the 6-month post-intervention were evaluated using 2 outcomes: PDC and PDC<0.80 vs. not. Multivariate linear and logistic regression models were constructed to control for imbalances in baseline characteristics including age, gender, number of medications, regimen complexity, low income subsidy status, prescriber specialty, comorbidities, 6-month prior hospitalization, baseline 6-month PDC, and Centers for Medicare and Medicaid Services risk score.

**RESULTS:** 743 patients were included in multivariate models. Patients completing ≥3 calls were more likely to be adherent in both linear (β=0.0604, P<0.001) and logistic model (OR, 1.53; 95% CI: 1.02-2.28, P=0.009). Other significant factors included baseline PDC, depression and number of medications.

**CONCLUSIONS:** The MI phone intervention by students was effective in improving adherence during the 6 months following initial call. Future research should examine the sustainability of intervention effect for longer periods and its influence on clinical outcomes.

**SPONSORSHIP:** Pharmaceutical Research and Manufacturers of America Foundation.

### 18 Time to Approval in Patients Requesting Access to PCSK9i Therapy by Payer Type

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1Excel Medical Clinical Trials; 2Amgen; 3QuintilesIMS

**BACKGROUND:** Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9is) have demonstrated unprecedented reductions in LDL-C for patients uncontrolled by statin and/or ezetimibe. Payers often restrict access to new therapies with utilization management criteria that are more restrictive than the approved indications, and that may lead to longer wait times for patients requesting these therapies.

**OBJECTIVE:** The goal of this study was to compare time to approval for a PCSK9i among Medicare beneficiaries and commercially insured patients.

**METHODS:** This is a retrospective cohort study of patients requesting evolocumab and/or alirocumab in the IMS Formulary Impact Analyzer (FIA) database (7/29/15-7/15/16). FIA is a nationally representative transactional claims database of paid, rejected, and reversed
prescription claims. Patients were required to have ≥30 days of follow-up to allow time for prescription adjudication. Time from first submission to approval and the percentage of patients who filled their prescription post-approval were evaluated.

**RESULTS:** There were 44,234 new prescriptions for PCSK9i during the study period. Overall, the approval rate (within 1-year) was 30% for commercially insured and 57% for Medicare patients requesting reimbursement for a PCSK9i. The mean (SD) time to approval was 20.3 days (39.8) for commercially insured, and 16.1 days (29.9) for Medicare patients. Nearly 60% of commercial and 57% of Medicare patients approved were approved within 7-days, however 91% of commercial and 17% of Medicare patients were approved between 31-60 days after their initial request. 10.3% of commercial and 11.9% of Medicare patients waited for more than 60-days for approval. Nearly three quarters (74.4%) of approved, commercially insured patients filled their prescription, compared to only 60.3% of approved, Medicare patients. Fill rates were relatively constant over time for both groups.

**CONCLUSIONS:** The approval rate for PCSK9is was low for both payer types but was much lower for commercially insured patients. Although the majority of patients who are eventually approved are approved in the first week, substantial numbers of patients wait ≥30-days for an approval. Overall, time to approval appears to be lower, and approval rate appears to be higher in Medicare than in commercially insured patients. However more Medicare patients never fill their approved prescriptions. This may be the result of higher copayments for patients as they reach the “donut hole” in coverage.

**SPONSORSHIP:** This study was funded by Amgen.

### 19 Treatment Patterns Among Early Initiators of Evolocumab and Alirocumab

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**QuintilesIMS, Amgen**

**BACKGROUND:** Elevated low-density lipoprotein cholesterol (LDL-C) levels are associated with premature atherosclerotic cardiovascular disease. Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9is) are indicated for patients with ASCVD or familial hypercholesterolemia who require additional lowering of LDL-C in addition to diet and maximally tolerated statin dose.

**OBJECTIVE:** The goal of this study was to assess utilization of lipid lowering therapy (LLT) prior to initiation of PCSK9i therapy, and the utilization patterns of PCSK9is evolocumab and alirocumab within the first 6 months of their market availability.

**METHODS:** The Quintiles-IMS longitudinal prescription claims database (LRx) was used to identify patients with ≥1 prescription fill for evolocumab or alirocumab between 8/1/2015 and 1/31/2016. The date of the first fill was the index date. Baseline LLT (prior to PCSK9i initiation) was evaluated in the 12 months pre-index. Patients were followed for 6 months post-index to estimate PCSK9i titration and switch rates.

**RESULTS:** There were a total of 4,853 PCSK9i users identified (mean age [SD] 63.8 [10.9], 52.3% male) with 2,834 patients initiating evolocumab (mean age [SD] 64.5 [11.1], 51.1% male) and 2,019 patients initiating alirocumab (mean age [SD] 63.9 [10.6], 54.1% male). Among all PCSK9i users, 60.4% had commercial health insurance, and 31% had Medicare. Pre-index LLT use was seen in 60.2% of evolocumab and 58.4% of alirocumab patients. All evolocumab patients started at 140 mg every 2 weeks (Q2W) and the majority (93.6%) initiated alirocumab at 75 mg Q2W. Among alirocumab patients, 10.2% titrated up from 75 mg to 150mg Q2W, and 5.9% patients switched to evolocumab in the 6-months post initiation, compared to 0.9% of patients switching from evolocumab to alirocumab.

**CONCLUSIONS:** Patients initiating evolocumab and alirocumab in the first year after approval had similar patient characteristics. Approximately 15% of patients initiating alirocumab modified treatment (uptitrated or switched therapy) in the first 6-months compared to less than 1% of evolocumab patients. Additional data is being collected with longer follow-up time, adequate to evaluate adherence and effectiveness of these therapies using real world data.

**SPONSORSHIP:** This study was funded by Amgen.

### 110 Cost-Effectiveness of Influenza Vaccination Against Major Adverse Cardiac Events

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**BACKGROUND:** Influenza vaccination has been shown to reduce the incidence of major adverse cardiac events (MACE) among those with existing cardiovascular disease (CVD). Although CDC’s Advisory Committee on Immunization Practices, the American Heart Association, and the American College of Cardiology recommend influenza vaccination for high risk patients, only 48%-60% of persons with CVD report influenza vaccination.

**OBJECTIVE:** To estimate the cost-effectiveness of both existing influenza vaccination rates and of increasing influenza vaccination among hospitalized acute coronary syndrome (ACS) patients, with the goal of reducing incidence of MACE.

**METHODS:** We built a Monte Carlo (probabilistic) spreadsheet-based decision tree to estimate the average cost-effectiveness of influenza vaccination to prevent MACE hospitalization among approximately 60% (status quo scenario) of the estimated 625,000 U.S. ACS discharges from the health care perspective. We also estimated the incremental cost per additional MACE case averted if all admitted ACS patients were vaccinated. We obtained input values from published literature on the cost of vaccination and cost of MACE-related hospitalizations. We also estimated the impact of increasing vaccination to 100% among only adults ≥65 years or adults 18-64 years old. Outpatient, nursing home, and outpatient prescription costs and time lost from work were not included.

**RESULTS:** In the status quo scenario, vaccination was cost-saving from the health care perspective and resulted in 683 (95% CI: 444-904) averted MACEs. When increasing the vaccination rate to 100% of all ACS patients admitted to hospital, each additional MACE case averted cost $89,123 (95% CI: 52,030-143,506). Increasing vaccination rate only in adults >65 years cost $86,682 (47,395-136,426) per additional MACE averted, and $90,767 (54,297-144,531 per additional MACE case averted in focus is only on adults 18-64 years old. Vaccinating 100% of all ACS patients could prevent an additional 1,268 (CI: 828-1,678) MACE cases.

**CONCLUSIONS:** Vaccinating ACS patients is cost-saving at current vaccination coverage estimates. Expanding coverage to all ACS patients will increase costs, but almost double number of current MACE cases averted.

**SPONSORSHIP:** None.

### 111 Utilization and Adherence Rates to Pulmonary Arterial Hypertension Medications

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**Magellan Rx Management**
BACKGROUND: Due to high costs of drug therapy and extensive utilization of ancillary medical services, patients with pulmonary arterial hypertension (PAH) can lead to significant financial burden on the health care system. The treatment of PAH is goal oriented. New medications are added onto existing treatments if the patient fails to reach treatment goals. However, lack of adherence to PAH medications may also contribute to treatment failure. Although adherence data is limited, one study suggested that more than 50% of patients reported suboptimal adherence. Suboptimal adherence may be associated with increased emergency room visits, hospitalizations, and increased overall medical expenses.

OBJECTIVE: To determine cost and utilization trends as well as adherence rates to PAH medications.

METHODS: Medical and pharmacy claims data from four regional and national payers between January 1, 2010 and December 31, 2015 were evaluated. Analysis included commercial members who were continuously enrolled for at least 2 years with a diagnosis of PAH and at least 2 pharmacy claims for a PAH medication. Adherence was measured by proportion of days covered (PDC).

RESULTS: 441 distinct members with PAH were identified. 59%, 28%, 12%, and 1% of patients were on mono, dual, triple, and quadruple therapies, respectively. Overall, annualized per patient cost was $42,649 and $56,555 for pharmacy and medical drugs, respectively. The most frequently utilized pharmacy products in order were sildenafil (58%), tadalafil (40%), bosentan (29%), and ambrisentan (28%). The most commonly seen dual therapy combinations in order were ambrisantan+tadalafil (10%), bosentan+sildenafil (10%), and ambrisantan+sildenafil (8%). Overall, average PDC for all drugs was 66% and only 40% of members had a PDC of ≥80%. Pharmacy products with the highest adherence rates in order were macitentan (97%), treprostinil diolamine (86%), and riociguat (84%), and those with the lowest adherence rates were iloprost (53%), treprostinil oral inhalation (58%), and sildenafil (61%).

CONCLUSIONS: Low adherence rates were observed consistently for majority of PAH medications. Further study is warranted to determine the impact of low adherence on outcome measures including ER visits, hospitalizations, and overall medical expenses. In response to the rising cost in the PAH space and entrance of additional therapies, payers should evaluate clinical program opportunities that focus on increasing adherence and promoting appropriate long-term utilization of PAH medications.

SPONSORSHIP: Magellan Rx Management.

Characteristics of Patients Treated for Pulmonary Arterial Hypertension in Real-World Database Representing a Large U.S. Health Plan

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BACKGROUND: Pulmonary arterial hypertension (PAH) is a chronic and progressive disease characterized by abnormally high pressure in the pulmonary arterioles, with increased pulmonary vascular resistance that can result in right heart failure and premature mortality. In the U.S., the estimated incidence of PAH is 2-8/million with an estimated prevalence of 15-50/million. In the REVEAL registry, PAH has been associated with common comorbidities including systemic hypertension, sleep apnea, diabetes, and renal insufficiency. With several new PAH medications available since 2013, more information is needed to characterize the patients treated with these medications.

OBJECTIVE: The purpose is to describe the characteristics and comorbidities of current patients in a large representative U.S. health plan.

METHODS: Patients with a diagnosis code for pulmonary hypertension and treated with an approved medication for PAH (ERAs, PDE-5is, prostacyclins, sGCs) identified by pharmacy claims between January 2010 and March 2015 were included. Patients were ≥18 years old with continuous enrollment in a large U.S. health plan with medical and pharmacy coverage for 6 months before and ≥1 year after initiating a PAH-related therapy. Patients were excluded for a PAH-related therapy claim in the prior 6 months. Patients were followed until disenrollment from the plan or end of study (March 2016). Diagnosis codes were used to identify baseline comorbidities and procedures.

RESULTS: The study included 1,637 patients. Most patients were female (63.7%) with mean (+SD) age 65.3 ± 13.8 years, and slightly more (54.4%) enrolled in Medicare Advantage than in commercial insurance plans. The mean (+SD) follow-up duration was 2.5 ± 1.2 years, with 53.8% followed >2 years and 12.7% followed >4 years. The mean Charlson Comorbidity Index score was 3.3, with 67.7% scoring >3. The most common comorbidity was lower respiratory disease (91.6%) followed by systemic hypertension (80.5%), lipid metabolism disorders (55.2%), other connective tissue diseases (42.6%), type II diabetes (30.2%), sleep apnea (37.3%), respiratory failure or insufficiency (31.8%), thyroid disease (23.3%), and depression (13.3%). Baseline cardiovascular medication usage included diuretics (72.3%), anticoagulants (48.6%), and digoxin (12.9%).

CONCLUSIONS: In this large U.S. health plan database study, the majority of patients maintained consistent health plan coverage for over 2 years following initiation of PAH therapy. These patients frequently presented with complex comorbidity profiles consistent with previously published data.

SPONSORSHIP: Actelion Pharmaceuticals.

Impact of Entresto on Overall Medical Cost in Heart Failure Patients

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Conduent

BACKGROUND: National heart failure (HF) treatment guidelines recommend patients with stage C HF and reduced ejection fraction, who are on an angiotensin-converting enzyme inhibitor (ACE) or angiotensin II receptor antagonist (ARB) be switched to Entresto (sacubitril/valsartan) to reduce cardiovascular death and HF hospitalizations. Data from Medicaid recipients was reviewed to assess the real-world effects of initiating sacubitril/valsartan.

OBJECTIVE: To determine if sacubitril/valsartan reduces overall cost of care in patients with HF to a greater extent than traditional care with an ACE/ARB.

METHODS: Claims data from 9/1/15-3/1/16 was analyzed to identify Medicaid recipients who were continuously eligible and had a hospital admission due to HF and were not on sacubitril/valsartan prior to admission. The target group consisted of individuals who received sacubitril/valsartan post admission while the control group did not. The cost of pharmacy and medical care 6 months prior to and post-admission was calculated for both groups. A secondary comparison involved individuals from the target group and the control group who were not on a maximum dose of an ACE/ARB pre-admission.

RESULTS: The control group consisted of 4,650 individuals that did not start sacubitril/valsartan at any point. Their pharmacy cost decreased by $8.50 (-6.88%) and medical cost decreased by $43.77 (-2.54%) resulting in an overall decrease of $52.27 (-2.83%). The target
group consisted of 144 individuals who were not on sacubitril/valsartan pre-admission, but were post-admission. Their pharmacy cost increased by $147.99 (84.4%) and medical cost decreased by $886.40 (-48.5%) resulting in an overall decrease of $738.40 (-36.8%). Of the 144 individuals, 101 were not at a maximum ACE/ARB dose pre-admission and went on to start sacubitril/valsartan post-admission. Their pharmacy cost increased by $24.44 (20.59%) and medical cost decreased by $453.46 (-24.96%) resulting in an overall decrease of $429.02 (-22.17%).

CONCLUSIONS: The data revealed that individuals with HF had an overall decrease in cost of care after starting sacubitril/valsartan compared to those who continued on traditional care with an ACE/ARB.

SPONSORSHIP: This research was funded internally by Conduent.

114 Retrospective Cohort Study to Assess the Differences in Persistence Between Dabigatran and Warfarin in Patients with Nonvalvular Atrial Fibrillation
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BACKGROUND: Previous studies have examined the relationship between socio-demographic and clinical variables and their impact on medication persistence. However, it remains unclear what factors influence differences in persistence between dabigatran and warfarin in patients with non-valvular atrial fibrillation (NVAF).

OBJECTIVE: To compare differences in persistence between new dabigatran and warfarin users in patients newly diagnosed with NVAF, adjusting for socio-demographic, clinical characteristics, patient OOP cost and other covariates.

METHODS: A retrospective matched-cohort study was conducted using a U.S. claims database among Medicare and commercially insured patients with NVAF aged ≥18 years, treated with dabigatran or warfarin from 01/01/10-12/31/12. Patients had 12 months of continuous enrollment prior to date of first dabigatran or warfarin fill within 3 months of first NVAF diagnosis (index) and were followed until the earliest of discontinuation, switch, disenrollment, death or end of study period. Persistence was the sum of days from index to the end date of the last claim before a 30-day gap. Monthly patient OOP cost for dabigatran or warfarin was calculated for the follow-up period. Matching was based on propensity score. Cox proportional hazard models [hazard ratio (HR) and 95% confidence interval (CI)] were used to assess association between treatment cohorts and persistence and among the cohorts and persistence, adjusting for covariates.

RESULTS: A total of 1,025 dabigatran users were matched with corresponding warfarin users. Several variables were found to be significantly associated with persistence. The number of cardiovascular medications [0.980 (0.971-0.990)] was associated with higher persistence. Antithrombotic use, congestive heart failure (CHF), atrial flutter, addition of a single other medication class, and a $10 increase in OOP cost were significantly associated with 33% [1.334 (1.163-1.528)], 20% [1.203 (1.012-1.442)], 19% [1.187 (1.098-1.290)], 1.5% [1.015 (1.001-1.029)], and 5% [1.005 (1.002-1.007)] increases in the likelihood of discontinuation, respectively. Persistence rate was significantly lower among dabigatran users compared to warfarin users (38.0% vs. 45.9%, P = 0.043). Adjusting for covariates rendered this difference significant [HR = 0.930 (0.766-1.122)].

CONCLUSIONS: After adjusting for socio-demographic, clinical characteristics and patient OOP costs, no difference in persistence between dabigatran and warfarin users was observed.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals and Humana.

115 Estimation of Decrements of Utility Associated with Hospitalizations in a Population with Heart Failure from the Systolic Heart Failure treatment with the IF inhibitor ivabradine Trial (SHIFT)
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BACKGROUND: Patients with heart failure (HF) are at high risk of recurrent hospitalizations. Reducing the rate of hospitalization is an essential treatment goal in this population, as there are patient quality of life, clinical, and economic benefits.

OBJECTIVE: The aim of this study was to estimate the impact of recurrent cardiovascular (CV) hospitalizations and treatment on patient quality of life (utility), as measured by the EuroQol instrument EQ-5D.

METHODS: Utility data was obtained from PRO-SHIFT (N = 5,038), a sub-study of the Systolic Heart failure treatment with the IF inhibitor ivabradine Trial (SHIFT). SHIFT was a randomized, double-blind, placebo-controlled study evaluating the effect of ivabradine on CV mortality and morbidity in patients with moderate-to-severe chronic HF and left ventricular systolic dysfunction with a heart rate ≥70 bpm. A linear mixed model was used to derive an equation for change from baseline in EQ-5D Index Score for patients with a baseline and at least one post-baseline value (N = 4,199). The model included treatment, baseline EQ-5D score, beta-blocker use at randomization, and time-dependent variables for number of HF- and non-HF CV hospitalizations at each follow-up visit (none, one, two, or three or more).

RESULTS: Baseline utility score in the selected population was 0.677. A trend was found for a positive effect of ivabradine on the utility of 0.009 (P = 0.055) when compared with placebo. The utility decrements associated with experiencing one or two consecutive HF-related hospitalizations vs. no hospitalizations were similar: 0.076 and 0.074, respectively. There was a larger utility decrement of 0.133 following the third or more HF-related hospitalization. Non-HF CV hospitalizations had smaller utility decrements of 0.020, 0.053, and 0.072 for the first, second, and third or more hospitalizations, respectively.

CONCLUSIONS: Reducing the incidence of hospitalization, particularly those related to HF, may avoid further decreases in HF patients' quality of life in addition to the economic benefits associated with fewer hospitalizations.

SPONSORSHIP: This study was funded by Servier, and this analysis was funded by Amgen.

116 Hyperkalemia in Heart Failure Was Associated with Excess Emergency Department Visits and Hospital Admissions
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BACKGROUND: We know little about the relation between hyperkalemia in heart failure (HF) patients and hospital use.

OBJECTIVE: To evaluate whether higher serum potassium (K) levels are associated with excess emergency department (ED) visits and hospital admissions.
hospital admissions after adjusting for patient characteristics and HF treatment. We hypothesize that, adjusting for conlounding and HF treatment, higher K levels are associated with excess ED visits and hospitalizations.

**METHODS:** We conducted a retrospective cohort study in adult HF patients with ≥2 outpatient serum K values between 2005 and 2013 at Kaiser Permanente Northwest. Patients’ start of follow-up was their highest K value: normal-K (3.5-5.1 mmol/L), mild-K (5.2-5.4), moderate-K (5.5-5.8), or severe-K (≥ 5.9). We estimated the incremental effect of K values during 90 days of follow-up using negative binomial regression, which adjusted for age, sex, race, dyspnea, HF emergency visits and hospitalizations, diabetes, kidney function, blood pressure and a comorbidity index. We stratified by current HF treatment: (ACE/ARB) or ACE/ARB plus aldosterone receptor antagonists (ACE/ARB/ARA).

**RESULTS:** The ACE/ARB/ARA subgroup included 4,966 patients. The ACE/ARB/ARA subgroup included 1,791 patients. Unadjusted rates of ED visits per 100 for the ACE/ARB subgroup were 46.0 (normal-K), 60.3 (mild-K), 73.7 (moderate-K), 118.7 (severe-K); P < 0.0001. Rates of ED visits for the ACE/ARB/ARA subgroup were 38.1 (normal-K), 57.7 (mild-K), 58.8 (moderate-K), 110.3 (severe-K); P < 0.0001. In the ACE/ARB subgroup, patients with severe-K (n = 132, 2.6%) visited the ED twice as often (ratio rate = 1.94; 95% CI, 1.49-2.51). In the ACE/ARB/ARA subgroup, severe-K occurred more frequently (n = 107, 6.0%), but the effect was similar (RR = 2.21, 95% CI, 1.62-3.02). Unadjusted rates of hospitalization per 100 for the ACE/ARB subgroup were 31.6 (normal-K), 40.2 (mild-K), 55.7 (moderate-K), 76.7 (severe-K); P < 0.0001. Rates of hospitalization for the ACE/ARB/ARA subgroup were 27.0 (normal-K), 46.7 (mild-K), 45.6 (moderate-K), 76.0 (severe-K); P < 0.0001. In the ACE/ARB/ARA subgroup, patients with severe-K were hospitalized 58% more often (RR = 1.58; 95% CI, 1.20-2.06). In the ACE/ARB subgroup, the effect was similar (RR = 1.71, 95% CI, 1.22-2.38).

**CONCLUSIONS:** Patients with severe hyperkalemia had a higher adjusted rate of emergency department visits and hospital admissions.

**SPONSORSHIP:** Relypsa sponsored this study through a contract with the Center for Health Research, Kaiser Permanente Northwest.

118 A Cost-Effectiveness Analysis of Patiromer and Spironolactone Therapy in Heart Failure Patients with Hyperkalemia

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**BACKGROUND:** Managing hyperkalemia in patients with heart failure (HF) can be challenging partly due to renin angiotensin aldosterone system inhibitor (RAASI) use causing the condition. Patiromer is a potentially important tool for providers to treat hyperkalemia. However, the economic implications of using patiromer in this patient population are unknown.

**OBJECTIVE:** To estimate the clinical and economic outcomes of using patiromer with spironolactone in patients with NYHA III-IV HF receiving an ACE inhibitor and otherwise unable to add spironolactone due to hyperkalemia.

**METHODS:** A Markov disease simulation model was developed to assess outcomes from a U.S. payer perspective over a 10-year time horizon. We assumed patiromer and spironolactone were co-administered for the first 3 years. Clinical inputs were derived from the RALES trial evaluating spironolactone vs. placebo in patients with NYHA class III-IV HF on an ACE inhibitor (angiotensin receptor blockers not studied), which showed a 30% reduction in mortality over 3 years; we assumed the RALES data applied to our model population. Quality of life estimates (utilities) were derived from the literature. The wholesale acquisition cost (WAC) was used for drug cost and hospitalization cost was estimated from a national survey. Outcomes included quality-adjusted life years (QALYs), costs and the incremental cost-effectiveness ratio (ICER). One-way sensitivity analyses were
An economic model was developed using nationally representative Medicare plans with exclusive vs. parity contracts for preferred and non-preferred treatments, and net effective rebate for this study estimates market uptake for the class, share chosen both exclusive and parity contracts providing a case-study to compare these scenarios. With growing concerns about specialty drug costs, health plans have increasingly considered exclusive contracts where health plans do not receive a rebate on non-preferred treatment in patients with HF with hyperkalemia could result in clinically meaningful improvements in life expectancy and may provide economic value. While we assessed data from the RALES trial applied to our model population, as long as the mortality risk reduction is approximately 15% or greater, concomitant use of patiromer and spironolactone appears to be cost effective.

**RESULTS:** The increase in QALYs with patiromer and spironolactone use was 0.31 and total health care costs increased by $18,000, giving an ICER of approximately $57,000/QALY in the base case. Hospital cost offsets were approximately $1,000. When the relative risk of survival was varied over the 95% CI from the RALES study (0.56 to 0.84), the ICER ranged from $41,000/QALY to $99,000/QALY. Varying the utility of HF from 0.45 to 0.68 resulted in an ICER from $71,000/QALY to $47,000/QALY. Other model parameters had less impact on uncertainty.

**CONCLUSIONS:** The modeled results suggest use of patiromer and spironolactone in patients with HF with high risk (established coronary heart disease [CHD] or CHD risk equivalents) or high (heterozygous familial hypercholesterolemia without CHD or risk equivalents) CV risk were pooled by ALI dose and comparator. Pool 1 (COMBO I, FHI, FHII), ALI 75 mg every two weeks (Q2W), with increase to 150 mg Q2W at Week (W)12 if pre-specified LDL-C target not met at W8, vs. placebo (PBO); Pool 2 (COMBO II), ALI 75/150 mg Q2W vs. ezetimibe; Pool 3 (LONG TERM, HIGH FH), ALI 150 mg Q2W vs. PBO. Patients received statin±other lipid-lowering therapies. Achievement of risk-based LDL-C thresholds (~70 mg/dL for very high risk or < 100 mg/dL for high risk) and LDL-C reductions were assessed at W24, 52, 78 and/or 104.

**OBJECTIVE:** This study estimates market uptake for each class, share for preferred and non-preferred treatments, and net effective rebate for Medicare plans with exclusive vs. parity contracts.

**METHODS:** An economic model was developed using nationally representative data. The 10 Medicare plans with the highest number of paid claims for PCSK9i therapy from 1/1/2016 to 11/24/2016 were identified. Market share and product uptake for preferred and non-preferred treatments was compared in plans with exclusive vs. parity contracts. Hypothetical rebate scenarios were evaluated and net effective rebate in exclusive vs. parity contract and the additional rebate needed from an exclusive contract to reduce total PCSK9i costs was calculated.

**RESULTS:** Market uptake was similar in Medicare plans with exclusive and parity contracts. Substantial use of non-preferred treatment was seen; and in the absence of a large additional rebate health plans would receive a lower net effective rebate if an exclusive vs. a parity contract was implemented. This suggests that parity access may actually save money for Medicare plans, while preserving choice for patients and physicians.

**SPONSORSHIP:** The study was funded by Amgen.

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**Impact of Having a Single Preferred Agent with Exclusive Contracts Versus Parity Access for Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors on Cost and Product Uptake in Medicare Plans**

**Background:** With growing concerns about specialty drug costs, health plans have increasingly considered exclusive contracts where health plans do not receive a rebate on non-preferred treatment in patients with HF with high risk (established coronary heart disease [CHD] or CHD risk equivalents) or high (heterozygous familial hypercholesterolemia without CHD or risk equivalents) CV risk were pooled by ALI dose and comparator. Pool 1 (COMBO I, FHI, FHII), ALI 75 mg every two weeks (Q2W), with increase to 150 mg Q2W at Week (W)12 if pre-specified LDL-C target not met at W8, vs. placebo (PBO); Pool 2 (COMBO II), ALI 75/150 mg Q2W vs. ezetimibe; Pool 3 (LONG TERM, HIGH FH), ALI 150 mg Q2W vs. PBO. Patients received statin±other lipid-lowering therapies. Achievement of risk-based LDL-C thresholds (~70 mg/dL for very high risk or < 100 mg/dL for high risk) and LDL-C reductions were assessed at W24, 52, 78 and/or 104.

**Methods:** Six ODYSSEY Phase 3 trials involving 4,219 patients at very high (established coronary heart disease [CHD] or CHD risk equivalents) or high (heterozygous familial hypercholesterolemia without CHD or risk equivalents) CV risk were pooled by ALI dose and comparator. Pool 1 (COMBO I, FHI, FHII), ALI 75 mg every two weeks (Q2W), with increase to 150 mg Q2W at Week (W)12 if pre-specified LDL-C target not met at W8, vs. placebo (PBO); Pool 2 (COMBO II), ALI 75/150 mg Q2W vs. ezetimibe; Pool 3 (LONG TERM, HIGH FH), ALI 150 mg Q2W vs. PBO. Patients received statin±other lipid-lowering therapies. Achievement of risk-based LDL-C thresholds (~70 mg/dL for very high risk or < 100 mg/dL for high risk) and LDL-C reductions were assessed at W24, 52, 78 and/or 104.

**Results:** In Pool 1, the proportion of ALI-treated patients in the intent-to-treat population at LDL-C threshold at W24 was 76.6% (487/636), remaining stable at 74.3% (447/602) at W52 (corresponding values for PBO-treated patients were 5.9% [19/324] and 5.0% [15/303], respectively). Similarly, proportions were stable over time in Pool 2 (77.8% [333/428] at W24, 77.5% [321/414] at W52 and 71.1% [276/388] at W104) and Pool 3 (79.9% [1,155/1,446] at W24, 77.1% [1,080/1,400] at W52 and 73.0% [966/1,323] at W78). Corresponding values were 47.5% (105/221), 43.6% (92/211) and 40.4% (78/193) for ezetimibe (Pool 2) and 8.3% (63/741), 4.6% (32/703) and 8.4% (57/679) for PBO (Pool 3). On-treatment results in each pool were similar. Corresponding with the threshold achievement data, significant reductions from baseline in LDL-C with ALI vs. control were observed across all pools and time-points (LS mean percent change -49.6 vs. +4.2 at W24 and -46.6 vs. +6.4 at W52 in Pool 1, -30.6 vs. -20.7 at W24, -49.5 vs. -18.3 at W52, and -44.2 vs. -15.2 at W104 in Pool 2, -60.4 vs. +0.5 at W24, -56.2 vs. +4.1 at W52 and -51.7 vs. +3.5 at W78 in Pool 3). Incidence of treatment-emergent adverse events (TEAEs) was similar across groups, TEAEs more frequent with ALI vs. control were nasopharyngitis (Pool 1) and upper respiratory tract infection (Pools 2 and 3).

**Conclusions:** ALI provided sustained lowering of LDL-C and was well-tolerated for up to 104 weeks in clinical trials.

**Sponsorship:** Sanofi and Regeneron Pharmaceuticals.
Impact of CYP3A4/P-gp Interacting Medications on Clinical Outcomes in Rivaroxaban Patients at a Health Plan Located in Central Texas

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BACKGROUND: Rivaroxaban has been identified as a substrate of the CYP3A4 enzyme and the P-glycoprotein (P-gp) system. Concomitant interacting medications (CIM) that affect these mechanisms of drug metabolism may significantly affect rivaroxaban pharmacodynamics. Evidence is lacking to assess the real-world risk of bleed or thromboembolism (TE) arising from use of rivaroxaban with CIM.

OBJECTIVE: To assess the individual and additive risk of bleed or TE associated with CIM in patients starting rivaroxaban therapy over one year of follow-up.

METHODS: This is a retrospective review of claims merged with EMR data from 2011-2016. Patients were included if they had: ≥1 prescription claim for rivaroxaban (index event) and continuous enrollment for ≥9 months pre- and post-index date to assess CIM use, bleed or TE occurring ≥3 days after the prescription date of a CIM and/or rivaroxaban, and pre-index comorbidity. Covariates included age, gender, and prior-year diagnosis of hypertension, atrial fibrillation, hypercholesterolemia, and other conditions in the Charlson Comorbidity Index. The primary endpoints were bleed and TE. Multivariable logistic regression assessed risk effects as odds ratios (OR) with their 95% confidence intervals (CI).

RESULTS: We identified 747 patients from January 2011 through December 2015 meeting enrollment criteria. Half of the patients were male (50%), with a mean age of 70.5 and an average Charlson Comorbidity Index score of 1.4. Use of CIM (51% overall) included P-gp inhibitors (29%), CYP3A4/P-gp inhibitors (17%), CYP3A4 inducers (4%), PAIs (8%) and NSAIDs (10%). Major comorbidities included hypertension (55%), atrial fibrillation (54%), and hypercholesterolemia (27%); 12% of patients had cancer. The rate of any bleed was 7% and of TE, 10%. In adjusted models, those with CYP3A4/P-gp inhibitors and PAIs were more likely to experience a bleed compared to non-users (OR = 4.4, CI 2.2-8.9, P < 0.001; OR = 4.4, CI 1.8-10.6, P < 0.001). No single CIM group was associated with lower rate of TE, but CIM users generally had lower rates of TE than non-users (7% vs. 13%, P = 0.003). Hypertension (OR = 2.1, CI 1.1-4.2, P = 0.03) was a significant predictor of any bleed. Hypercholesterolemia (OR = 1.9, CI 1.1-3.5, P = 0.02) and atrial fibrillation (OR = 0.14, CI 0.07-0.29, P < 0.001) were identified as significant predictors of TE with opposite effects.

CONCLUSIONS: CYP3A4/P-gp inhibitor use was common in patients on rivaroxaban in a central Texas health plan population and was associated with higher likelihood of bleeding but lower likelihood of TE.

SPONSORSHIP: This research did not receive any internal or external funding.

Atherosclerotic Cardiovascular Disease Risk Estimator Among Primary Care Physicians in a Medicare Advantage Plan

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BACKGROUND: Cardiovascular disease (CVD) is the leading cause of death among Americans. The American College of Cardiology/American Heart Association (ACC/AHA) Atherosclerotic Cardiovascular Disease (ASCVD) risk estimator, an online calculator tool, can aid health care providers in assessing the 10-year and lifetime risks for ASCVD (defined as coronary death or nonfatal MI) as well as fatal or nonfatal stroke, greatly assisting providers in managing high risk patients. However, primary care physician (PCP) awareness of the ACC/AHA ASCVD risk estimator has not been adequately examined.

OBJECTIVE: To investigate overall awareness of the ASCVD risk estimator among PCPs contracted within a Texas-based Medicare Advantage Plan (MAP) as well as examine differences in awareness based on PCP and practice characteristics.

METHODS: A survey was developed and administered to PCPs during an all-PCP quarterly meeting in July 2016. The survey included questions regarding PCP awareness of the ACC/AHA ASCVD risk estimator location as well as the predominant socioeconomic status of the patient population (upper, middle or indigent population). Demographic and practice variables such as gender, race, ethnicity, age, years in practice, and specialty were collected and recorded from both the health plan data base and/or the Texas Medical Board website. Risk estimator awareness was determined overall, and group differences by PCP and practice characteristics were examined using chi square tests for categorical variables as well as t-tests for continuous variables.

RESULTS: A total of 214 out of 215 physicians from the Southwest and Southeast Texas regions completed the survey. Among those surveyed, 58% indicated that they were aware of the ASCVD risk estimator. PCP awareness was significantly associated with the patients’ socioeconomic status, where physicians treating mostly the indigent patient population were significantly more aware of the risk estimator compared to those treating mostly middle and upper class patient populations. No other significant associations were documented.

CONCLUSIONS: Over 40% of the surveyed PCPs were unaware of the ACC/AHA ASCVD risk estimator, indicating a need for education among PCPs, especially as it pertains to improving patient care in high risk CVD patients. PCPs treating indigent CVD patients may possibly be more aware of the risk estimator because they may be treating high risk patients and are looking for tools to aid them in their management.

SPONSORSHIP: Cigna-HealthSpring, University of Houston College of Pharmacy.

Diseases of the Respiratory System (e.g., Asthma, COPD, Rhinitis, RSV)

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BACKGROUND: Community-Acquired Pneumonia (CAP) is a significant cause of morbidity and mortality across the U.S. Despite the high reported rates of Antibiotic treatment failure (ATF), the association between treatment failure and mortality has not been well described.

OBJECTIVE: This study sought to compare 30-day mortality rates between adult outpatients who experienced ATF to those who did not.

METHODS: U.S. retrospective claims analysis of MarketScan Commercial & Medicare Supplemental Databases was employed. Patients were included if: (1) ≥18 years old, (2) ICD-9-CM codes for CAP in the outpatient setting from 2011 to 2013, and (3) received one course of antibiotic treatment.
of the following antibiotic classes as monotherapy: fluoroquinolone, macrolides, beta-lactam, or tetracycline. Patients were excluded if an antibiotic prescription claim was identified in the 30 days prior to the CAP episode. Treatment failure was defined as any of the following events within 30 days of initial antibiotic claim: (1) antibiotic refill, (2) antibiotic switch, (3) ER visit, (4) hospitalization. Patient demographics, insurance data, comorbid conditions, pharmacy claims, and vital status were collected. The Charlson Comorbidity Index (CCI) was calculated for each patient.

RESULTS: 251,947 unique patients met inclusion criteria. Mean age was 52.2 years old, 47.7% were male, 21.9% had Medicare coverage and 20.5% had a CCI score of ≥2. The majority of patients received fluoroquinolones (44.4%) or macrolides (43.6%), with beta-lactams (6.5%) and tetracyclines (5.5%) being prescribed less frequently. Of the included patients, 22.1% were classified as ATF. The most common ATF event was antibiotic switch (70.7%) followed by antibiotic refill (20.6%), hospitalization (3.4%), and ER visit (3.3%). ATF rates for tetracyclines (22.5%) and macrolides (22.9%) were similar, while failure rates were lower for fluoroquinolones (20.8%) and higher for beta-lactams (25.3%) [P< 0.0001]. Among patients classified as ATF, mortality rate was 18.1% compared to 4.6% in the non-ATF cohort (OR = 4.60 [4.46-4.74], P< 0.0001). In the working age (i.e. 18-64 years old) cohort, 16.1% of ATF patients died compared to 3.9% of non-ATF patients (OR = 4.09 [3.94-4.24], P< 0.0001). In the elderly (i.e. ≥65 years old) cohort, 24.3% of ATF patients died compared to 7.3% of non-ATF patients (OR = 3.39 [3.17-3.53], P< 0.0001).

CONCLUSIONS: The high incidence of ATF-associated 30-day mortality rates observed in this study highlights the vulnerable nature of this population and the critical importance of reducing antibiotic treatment failure.

SPONSORSHIP: Cempra.

J2 Medical and Pharmacy Costs Associated with the Treatment of Adult Patients with Community-Acquired Pneumonia in the Outpatient Setting

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BACKGROUND: The American Lung Association estimates annual direct medical costs linked to pneumonia to exceed $15 billion. While many studies have quantified the cost of treating patients with pneumonia in the inpatient setting, few have evaluated costs associated with managing patients with community-acquired pneumonia (CAP) in the outpatient setting.

OBJECTIVE: To quantify and differentiate costs between patients who were treatment failures vs. non-failures.

METHODS: Study was a retrospective claims analysis using MarketScan Commercial & Medicare Databases. Key inclusion criteria included age ≥18 years old, outpatient visit for CAP (based on ICD-9-CM codes) between 2011 and 2015 and monotherapy antibiotic pharmacy claim for one of the following drug classes: macrolides, fluoroquinolones, beta-lactams or tetracyclines. Treatment was considered a failure if one of the following events occurred within 30 days: (1) antibiotic refill, (2) antibiotic switch, (3) ER visit or (4) hospitalization. Costs data represent the total dollars paid to the provider (payer + copayment + coinsurance + deductible + coordination of benefits) and were inflated to 2015 U.S. dollars using the medical component of the Consumer Price Index. All costs presented are within a 30-day follow-up period from initial antibiotic prescription fill.

RESULTS: Over the 5 year study period, 251,947 patients met inclusion criteria. 112,054 (44.5%) patients received macrolides followed by 109,179 (43.3%) fluoroquinolones, 16,526 (6.6%) beta-lactams and 14,188 (6.5%) tetracyclines. Mean per-patient CAP related costs for all treated patients were $516 ($SD = $7,180). Mean per-patient CAP related costs were $54 ($SD = $252) among non-failures compared to $2,140 ($SD = $15,145) for patients that failed treatment (P< 0.0001). Among treatment failure costs, inpatient costs accounted for $1,860/$2,140 (86.9%), outpatient costs for $239/$2,140 (11.2%) and pharmacy costs for $41/$2,140 (1.9%). Antibiotic failure resulting in hospitalization led to the highest per-patient cost (mean = $26,867, SD = $54,199), followed by ER visit (mean = $3,927, SD = $11,733), antibiotic refill (mean = $648, SD = $8,415) and antibiotic switch (mean = $599, SD = $4,774) (P< 0.0001).

CONCLUSIONS: Treating CAP in the outpatient setting becomes extremely costly when a patient fails antibiotic therapy. This analysis highlights the importance of appropriate initial antibiotic selection among adult patients with CAP in the outpatient setting.

SPONSORSHIP: Cempra.

J5 Per-Member-Per-Month Cost of Subcutaneous Immunotherapy in a Large Insured Population in the United States

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BACKGROUND: Direct costs of subcutaneous immunotherapy (SCIT) to payers and patients are important for health policy and coverage decisions.

OBJECTIVE: To determine per-member-per-month (PMPM) cost of SCIT in a large U.S. administrative claims database and to understand characteristics of patients receiving SCIT relative to the general population.

METHODS: The SCIT cohort consisted of patients from Optum Research Database with ≥1 medical claim for SCIT and ≥1 claim for allergic rhinitis January 1, 2013-December 31, 2015, and the control cohort were members without SCIT Index date was either 1st date of SCIT or a randomly-assigned date. All subjects must have ≥90-day continuous enrollment with both medical and pharmacy coverage pre-index for comorbidity measures. Cases must have no claims for insect-venom or insect-bite SCIT. PMPM cost was calculated for 2013, 2014 and 2015 separately, and for all three years combined. Health-plan-paid PMPM cost is a ratio of total health-plan-paid costs for SCITs and related procedures (i.e., skin tests and allergen tests) over total member-months in that period. Total member-months were the number of enrolled months contributed for all members with ≥1 day of coverage. Patient-paid PMPM cost was calculated similarly using total patient-paid costs.

RESULTS: A total of 131,493 SCIT patients were followed-up for a mean 543 (SD 365) days, with a mean SCIT duration of 463 (SD 514) days. Compared to the 406,101 controls, SCIT patients were, on average, significantly younger (39.3 vs. 41.4 years), more likely to be female (56.4% vs. 50.7%), and to have respiratory-related comorbidities: asthma (23.6% vs. 1.9%), acute upper respiratory tract infection (21.6% vs. 8.0%), other upper respiratory conditions (15.6% vs. 1.3%), chronic asthma (23.6% vs. 1.9%), acute upper respiratory conditions (15.6% vs. 8.0%), other upper respiratory conditions (15.6% vs. 1.3%), chronic obstructive pulmonary disease (13.1% vs. 1.0%), and cough (13.1% vs. 3.1%), all P<0.001. The health-plan-paid PMPM cost for SCIT was $0.57, $0.47, $0.40 and $0.35 in 2013, 2014 and 2015 respectively. Direct costs of SCIT patients were $543 ($SD = $15,145) for patients that failed treatment (P< 0.0001). Among treatment failure costs, inpatient costs accounted for $1,860/$2,140 (86.9%), outpatient costs for $239/$2,140 (11.2%) and pharmacy costs for $41/$2,140 (1.9%). Antibiotic failure resulting in hospitalization led to the highest per-patient cost (mean = $26,867, SD = $54,199), followed by ER visit (mean = $3,927, SD = $11,733), antibiotic refill (mean = $648, SD = $8,415) and antibiotic switch (mean = $599, SD = $4,774) (P< 0.0001).

CONCLUSIONS: Our PMPM values are comparable to $0.54 PMPM cost on covering contraceptive and pregnancy-related care. Findings provide insights on cost burden of SCIT to patients and payers, and SCIT patient profile relative to the general population. Given that the SCIT cost may reflect a negotiated price between a payer and its providers, future research with other payers is needed.

SPONSORSHIP: Mercer & Co.
J7 Changes in Symptom Control, Work Productivity and Activity Impairment, and Anxiety Symptoms in Chronic Idiopathic Urticaria Patients After 24-Week Treatment with Omalizumab

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BACKGROUND: Patients with chronic idiopathic urticaria (CIU), characterized by itchy hives, may experience significant impact on their health-related quality of life.

OBJECTIVE: To examine changes in percentages of patients achieving complete response (absence of itch and hives, 7-day Urticaria Activity Score, UAS7 = 0), work productivity and activity impairment, and generalized anxiety disorder scores during the 24-week open-label single-arm period of XTEND-CIU: a multicenter, randomized, double-blind, placebo-controlled, Phase IV study of omalizumab in CIU patients (≥ 12 years of age).

METHODS: XTEND-CIU is an ongoing study that enrolled CIU patients, symptomatic despite guideline-based care. Qualifying patients (those with moderate or worse CIU disease activity [UAS7 ≥ 16 patients, symptomatic despite guideline-based care. Qualifying patients until week 24.

RESULTS: Among 206 enrolled patients, 75% were female, with a median age of 45 years. The percentages of patients reporting a complete absence of itch and hives (UAS7 = 0) increased as treatment progressed: 0% (baseline), 17.6% (week 4), 28.4% (week 8), 36.8% (week 12), 43.1% (week 16), 47.5% (week 20), and 52.0% (week 24). Mean (SD) GAD-7 scores decreased from 7.6 (6.3) at baseline to 3.8 (4.9) at week 12 and 3.0 (3.9) at week 24. Mean (SD) WPAI percent Activity Impairment scores decreased (improved) from 51.7 (26.8) at baseline to 14.0 (22.6) at week 12 and 6.8 (16.6) at week 24. Mean (SD) WPAI percent Overall Work Impairment scores decreased (improved) from 44.7 (29.3) at baseline to 10.1 (18.2) at week 12 and 8.2 (18.9) at week 24.

CONCLUSIONS: During the open label, non-placebo controlled part of XTEND-CIU, over half (52%) of CIU patients initiating omalizumab achieved a complete response (absence of itch and hives) within 24 weeks of treatment. Treated patients reported considerable reduction in anxiety scores and work productivity and activity impairment. The most dramatic results occurred within the 4 weeks following omalizumab initiation, however, additional improvements continued up until week 24.

SPONSORSHIP: Genentech.

J8 Reduction in Asthma Exacerbations, Hospitalizations, and Work Productivity and Activity Impairment After Omalizumab Initiation: Results from a 48-Week Single-Arm, Open-Label Treatment Registry

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BACKGROUND: Patients with uncontrolled allergic asthma experience substantial disease burden including exacerbations, impairment in work or school productivity, and health care utilization.

OBJECTIVE: To describe changes in exacerbations, hospitalizations, and work productivity and activity impairment after initiation of omalizumab treatment.

METHODS: The Prospective Observational Study to Evaluate Predictors of Clinical Effectiveness in Response to Omalizumab (PROSPERO) was a U.S.-based, multicenter, 48-week, single-arm, open-label treatment registry in adolescents and adults with allergic asthma, initiating omalizumab treatment based on physician assessment of need. Patients reported exacerbations and hospitalizations at baseline and each monthly study visit and completed the Work Productivity and Activity Impairment-Asthma (WPAI-A) questionnaire at baseline and at 6- and 12-months follow-up. Asthma exacerbations and asthma-related hospitalizations were summed in 6-month groupings 1-6, months 7-12, and for the entire follow-up period.

RESULTS: PROSPERO enrolled 806 patients (median age 49 years, range 12-100 years). In the year prior to initiating omalizumab, 60.8% of patients (489/804) had ≥ 2 asthma exacerbations and 29.8% of patients (178/598) had ≥ 1 asthma hospitalization. Exacerbation rates decreased from a mean (SD) of 3.0 (3.3) at baseline to 0.48 (0.96) during months 1-6 (n = 795), 0.35 (0.74) in months 7-12 (n = 698), and 0.78 (1.4) during months 1-12. At 12 months, 80.7% of patients had ≤ 1 exacerbation. Asthma hospitalization rates decreased from a mean (SD) of 0.1 (0.45) 90 days before baseline to 0.03 (0.23) during months 1-6, 0.03 (0.21) during months 7-12, and 0.06 (0.35) during months 1-12. 96% of patients had no asthma related hospitalization during the study. Mean (SD) WPAI-A percent activity impairment scores decreased (improved) from 47.7 (28.9) at baseline (n = 784) to 28.9 (27.0) at month 6 (n = 638) and 25.7 (28.3) at month 12 (n = 650). Mean (SD) percent WPAI-A work time missed decreased from 7.7 (19.9) at baseline (n = 784) to 7.7 (19.9) at baseline (n = 404), to 3.9 (14.6) at month 6, (n = 327) and 3.6 (13.0) at month 12 (n = 332). Mean (SD) WPAI-A percent work impairment scores decreased (improved) from 31.2 (27.1) at baseline (n = 401) to 15.2 (21.0) at month 6 (n = 338) and 15.3 (22.1) at month 12 (n = 336).

CONCLUSIONS: Adolescents and adults with uncontrolled allergic asthma reported reductions in asthma exacerbations, hospitalizations, work absenteeism, and activity and work impairment at 6 and 12 months after initiation of omalizumab treatment.

SPONSORSHIP: Novartis Pharma AG and Genentech.

J9 Health Care Costs in Asthma and/or Chronic Obstructive Pulmonary Disease Patients Using Albuterol Inhalation Aerosol with and Without an Integrated Dose Counter

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BACKGROUND: Patient-reported asthma exacerbation rates were 42.5% (n = 178) for patients treated with albuterol inhalation aerosol (IA) with dose counter and 44.6% (n = 179) IA without dose counter. Asthma hospitalization rates were 2.9% (n = 14) and 4.7% (n = 16), respectively. These results suggest that IA with dose counter may be associated with lower health care costs in asthma and/or chronic obstructive pulmonary disease patients.

METHODS: The Prospective Observational Study to Evaluate Predictors of Clinical Effectiveness in Response to Omalizumab (PROSPERO) was a U.S.-based, multicenter, 48-week, single-arm, open-label treatment registry in adolescents and adults with allergic asthma, initiating omalizumab treatment based on physician assessment of need. Patients reported exacerbations and hospitalizations at baseline and each monthly study visit and completed the Work Productivity and Activity Impairment-Asthma (WPAI-A) questionnaire at baseline and at 6- and 12-months follow-up. Asthma exacerbations and asthma-related hospitalizations were summed in 6-month groupings 1-6, months 7-12, and for the entire follow-up period.

RESULTS: PROSPERO enrolled 806 patients (median age 49 years, range 12-100 years). In the year prior to initiating omalizumab, 60.8% of patients (489/804) had ≥ 2 asthma exacerbations and 29.8% of patients (178/598) had ≥ 1 asthma hospitalization. Exacerbation rates decreased from a mean (SD) of 3.0 (3.3) at baseline to 0.48 (0.96) during months 1-6 (n = 795), 0.35 (0.74) in months 7-12 (n = 698), and 0.78 (1.4) during months 1-12. At 12 months, 80.7% of patients had ≤ 1 exacerbation. Asthma hospitalization rates decreased from a mean (SD) of 3.0 (3.3) at baseline to 0.48 (0.96) during months 1-6, 0.35 (0.74) in months 7-12, and for the entire follow-up period. Mean (SD) percent WPAI percent activity impairment scores decreased (improved) from 47.7 (28.9) at baseline (n = 784) to 28.9 (27.0) at month 6 (n = 638) and 25.7 (28.3) at month 12 (n = 650). Mean (SD) percent WPAI-A work time missed decreased from 7.7 (19.9) at baseline (n = 784) to 7.7 (19.9) at baseline (n = 404), to 3.9 (14.6) at month 6, (n = 327) and 3.6 (13.0) at month 12 (n = 332). Mean (SD) WPAI-A percent work impairment scores decreased (improved) from 31.2 (27.1) at baseline (n = 401) to 15.2 (21.0) at month 6 (n = 338) and 15.3 (22.1) at month 12 (n = 336).

CONCLUSIONS: Adolescents and adults with uncontrolled allergic asthma reported reductions in asthma exacerbations, hospitalizations, work absenteeism, and activity and work impairment at 6 and 12 months after initiation of omalizumab treatment.

SPONSORSHIP: Novartis Pharma AG and Genentech.
BACKGROUND: Accurate tracking of rescue medication remaining in an inhaler is necessary for optimal symptom control, which may affect health care costs.

OBJECTIVE: To assess health care costs among patients with asthma and/or chronic obstructive pulmonary disease (COPD) using albuterol sulfate inhalation aerosol with or without a dose counter.

METHODS: This retrospective claims study used a 5% sample of the Medicare claims database. Patients were included if they had ≥1 prescription for albuterol sulfate inhalation aerosol (ProAir HFA only, with or without dose counter) during the identification period (January 1, 2011, through December 31, 2013); had ≥1 diagnostic medical claim for asthma and/or COPD; were aged ≥65 years on the index date; had continuous enrollment for 12 months pre-index (baseline period); and had continuous enrollment for 12 months post-index (follow-up period) or died during that time. Patients who received other short-acting beta agonists during the follow-up period were excluded. Economic outcomes (utilization and costs for inpatient, outpatient, emergency department [ED], outpatient office, pharmacy, skilled nursing facility [SNF], home health agency [HHA], and hospice services) were assessed during the follow-up period. Total medical costs (inpatient + outpatient + ED) and total costs (medical + outpatient office + pharmacy + SNF + HHA + hospice) were calculated. Propensity score matching was used to create cohorts with similar baseline demographic and clinical characteristics.

RESULTS: After propensity score matching, the albuterol inhalation aerosol with dose counter and without dose counter groups each had 13,339 patients. Compared with albuterol inhalation aerosol without a dose counter, a dose counter was associated with significantly lowered all-cause health care costs including inpatient ($7,803 vs. $10,413, P < 0.0001), outpatient office ($3,584 vs. $3,805, P = 0.0078), HHA ($1,195 vs. $1,384, P < 0.0001), SNF ($1,776 vs. $2,404, P < 0.0001), hospice ($441 vs. $649, P < 0.0001), total medical ($10,563 vs. $13,274, P < 0.0001), and overall total costs ($22,011 vs. $25,653, P < 0.0001) but significantly increased all-cause ED costs ($211 vs. $186, P < 0.0001) and pharmacy costs ($4,452 vs. $4,137, P = 0.0002).

CONCLUSIONS: Use of albuterol inhalation aerosol (ProAir HFA) with a dose counter is associated with lower all-cause inpatient and total health care costs. Outpatient ED and pharmacy costs with dose counter use may be higher due to increased utilization of corticosteroids and a greater number of prescription refills.

SPONSORSHIP: This study was supported by Teva Pharmaceuticals.

J10 Development and Validation of a Predictive Model to Identify Patients at Risk of Severe Chronic Obstructive Pulmonary Disease Exacerbations Using Administrative Claims Data

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BACKGROUND: Patients with chronic obstructive pulmonary disease (COPD) often experience severe exacerbations involving hospitalizations which accelerate lung function decline and reduce quality of life. Identification of patients at risk of future exacerbations can facilitate appropriate disease management programs.

OBJECTIVE: Develop and validate a predictive model to identify patients at risk of severe COPD exacerbations using administrative claims data.

METHODS: A predictive model was developed using a retrospective cohort of COPD patients, 55-89 years, from Medicare Advantage Prescription Drug and commercial plans, identified between July 1, 2010 and June 30, 2013 using Humana’s claims data. Patients had a minimum of 2 years post- and 6 months pre-diagnosis continuous enrollment. The baseline period was diagnosis date to 12 months post-diagnosis and prediction period was 12 to 24 months post-diagnosis. Patients with and without severe exacerbations (resulting in a hospitalization) in the prediction period were compared to identify characteristics associated with a severe COPD exacerbation. Stepwise logistic regression was used to develop the models, and the models were validated in a randomly partitioned subset of the data. The final model was chosen based on the Area Under the Curve (AUC) index and the optimal cut-off point of the Receiver Operating Characteristics (ROC) curve was based on optimization of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

RESULTS: Of 45,722 patients, 5,317 had severe exacerbations in the prediction period. Patients with severe exacerbations had significantly higher comorbidity burden, use of respiratory medications and tobacco cessation counseling compared to those without severe exacerbations in baseline period. The predictive model included 29 variables that were significantly associated with severe exacerbations; the strongest predictors were prior severe exacerbations and higher Deyo Charlson Comorbidity Index score (odds ratios 1.50 and 1.47, respectively). The predictive model selected had an AUC of 0.77, ROC cutoff of 0.4, sensitivity of 17%, specificity of 98%, PPV of 48%, and NPV of 90%. Out of every 2 patients identified by the model to be at risk for severe exacerbation, one patient may have severe exacerbation.

CONCLUSIONS: This predictive model may provide an economically efficient method to identify COPD patients at risk of future severe exacerbations. Once at risk patients are identified, appropriate maintenance medications, implementation of disease management programs, and education may prevent future exacerbations.

SPONSORSHIP: Boehringer Ingelheim and Humana.

J11 Prescription Fill Patterns After Reaching the Medicare Part D Coverage Gap Among Chronic Obstructive Pulmonary Disease Patients on Maintenance Bronchodilators

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BACKGROUND: Medicare Part D beneficiaries without a low-income subsidy (LIS) bear significant out-of-pocket prescription costs after reaching the coverage gap (‘donut hole’), potentially impacting prescription fill patterns in diseases, such as COPD. Long-acting bronchodilators (LABD) are the key of COPD treatment, reimbursed under Medicare Part D, or Part B in case of nebulized drugs (eg, arformoterol [ARF]).

OBJECTIVE: To examine change in LABD prescription fills after reaching the donut hole between non-LIS and LIS COPD patients (pts).

METHODS: Medicare fee-for-service enrollees with ≥1 COPD diagnosis and continuous enrollment in Medicare Part A, B, and D in 2013 were identified. Pts were classified into ARF and tiotropium (TIO) cohorts based on prescriptions in the first month of 2013 (index). Non-LIS pts who reached the donut hole were matched 1:1 to LIS pts based on age, gender, race, and U.S. region. For each patient, monthly fills of index and any LABA therapy in the initial coverage (P1) and donut hole (P2) periods were calculated using total number of fills divided by total number of months in each period. Generalized linear models were used to compare the mean change in monthly fills (P2-P1) between LIS and non-LIS patients in the ARF and TIO groups.

SPONSORSHIP: Boehringer Ingelheim and Humana.
coauthors, adjusting for monthly fills in P1, demographic, and clinical characteristics. The mean percentage change in monthly fills was also calculated.

RESULTS: In the ARF and TIO cohorts, 7,374 and 148,168 pts were included, respectively. After adjusting for baseline characteristics, non-LIS pts in the ARF cohort had similar mean monthly fills of ARF (0.70 vs. 0.69; \(P=0.149\)) but fewer mean monthly fills of any LABD (1.03 vs. 1.14; \(P<0.001\)) compared to LIS pts in P2. Regarding percentage change, the reduction in monthly fills in the ARF cohort was 15% vs. 17% on ARF and 19% vs. 11% on any LABD for non-LIS and LIS pts, respectively. For the TIO cohort, non-LIS pts had significantly fewer monthly fills of TIO (0.47 vs. 0.61; \(P<0.001\)) and any LABD (0.84 vs. 1.08; \(P<0.001\)) compared to LIS pts in P2. The corresponding mean percent reductions in monthly fills of TIO were 33% vs. 13% and of any LABD were 28% vs. 8% in the non-LIS and LIS groups of TIO cohort, respectively.

CONCLUSIONS: Compared to LIS pts, monthly fills for COPD drugs were significantly lower among non-LIS pts during the donut hole period. The adverse impact on prescription fills was much stronger for maintenance drugs reimbursed under Part D (TIO).

SPONSORSHIP: Sunovion Pharmaceuticals, STATinMED Research, and Center for Innovation & Outcomes Research, Columbia University.

J12 The Burden of Childhood Asthma in the United States: Impact on Productivity Loss in a Nationally Representative Study

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BACKGROUND: Previous research has documented a significant national burden of lost productivity due to asthma and poor asthma control in adults. However, asthma-related productivity estimates specific to children are lacking.

OBJECTIVE: To estimate lost productivity due to asthma and poor control in children and their caregivers.

METHODS: This was a retrospective cross-sectional analysis of children (aged 6-17) and their caregivers in the nationally representative 2007-2013 Medical Expenditure Panel Survey. Indicators of poor control included: self-reported exacerbation, use of > 3 canisters of short-acting beta agonist (SABA) in 3 months (self-reported); and asthma-specific (AS) Emergency Department (ED) visit or hospitalization (utilization-based). Missed work days for caregivers of children with asthma and an indicator of poor control were compared to caregivers of children without asthma. Missed school days for children with asthma and an indicator of poor control were compared to children without asthma. Negative binomial regression was used controlling for sociodemographics, current family smoking, caregiver health status and comorbidities. National Vital Statistics Data was used separately to estimate the number of childhood deaths due to asthma and the resultant lost lifetime productivity due to premature mortality. Lost productivity included the present value of future earnings including fringe benefits and household production.

RESULTS: Children with asthma missed more school days (Incident Rate Ratio [IRR]=1.5; \(P<0.001\)) and their caregivers missed more work days (IRR=1.16; \(P<0.05\)) than children without asthma. Children with asthma and an exacerbation, use of > 3 canisters SABA or an AS ED/hospital visit missed more school days than those without asthma (IRR=1.76, 2.73, 3.82; \(P<0.001\)). Caregivers of children with asthma and an exacerbation or an AS ED/hospital visit missed more work days to care for others than caregivers of children without asthma (IRR=1.2, 1.76; \(P<0.05\)). There were 130 deaths in 5-14 year olds due to asthma in 2013. The corresponding lifetime cost of lost productivity due to asthma-related premature mortality was $210.6 million in 2015.

CONCLUSIONS: Despite renewed efforts and availability of guidelines, poor asthma control continues to be a significant burden to children, their caregivers and society. This results in significant school and work absence along with lost productivity due to premature mortality. Improved drug treatment and asthma management programs for children are needed to address this national burden.

SPONSORSHIP: Novartis Pharmaceuticals.

J18 Budget Impact Analysis of Keytruda for Non-Small Cell Lung Cancer: A U.S. Payer Perspective

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BACKGROUND: KEYTRUDA recently received FDA approval for the first-line (1L) treatment of metastatic non-small cell lung cancer (NSCLC) patients who have tumor proportion score (TPS) ≥50% with no EGFR or ALK genomic tumor aberrations, and no prior systemic chemotherapy. KEYTRUDA is also approved as a second-line plus (2L+) treatment option in patients with TPS ≥1% and with disease progression on or after platinum-containing chemotherapy and patients with EGFR or ALK genomic tumor aberration who have disease progression on approved therapy.

OBJECTIVE: We aimed to assess the annual and 3-year budget impact (BI) of including KEYTRUDA into the formulary for the treatment of metastatic NSCLC from a U.S. payer’s perspective.

METHODS: The BI was calculated as the cost difference between the reference scenario (RS) and the new drug scenario (NDS) among a hypothetical 1M member health plan in the U.S. In RS KEYTRUDA (200 mg flat dose) is only available as a 2L+ therapy with TPS ≥1% and in NDS KEYTRUDA (200 mg flat dose) is available for both a 1L and 2L+ therapy as indicated above. Costs considered in the analysis includes the cost of drug acquisition and administration, hospitalization cost associated with grade 3+ adverse events (AEs), and the drug wastage cost. Wholesale average costs were used to calculate the drug acquisition cost, with 20% patient co-insurance. If any chemotherapy is used in both 1L and 2L+, we assumed he same number of doses were used and the incidence of adverse events.

RESULTS: 313 to 320 patients were estimated to have metastatic NSCLC between the base year and year 3. Based on market research, 41% of these patients would receive PD-L1 testing in the base year and the proportion would rise to 80% in year 3. Assuming that 80% of the tested patients received 1L treatment, 28 and 55 patients were eligible for receive KEYTRUDA for the 1L therapy in the base year and year 3, respectively. In the 2L+ setting, 32 patients were eligible to receive KEYTRUDA in the base year and the number increased to 41 in year 3 with expanded 2L+ label. The 3-year annual average cost was estimated to be $4.1M in RS and $5.7M in NDS. The net budget impact was $1.6M per year, $1.559 per treated patient per month and $0.134 per member per month. The results increased to $1.9M, $1.559 and $0.16, respectively, when 20% more patients received PD-L1 testing.

CONCLUSIONS: Including KEYTRUDA for the treatment of metastatic NSCLC resulted in a modest increase in budget. The net increase was primarily driven by the additional drug acquisition cost and results were sensitive to the uptake of PD-L1 testing and market share.

SPONSORSHIP: Merck.
Cost-Effectiveness of Palivizumab Prophylaxis by Gestational and Chronologic Age Among Infants at Increased Risk of Hospitalization for Respiratory Syncytial Virus

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BACKGROUND: Palivizumab is indicated for the prevention of severe respiratory syncytial virus (RSV) disease in preterm and other high-risk infants. New research in U.S. preterm infants has found the risk and cost of RSV hospitalization as well as the cost of palivizumab vary considerably by gestational age (GA) and chronologic age (CA).

OBJECTIVE: To estimate the cost-effectiveness of palivizumab prophylaxis by GA and CA among preterm infants compared with no prophylaxis.

METHODS: A 4-state Markov cohort model consisting of community-dwelling untreated infants, medically treated RSV, post-RSV, and death was developed and populated. The model applied seasonal risk of RSV with and without palivizumab and accrued costs (palivizumab prophylaxis and RSV hospitalizations) and outcomes (health-related quality of life, disutility from wheezing, mortality) over 1-year horizon from the health care payer perspective. Subgroups of infants were defined using combined categories of GA (29-30, 31-32, and 33-34 weeks) and CA (<3, 3-6, and >6 months). Risk of RSV hospitalization and hospitalization costs were estimated from 2014-2015 Marketscan health insurance claims data. Palivizumab treatment costs were estimated using Fenton preterm infant growth charts. The incremental costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs) associated with palivizumab prophylaxis in the 9 subgroups were estimated. Both one-way and probabilistic sensitivity analyses were conducted to evaluate the robustness of the model and findings.

RESULTS: Palivizumab was associated with positive incremental QALYs in all subgroups. Among infants <3 months regardless of GA, ICERs were below typical cost-effectiveness thresholds. Among the 29-30 and 31-32 weeks GA cohorts at <3 months, palivizumab had lower total costs and slightly higher incremental QALYs compared with no prophylaxis. However, among infants >3 months, increased patient weight resulted in higher incremental costs with palivizumab and >6 months generated ICERs beyond typical cost-effectiveness thresholds. The increased incremental QALYs finding was consistent regardless of the inclusion of wheezing disutility and RSV-related mortality and was confirmed by probabilistic sensitivity analysis. The model results were most sensitive to RSV hospitalization cost, RSV hospitalization risk, and palivizumab cost.

CONCLUSIONS: In infants <3 months regardless of GA, palivizumab prophylaxis improved QALYs and reduced costs. Prophylaxis appears to be less cost-effective with increasing CA.

SPONSORSHIP: This study was supported by AstraZeneca.

Understanding the Cost of Chronic Idiopathic Constipation: Evidence from the BURDEN–CIC (Better Understanding and Recognition of the Disconnects, Experiences, and Needs of Patients with Chronic Idiopathic Constipation) Study

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BACKGROUND: Opioid use for the treatment of chronic pain is associated with constipation. Opioid-induced constipation (OIC) is associated with multiple symptoms that significantly affect quality of life. Naldemedine (NAL) is a peripherally-acting μ-opioid receptor antagonist in development for the treatment of OIC.

OBJECTIVE: To assess the effect of NAL on the Patient Assessment of Constipation Symptoms (PAC-SYM) and Quality of Life (PAC-QOL).

METHODS: Data from two identical randomized double-blind placebo (PBO)-controlled studies of NAL were analyzed. Eligible subjects were 18 to 80 years of age, and had ≤4 spontaneous bowel movements (SBM) over 2 weeks, with ≤3 SBMs in a given week and symptoms of constipation in ≥25% of SBMs. Subjects were either not on laxatives or discontinued their use at screening. Subjects with gastrointestinal (GI) abnormalities or taking drugs that could affect GI motility were excluded. Eligible subjects were randomized 1:1 to NAL 0.2 mg once daily or PBO for 12 weeks. Primary endpoints were change in baseline in the frequency of bowel movements (BM)/week over the 12 weeks' treatment, and PAC-SYM and PAC-QOL scores at weeks 2, 4, and 12. Data were analyzed using mixed model repeated measures.

RESULTS: Across both studies, 1,100 subjects were randomized (n=551 to NAL, n=549 to PBO; 60% female, 81% white). NAL treatment led to a significant (P ≤ 0.0144) increase in the frequency of BM/week from baseline to week 12 compared with PBO (Study 1: NAL 2.75 vs. PBO 1.71 BMs/week, Study 2: NAL 2.92 vs. PBO 1.60 BM/week). NAL treatment led to significant (P ≤ 0.0022) improvement from baseline in the mean overall PAC-SYM score for all assessed time points (weeks 2, 4, and 12) compared with PBO (Study 1: NAL -0.88, -0.88, and -0.93; PBO -0.59, -0.55, and -0.62, respectively; Study 2: NAL -0.98, -0.99, and -1.01; PBO -0.69, -0.66, and -0.69, respectively). Similarly, NAL treatment led to significant (P ≤ 0.0014) improvement from baseline in the mean overall PAC-QOL score in both studies for all these time points compared with PBO (Study 1: NAL -0.85, -0.92, and -0.93; PBO -0.54, -0.92, and -0.93, respectively; Study 2: NAL -1.02, -1.10, and -1.08; PBO -0.73, -0.77, and -0.80, respectively). Treatment with NAL for 12 weeks was generally well tolerated and the most frequently reported adverse events were abdominal pain, diarrhea and nausea.

CONCLUSIONS: Treatment with NAL 0.2 mg once daily for up to 12 weeks significantly improved the frequency of BM, as well as symptoms of constipation and quality of life compared with PBO. Treatment with NAL was generally well tolerated.

SPONSORSHIP: Shionogi & Co.
Characteristics of Patients with Irritable Bowel Syndrome with Constipation and Chronic Idiopathic Constipation and Associated Burden of Illness in the United States


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BACKGROUND: Irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) are common overlapping functional gastrointestinal (GI) disorders that impose a substantial burden on patients and the health care system.

OBJECTIVE: To evaluate clinical characteristics and health care resource use (HCRU) among IBS-C and CIC patients vs. matched controls in a sample of the U.S. population.

METHODS: Electronic health records data from 01/01/08 to 12/31/2013 were extracted from the Humedica database. Patients with IBS-C (≥ 1 IBS claim plus met criteria for CIC) or CIC (≥ 2 constipation claims or ≥ 1 constipation-related pharmacy claim) were matched 1:1 with controls in a sample of the U.S. population.

RESULTS: Of 1,246 subjects were randomized (n = 623 in each group). Subjects were 63.3% female and 79.7% white. Treatment with NAL led to a significantly (P<0.0001) greater increase in the frequency of bowel movements (BM/week) from baseline to each assessed time point (NAL 3.70, 3.77, 3.88, and 3.92 vs. PBO 2.42, 2.77, 2.88, and 2.92 BM/week, at weeks 12, 24, 36, and 52, respectively). Treatment with NAL significantly improved (P<0.0001) the mean overall PAC-QOL score from baseline to each assessed time point (weeks 2, 12, 24, 36, and 52) compared with PBO (NAL -1.15, -1.11, -1.16, -1.21, and -1.22, PBO -0.81, -0.86, -0.87, -0.85, and -0.98, respectively). Similarly, NAL treatment significantly improved (P<0.0001) the mean overall PAC-QOL score from baseline to each assessed time point.
Health Care Costs of Patients with Crohn's Disease Receiving Certolizumab Pegol with and Without Home Health Nurse Assistance: Results from a Retrospective Analysis of Patient Claims Data

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BACKGROUND: Certolizumab pegol (CZP) is a subcutaneously administered TNFα antagonist approved for the treatment of moderate to severe Crohn's disease (CD). Patients are not always equipped to self-administer injections. A home health nurse program sponsored by UCB Pharma provides skilled nurses who offer home-based assistance with the administration of CZP injections in CD patients.

OBJECTIVE: The aim of this analysis was to measure the impact of the home health nurse program on health care costs for CD patients who were treated with CZP.

METHODS: A retrospective analysis of U.S. patient claims data from PharMetrics Plus was conducted using data from January 1, 2007 through September 30, 2015. Eligible patients starting the nurse assistance program between January 1, 2008 and September 30, 2014 had to have a CD diagnosis on index date (defined as the first dose of CZP) or in the pre-index period; had to be continuously enrolled in a health plan for 12 months prior to the index date and for ≥60 days after the index date; and had to be newly treated with CZP within 60 days before or after program initiation. Patients were excluded if they had rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis. Patients could receive nurse-administered CZP injections or receive instructions on self-administration (or both). Exact matching was performed on gender and categorical age, with a 1:1 ratio of patients with/without assistance. All other baseline variables were balanced. A multivariate regression analysis was performed using a generalized linear model adjusting for additional covariates to compare the effect of CZP with and without nurse assistance on costs related to hospitalization and total costs.

RESULTS: A total of 552 patients (n = 276 in each cohort) were evaluated for the cost of hospitalization and total health care costs. The median cost of hospitalization per patient was lower with nurse assistance than without ($21,448 vs. $25,001). The median total health care cost per patient with nurse assistance was also lower ($40,929 vs. $44,445). Results from the multiple regression analysis revealed a significant reduction in hospitalization costs (55.8%, P = 0.0026) and total health care costs (14.3%, P = 0.0045) with nurse assistance.

CONCLUSIONS: CZP administration with home health nurse assistance led to a significant reduction in hospitalization and total health care costs compared with CZP administration without nurse assistance.

SPONSORSHIP: This study was sponsored by UCB Pharma.

K7 The Impact of Plecanatide on Quality of Life for Patients with Chronic Idiopathic Constipation: Results from Two Phase 3 Clinical Studies

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BACKGROUND: Chronic idiopathic constipation (CIC) significantly affects quality of life.

OBJECTIVE: This analysis investigates whether plecanatide, a uroguanylin analog that increases fluid secretion in gut, improved health-related quality of life (HRQoL) in 2 clinical trials of patients with CIC.

METHODS: Patients who met modified Rome III CIC criteria were randomized to placebo (PBO), plecanatide 3 mg or 6 mg daily for 12 weeks. The primary endpoint was the proportion of durable overall CSBM responders (≥ 3 CSBMs plus increase of ≥ 1 CSBM over baseline in the same week) for ≥9 of 12 treatment weeks, including ≥3 of the last 4 weeks. Weekly SBM frequency was also assessed. HRQoL assessment included Patient Assessment of Constipation–Symptoms (PAC-SYM); Patient Assessment of Constipation–Quality of Life (PAC-QOL) and Treatment Satisfaction.

RESULTS: A total of 2683 patients were included (ITT) with similar baseline characteristics. Pooled efficacy showed significantly greater overall durable CSM responders with plecanatide 3 mg (n = 184, 20.5%) and 6 mg (n = 176, 19.8%) vs. PBO (n = 103, 11.5%; P < 0.001 both doses). Significant increases in CSBMs were seen during Week 1 and were maintained through Week 12. Improvements in weekly SBMs for plecanatide 3 mg (+1.5) and 6 mg (+1.7) vs. PBO were observed (P < 0.001, both doses). The PAC-SYM was significantly improved for plecanatide 3 mg and 6 mg vs. PBO at Weeks 4, 8 and 12 in both studies, with a mean change difference from PBO at Week 12 of -0.22 (P < 0.001) and -0.23 (P < 0.001) [Study 1] and -0.18 (P = 0.002) and -0.15 (P = 0.009) [Study 2]. A similar improvement in PAC-QOL was noted for plecanatide 3 mg and 6 mg vs. PBO at Weeks 4, 8 and 12 in both studies; the mean change difference from PBO at Week 12 for plecanatide 3 mg and 6 mg were -0.25 (P = 0.001) and -0.28 (P < 0.001) [Study 1] and -0.20 (P < 0.001) and -0.19 (P = 0.001) [Study 2]. The most common AE was diarrhea (3 mg, 4.6%; 6 mg, 5.1%; PBO, 1.3%). Discontinuation rates were 4.1% (3 mg) and 4.5% (6 mg) and 2.2% (PBO) for AEs, and discontinuation rates due to diarrhea were 1.9% (3 mg), 1.8% (6 mg) and 0.4% (PBO). Plecanatide yielded higher mean treatment satisfaction scores at each assessment point and increased over time; treatment differences for plecanatide were significant (P ≤ 0.001) vs. PBO at all assessment points.

CONCLUSIONS: Plecanatide 3 mg and 6 mg significantly improved bowel symptoms and HRQoL at all time points and increased the proportion of durable overall CSBM responders vs. PBO, with a low incidence of diarrhea and other AEs. These data suggest plecanatide will be a useful treatment option in the management of CIC patients.

SPONSORSHIP: Synergy Pharmaceuticals.
active CD and UC. Few studies have compared IBD health care resource utilization among biologic-naive VDZ and IFX patients.

**OBJECTIVE:** The objective was to compare IBD-related resource utilization for office visits, emergency department (ED) visits, endoscopies, and scans (e.g., magnetic resonance imaging and computed tomography) between biologic-naive IBD patients persistent on either VDZ or IFX therapy.

**METHODS:** Adult IBD patients (≥18 years old) initiating VDZ or IFX therapy (first claim as index date) from 5/20/2014 to 3/31/2015 were identified from the Symphony Health Integrated Dataverse, a longitudinal pharmacy and medical claims database. Biologic-naive patients were required to have ≥12 months pre-/post-index enrollment with no history of prior biologic use and to be persistent on therapy (no therapy gap >90 days) during 12-month follow-up. Poisson models were used to estimate the adjusted mean counts, 95% confidence intervals (CI), and incidence rate ratios (IRR). Covariates included diagnosis (CD/UC), geographic region, 12-month pre-index IBD-related resource utilization counts, and Charlson Comorbidity Index.

**RESULTS:** 1,105 biologic-naive patients (n = 164 VDZ; n = 941 IFX) persistent on index therapy were identified. After adjusting for covariates, the mean number of office visits for the IFX group was 1,911 per 1,000 (1k) patients (95% CI: 1,824-2,002) versus 1,537 per 1k patients (95% CI: 1,390-1,745) for the VDZ group, reflecting a 23% greater risk of biologic-naive IFX patients having an office visit than biologic-naive VDZ patients (IRR: 1.23, 95% CI: 1.09-1.38, P < 0.001). The adjusted mean number of ED visits was higher for the IFX group (123 per 1k) than the VDZ group (70 per 1k), reflecting a 75% greater risk for biologic-naive IFX patients than biologic-naive VDZ patients (IRR: 1.75, 95% CI: 1.00-3.07, P = 0.049). The IFX group had a non-statistically significant higher rate of endoscopies than the VDZ group (286 vs. 223 per 1k, P = 0.153) and scans (107 vs. 97 per 1k, P = 0.683).

**CONCLUSIONS:** Using real-world data, biologic-naive patients persistent on VDZ therapy had a statistically significantly lower adjusted rate of IBD-related office visits and ED visits, and a non-significant lower rate of endoscopies and scans than patients persistent on IFX therapy over a 12-month follow-up period.

**SPONSORSHIP:** Funded by Takeda Pharmaceuticals USA.

**L00-L99 Diseases of the Skin and Subcutaneous Tissue (e.g., Psoriasis, Pressure Ulcers)**

**L4 Treatment Patterns with Systemic Therapy or Phototherapy in Patients with Moderate-to-Severe Psoriasis**

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**BACKGROUND:** Moderate-to-severe psoriasis is a chronic condition, often treated by phototherapy, systemic non-biologic therapy (NBT), and biologic therapy. Although short-term treatment patterns among patients with moderate-to-severe psoriasis have been assessed, longer-term (1+ year) treatment patterns are not fully characterized.

**OBJECTIVE:** To describe the treatment patterns of patients with moderate-to-severe psoriasis over the 5 years after psoriasis diagnosis.

**METHODS:** Adult patients in the OptumHealth Reporting and Insights claims database with ≥2 psoriasis diagnoses from January 1998 to March 2015 were identified. Moderate-to-severe psoriasis was defined as the use of ≥1 NBT, biologic, or phototherapy over the 5-year follow-up period after the first psoriasis diagnosis date (index date).

Patients were required to have continuous eligibility ≥3 years before (baseline period) and ≥5 years after the index date (study period). Time to the first phototherapy, NBT, and biologic were assessed using Kaplan-Meier analyses. Patients were censored after 5 years. Up to 5 treatments received during the study period were described. A new treatment was defined as initiating a different treatment, re-initiating the same treatment after a gap of >90 days, adding a different agent to the existing treatment, or discontinuing an agent from the existing treatment.

**RESULTS:** The sample of 1,098 patients had a mean age of 53 years and 46% were female. Of all patients, 48%, 27%, 16%, and 11% initiated 2, 3, 4, and 5 treatments over the study period, respectively. At 5 years, 52% of patients had initiated phototherapy, 46% for a NBT, and 30% for a biologic. The median time from index date to initiation was 4.5 years for phototherapy, 9.6 years for NBT, and never reached for biologics. The most common 1st treatments were ultraviolet-B light (40%) and NBT (38%), with the percentages decreased for later line use (5th treatment: 13% and 26%, respectively). The proportion of patients using biologics increased from 17% to 56% from the 1st to 5th treatment.

**CONCLUSIONS:** Phototherapy and systemic non-biologics were commonly used as 1st treatment among patients with moderate-to-severe psoriasis, with reduced utilization at later line treatment. Biologics tended to be reserved for later lines, and overall biologic use was low over 5 years after psoriasis diagnosis.

**SPONSORSHIP:** Novartis Pharmaceuticals.

**L5 Cost-Effectiveness of Clostridial Collagenase Ointment Compared with Medicinal Honey for Treatment of Pressure Ulcers in the Hospital Outpatient Department Setting**

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**BACKGROUND:** Pressure ulcer (PU) treatment poses substantial clinical and economic challenges to health care systems. Clostridial collagenase ointment (CCO) is the only FDA-approved enzymatic agent indicated for debriding chronic dermal ulcers and severely burned areas. Currently there is a lack of evidence comparing the cost and clinical benefits of enzymatic debridement to autolytic debridement with medicinal honey (MH) in PU.

**OBJECTIVE:** To assess the cost-effectiveness of enzymatic debridement with CCO compared with autolytic debridement with MH for PU treatment in the hospital outpatient department (HOPD) setting.

**METHODS:** A 3-state decision-analytic Markov model was developed from a U.S. payer/Medicare perspective using a 1-week cycle length. The three health states were: (1) granulation/healing; (2) continued healing (patients achieving 100% granulation); and (3) epithelialization/wound closure. The base-case analysis assumed a cohort of adult patients (≥18 years) with stage III and IV PUs treated in a HOPD. Data sources included the U.S. Wound Registry, Medicare fee schedules, and other published clinical and cost studies about PU treatment. Outcome measures included costs (2016 U.S. dollars), number of granulation and epithelialization weeks, number of clinic visits and debridements, quality-adjusted life weeks (QALWs), and incremental cost-effectiveness ratios (ICERs).

**RESULTS:** In the base-case analysis over a 1-year time horizon, patients treated with CCO achieved 11.51 granulation weeks and 6.04 epithelialization/wound closure weeks compared with 10.64 and 4.38 weeks for MH, respectively. The number of clinic visits was 40.07 for CCO vs. 43.38 for MH, and the number of debridements was 12.31 for
CCO compared with 17.61 for MH. Patients treated with CCO experienced 22.73 QALWs at a cost of $6,253 over one year, while MH patients experienced 21.89 QALWs at a cost of $7,230. Therefore, CCO was the economically dominant strategy (i.e., simultaneously conferring greater benefit at less cost). Probabilistic sensitivity analyses determined CCO to be cost-effective in 77% of the 10,000 iterations, assuming a benchmark willingness-to-pay threshold of $50,000/quality-adjusted life year ($962/QALW).

CONCLUSIONS: Results from these cost-effectiveness modeling analyses suggest CCO is a cost-effective alternative to MH in the treatment of adult patients with stage III and IV PUs in the HOPD setting.

SPONSORSHIP: Smith & Nephew.

L8 Evaluating the Impact of Treatment Persistence on the Economic Burden of Moderate-to-Severe Psoriasis and/or Psoriatic Arthritis Patients in the U.S. Department of Defense Population

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BACKGROUND: Psoriasis (PsO) is a chronic, inflammatory, dermatological condition that may be associated with arthritis [psoriatic arthritis(PsA)]. There remains a shortage of real-world evidence for impact of treatment pattern on the economic burden of PsO patients (pts).

OBJECTIVE: Examine the health care costs and utilization between pts who were persistent and non-persistent to biologics among moderate-severe PsO and/or PsA populations.

METHODS: Adult pts with at least two diagnoses of PsO and/or PsA between 11/2010-10/2015 were identified in the U.S. Department of Defense data; the first diagnosis date during 11/2011-10/2014 defined as the index date. Pts were required to have continuous enrollment during the 1-year pre- and post-index period and were considered moderate-severe on index date if they had ≥1 non-topical systemic therapy or phototherapy during the 12 months pre- or 1 month post-index date. Persistence to index therapy, defined as the first biologic used (etanercept, adalimumab, ustekinumab, infliximab) within 30 days post-index date, was determined based on the biologic dosing schedule and a 90-day gap. Generalized linear models were used to compare health care utilization and costs between persistent and non-persistent pts during the 1-year post-index period.

RESULTS: A total of 2,945 moderate-severe PsO and/or PsA pts were identified. Of those, 1,899 (64.5%) were persistent and 1,046 (35.5%) were non-persistent. Compared to non-persistent pts, persistent pts were older (49.2 vs. 45.5 years, P < 0.001) and have a diagnosis of dyslipidemia (40% vs. 35%, P = 0.002) and statin use (23% vs. 18%, P = 0.002), but lower anxiolytic use (30% vs. 37%, P < 0.001). After adjusting for pts demographic and clinical characteristics, non-persistent pts had a significantly higher number of ambulatory visits (23.9 vs. 21.4, P = 0.009), which resulted in higher total medical costs ($12,448 vs. $7,866, P < 0.001) compared to persistent pts. About 40% of the total medical costs were attributed to PsO and PsA. Although persistent pts incurred higher pharmacy costs ($10,774 vs. $7,856, P < 0.001) mainly due to more usage of biologics, their PsO/PsA-related medical costs were significantly lower than non-persistent pts ($3,414 vs. $5,022, P < 0.001) compared to persistent pts. Among working patients with moderate-to-severe psoriasis, those achieving and sustaining PASI improvement ≥90 were associated with a prominent increase in workplace productivity and reduction in annual indirect costs. These results indicate that effective skin clearance may contribute to reduced productivity loss.

SPONSORSHIP: Novartis Pharmaceuticals.
Connecting Patient and Physician Treatment Satisfaction by Severity in Psoriasis to Patient-Reported Outcomes in the United States

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BACKGROUND: Patient satisfaction is a measure of health system performance and a crucial element of patient-centered care.

OBJECTIVE: To explore psoriasis severity and Dermatologic Life Quality Index (DLQI) score as determinants of treatment satisfaction in a sub-analysis comparing patients across treatment groups in the United States (U.S.) population.

METHODS: This is a retrospective study of eligible adult patients with psoriasis (PsO) and their physicians from the 2015 Adelphi PsO Disease Specific Program (DSP). The PsO DSP captures responses from patients and physicians in the U.S. Patients self-reported responses for the DLQI, a validated questionnaire of 10 questions with a composite score of 0-30 used to measure quality-of-life (QoL) in dermatology. Higher scores indicate more severe QoL impairment. Physicians and patients self-reported treatment satisfaction on the Adelphi questionnaire, and physicians reported severity through the Body Surface Area (BSA) measure. Study groups considered were no therapy, topical/phototherapy, systemics, apremilast, and biologics. Statistical analyses controlling for patient and physician demographics and clinical characteristics were conducted.

RESULTS: 70 physicians and 394 eligible patients completed paired responses related to their perceptions of treatment satisfaction. From the patient sample, 45.9% were female, and mean age and DLQI score were 44.5 years and 5.0, respectively. From the physician sample, 37.1% were female and median time in practice was 18 years. Median baseline PsO severity for patient respondents was 12% of BSA. Among U.S. patients, 33.2% were satisfied with biologic treatments compared to 27.4% for all other treatments. Patients satisfied with biologics showed lower DLQI scores (Mean: 3.10; 95% CI: 2.47-3.73) compared to patients not satisfied with biologics (Mean: 7.86; 95% CI: 6.76-8.97). The DLQI question on itching, soreness, pain, and stinging of the skin contributed most to the overall DLQI score. Comparing across treatment groups, patients not satisfied with current therapy had mean DLQI scores ranging from 7.86-14.0. A greater number of unsatisfied patients across treatment groups had severe psoriasis, based on BSA, ranging from 62.3-100%.

CONCLUSIONS: Patients unsatisfied with current treatment reported higher DLQI scores and higher BSA severity across treatment groups. New treatment options for psoriasis are needed because a high percentage of patients in both the non-biologic and biologic cohorts were unsatisfied with their current treatment.

SPONSORSHIP: Janssen Scientific Affairs.

ABP 501 (Amjevita) Biosimilar to Adalimumab: Demonstration of Value with Lower Perception of Injection Site Pain

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BACKGROUND: ABP 501 was recently approved by the U.S. FDA as the first biosimilar to adalimumab (Humira), a fully human recombinant monoclonal antibody. Totality of evidence based on analytical and pharmacokinetic comparisons and two clinical efficacy, safety, and immunogenicity studies indicates that ABP 501 is highly similar to adalimumab. Formulation excipients of a biosimilar can differ provided there is no clinically meaningful difference with the reference. ABP 501 is formulated with different excipients than are used for the adalimumab reference product and the two phase 3 studies included evaluation of injection site pain perception.

METHODS: We performed a retrospective observational study using the Truven MarketScan claims database. Patients newly diagnosed with RA (ICD-9: 714.0x-714.2x) from 2009-2013, age 18+ at diagnosis (index), with ≥1 RA diagnoses, ≥1 year continuous enrollment pre-/post-index, and no RA diagnosis or DMARDs in the 1y pre-index were included. Patients with 1+ DMARD claim in the 1y post-index were categorized as DMARD initiators. Within the DMARD initiation group, patients were categorized as bDMARD initiators, as opposed to conventional DMARD (cDMARD) initiators, if a bDMARD appeared as the first DMARD claim or in the 14 days after the first cDMARD claim. Predictors of DMARD initiation and initiation of first-line bDMARD were assessed using multivariable logistic regression.

RESULTS: 25,909 patients met selection criteria; mean±SD age of 57±15 years, 74% female, 14,680 patients (57%) initiated a DMARD within 1y of diagnosis. Compared to those who did not initiate a DMARD, patients who initiated DMARD were younger (54 vs. 61y), more likely to have seen a rheumatologist (46 vs. 19%), received RA workup (serologic tests: 61 vs. 20%; joint imaging: 72 vs. 50%), opioids (49 vs. 46%), or glucocorticoids (60 vs. 41%) in the 1y pre-index (all P<0.05). Of the DMARD initiators, 854 (5.8%) initiated on first-line bDMARD. Compared to the cDMARD initiators, patients initiating bDMARDs were younger (50 vs. 55y), more frequently male (30 vs. 26%), had 1.6-10 times higher rates of other autoimmune comorbidities (e.g. Psoriasis: 4.8 vs. 1.0%; Ankylosing Spondylitis: 3.4 vs. 0.3%), less likely to have received RA workup (serologic tests: 43 vs. 62%; joint imaging: 56 vs. 72%), opioids (42 vs. 50%), or glucocorticoids (50 vs. 60%), and more likely to have seen a rheumatologist (50 vs. 46%) in the 1y pre-index (all P<0.05).

CONCLUSIONS: 43% of patients failed to initiate a DMARD during follow-up, demonstrating that improvement towards guidelines is needed. Multiple demographic and clinical variables predicted DMARD initiation and first-line use of bDMARD vs. cDMARD. Further research into the role of patients, providers and payers in DMARD decision-making is needed.

SPONSORSHIP: Eli Lilly and Company.
OBJECTIVE: To present results of patient perception of injection site pain.

METHODS: Both studies were randomized, double-blind, active-controlled trials: one in patients with moderate to severe rheumatoid arthritis (RA; N = 526) and the other in patients with moderate to severe plaque psoriasis (PsO; N = 350). The details of the two study designs and their efficacy, safety, and immunogenicity results have been previously reported. In both studies, injection site pain perception was assessed at baseline and at weeks 4, 8, and 12 using an adjusted 100 mm horizontal visual analog scale measured within 5 minutes after injection.

RESULTS: In the RA study, mean injection site pain perception scores were lower in the ABP 501 group (range: 10.0-10.7 mm) vs. the adalimumab group (range: 16.1-21.4 mm) at each evaluated visit. In the PsO study, mean injection site pain perception scores were also lower in the ABP 501 group (range: 3.3-4.5 mm) compared with the adalimumab group (range: 12.4-19.3 mm) at each of the four time-points. There were no withdrawals in either study due to injection site pain.

CONCLUSIONS: These results confirm that in addition to being clinically highly similar, perception of injection site pain was lower with ABP 501 compared with adalimumab reference product. Results are attributed to the different excipients in the ABP 501 formulation from that of the adalimumab reference product.

SPONSORSHIP: Amgen

M3 Adverse Event Data as Proxy to Determine Total Medical Costs for TNF-Alpha Inhibitors

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BACKGROUND: Efficacy for new drugs is generally studied carefully, but long term follow up in populations possessing comorbidities not contemplated in FDA safety evaluations is generally less well studied. We suggest that better ADE awareness and severity stratification may be achieved by combining signal from the aggregated practitioner reported observations along with other insurance claim data. Combined voluntary reported data and claims data may corroborate a suspected ADEs by examining downstream medical costs that are associated with ADEs.

OBJECTIVE: This study examined downstream medical costs associated with infections from the use of TNF-alpha inhibitors. The goal was to establish whether ADE cost analytics can be compared with claims databases to model safer and more cost-effective drug decisions.

METHODS: We analyzed ADE and claims data for six TNF-Alpha inhibitors from August 2013 through July 2015. We examined: (1) ADE and outcome-specific medical costs obtained from AHRQ; (2) ADE and outcome data from FAERS; (3) drug usage information from Evaluate Pharma; and (4) claims data from WEA Trust. ICD-9 diagnoses were mapped to each ADE. Focus was limited to EudraVigilance Important Medical Events and “primary suspect” ADE reports. CPT Service Codes were used to establish three cost measurements: ER visits, hospitalizations, and ambulance transportation.

RESULTS: Certolizumab and golimumab were associated with a higher incidence of ADEs compared to other TNF-alphas in both ADE and claims data. Downstream medical cost per dispense were: $322, $250, and $190 for certolizumab, adalimumab and etanercept, respectively, for ER visits. Hospitalizations costs were $156, $79, and $57 and ambulance transportation were $30, $19, and $19 for certolizumab, adalimumab, and etanercept, respectively.

CONCLUSIONS: Given that both ADE and claims data suggested that two TNF-alpha inhibitors were more likely to cause infections and higher medical costs, WEA Trust will be working with providers to modulate TNF-alpha inhibitor prescriptions to lower cost and improve safety. Future work will examine other drug classes regarding the use of ADE analytics as a proxy for drug benefit design.

SPONSORSHIP: Collaborative between WEA Trust and Advera Health Analytics, with no sponsorship or funding of the project.

M4 Using Self-Reported Patient Experiences to Evaluate Barriers to Treatment Access: Learnings from Digital Patient Communities in Psoriatic Arthritis

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BACKGROUND: Psoriatic arthritis (PsA) is a debilitating disease which can be effectively managed with proper access to treatment options such as biologics and small-molecule inhibitors.

OBJECTIVE: To characterize the challenges and barriers to treatment access faced by patients with PsA using self-reported online narratives.

METHODS: Unguided patient narratives were collected between January 2010 and May 2016 from 31 online sources (general health social networking sites, disease-focused patient forums, treatment reviews, general health forums and mainstream social media sites) for analysis of functional impairment and 40 online sources for assessment of barriers to treatment for patients with PsA. Using a natural language processing platform (RLytics) and manual expert curation, these narratives were categorized into 5 high-level concepts of functional impairment (social, physical, emotional, cognitive and role activity), and 6 categories to assess barriers to treatment access (coverage ineligibility, out-of-pocket cost, issues with assistance programs, clinical ineligibility, formulary placement/sequence and doctor guidance).

RESULTS: Of 15,390 narratives collected from 3,139 patients with PsA, physical aspects of disease were the most commonly reported high-level concept (81.6%), followed by emotional (50.7%), cognitive (20.0%), role activity (8.1%) and social (5.6%) concepts. Overall, 27.5% of 1,485 patients with PsA reported barriers to treatment access. Coverage ineligibility (51.7%) and out-of-pocket costs (31.7%) were the most commonly reported barriers to treatment access, followed by clinical ineligibility (11.7%), issues with assistance programs (8.3%), formulary sequence requirements (8.3%) and doctor guidance (0.8%). Among those who reported coverage ineligibility, patients cited delayed access (19.8%), reduced coverage (11.3%) and discontinued coverage (65%), the majority of ineligibility reasons (75.8%) were unspecified. Among patients citing out-of-pocket costs as their main barrier to treatment access, out-of-pocket affordability (79.6%) and copay/insurance affordability (29.6%) were the most common reasons given.

CONCLUSIONS: Physical aspects of PsA were the most discussed concept online. Nearly one-third of patients with PsA reported barriers to treatment access, the most common of which were coverage ineligibility and out-of-pocket costs. Further research is needed to mitigate access barriers in order to optimize treatment and improve clinical outcomes and quality of life in patients with PsA.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.
M5 Real-World Use of Secukinumab Among Patients with Psoriatic Arthritis in the United States: Patient Profile and Dosing

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BACKGROUND: As of January 15, 2016, secukinumab became the first fully human anti-interleukin-17 monoclonal antibody approved for the treatment of patients with psoriatic arthritis (PsA) in the United States. The use of secukinumab in a real-world setting of patients with PsA has not been evaluated since its approval.

OBJECTIVE: To describe the demographic and clinical characteristics of patients with PsA treated with secukinumab and examine its dosing in routine clinical practice in the United States.

METHODS: Retrospective data from the Symphomy Health Solutions Lx commercial claims database were used to identify patients who were ≥ 18 years of age, had ≥ 1 ICD-9 code of 696.0 or ICD-10 code of L40.5 for PsA, had ≥ 1 pharmacy or medical claim in the 12 months prior (baseline period) to their index date (first secukinumab claim between 01/15/2016 and 06/30/2016) and had ≥ 1 secukinumab claim during the study period. Patient demographics and secukinumab dosage were examined at the index date. Clinical characteristics, comorbidities and treatment history were identified during the baseline period.

RESULTS: A total of 1,797 patients treated with secukinumab were included; at the index date, 1,475 patients (82.1%) received secukinumab at the 300-mg dose and 322 patients (17.9%) received the 150-mg dose. The mean (SD) age was 50.7 (11.4) years, 56.9% of patients were female and 41.1% of patients were from the south. The most prevalent comorbidities were psoriasis (PsO; 65.7%), hypertension (32.7%) and hyperlipidemia (24.9%). The majority of patients (76.2%) received a biologic during the baseline period, with the most common being prior secukinumab (36.4%) and ustekinumab (20.3%). Other prior treatments included csDMARDs (33.4%), oral corticosteroids (25.8%) and tsDMARDs (21.5%). The most common specialties prescribing secukinumab to patients with PsA were rheumatologists and dermatologists (40% each), with both more likely to prescribe the 300-mg dose (99% dermatologists, 64% rheumatologists).

CONCLUSIONS: This claims-based study found the majority of patients with PsA received secukinumab at the 300 mg dose. Most patients had received a prior biologic, including previous treatment with secukinumab, which is an indicator of patients with comorbid PsA and PsO who began treatment in the previous year for the drug’s PsO indication. Overall, secukinumab was equally prescribed for PsA by both rheumatologists and dermatologists. These results provide insight into real-world use of secukinumab in patients with PsA in the United States.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.

M6 Patterns of Treatment Adherence, Persistence, and Discontinuation of Biologic Therapy Among Patients with Psoriatic Arthritis in the United States—Descriptive Analyses from an Administrative Claims Database

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BACKGROUND: In patients with psoriatic arthritis (PsA) receiving biologic therapy, treatment persistence is critical to achieving optimal outcomes; however, recent real-world data on biologic treatment patterns in patients with PsA are limited.

OBJECTIVE: To describe patterns of adherence, persistence and discontinuation of biologic therapies in patients with PsA.

METHODS: This study used administrative claims data from the Optum Research Database. Adults with PsA who newly initiated (no evidence of use in the 12 months prior) a biologic between January 1, 2013 and January 31, 2015, and were continuously enrolled in a commercial or Medicare Advantage health plan 12 months before (baseline period) and 15 months following the index date, defined as the date of first pharmacy fill or medical infusion, were included. Outcomes included persistence and discontinuation (>90-day gap) of the index biologic, post-persistence treatment patterns (switching to a different biologic; discontinuing and restarting the index biologic or discontinuing the index biologic without switching or restarting), and treatment adherence (proportion of days covered [PDC] by index medication).

RESULTS: Of the 1,235 patients with PsA included, 52.5% were female and the mean (SD) age was 50.3 (12.1) years. The mean (SD) baseline Charlson Comorbidity Index score was 0.7 (1.2); the most common Agency for Health Care Research and Quality comorbidities were other disorders (73.4%). Patients initiated etanercept (48.1%), adalimumab (24.0%), infliximab (10.4%), golimumab (8.3%), ustekinumab (7.2%) or certolizumab (2.0%) as their index biologic. The mean (SD) duration of persistence with the index biologic was 246 (128) days; 44.5% of patients persisted on the index biologic for ≥ 12 months. Infliximab had the highest 12-month persistence rate (61.2%), and certolizumab had the lowest (32.0%). During the 12-month follow-up period, 22.9% of patients switched to a different biologic, 5.8% discontinued and restarted the index biologic and 26.8% discontinued without switching or restarting. The overall mean (SD) PDC was 0.59 (0.30).

CONCLUSIONS: In this descriptive, administrative claims-based study, the majority of patients with PsA discontinued their index biologic prior to 1 year, among those who discontinued, only 10.5% restarted the same biologic within that year. These findings provide a better understanding of real-world treatment patterns of biologics in PsA and unmet treatment needs of patients.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.

M11 Using Self-Reported Patient Experiences to Evaluate Barriers to Treatment Access in Ankylosing Spondylitis: Learnings from Digital Patient Communities

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BACKGROUND: Accessibility of treatment options is critical in achieving optimal monitoring and treatment in patients with ankylosing spondylitis (AS).

OBJECTIVE: To examine the disease burden and barriers to treatment access faced by patients with AS by analyzing patient narratives reported in online communities.

METHODS: Patient narratives were collected between January 2010 and January 31, 2015, and were continuously enrolled in a commercial or Medicare Advantage health plan 12 months before (baseline period) and 15 months following the index date, defined as the date of first pharmacy fill or medical infusion, were included. Outcomes included persistence and discontinuation (>90-day gap) of the index biologic, post-persistence treatment patterns (switching to a different biologic; discontinuing and restarting the index biologic or discontinuing the index biologic without switching or restarting), and treatment adherence (proportion of days covered [PDC] by index medication).

RESULTS: Of the 1,235 patients with PsA included, 52.5% were female and the mean (SD) age was 50.3 (12.1) years. The mean (SD) baseline Charlson Comorbidity Index score was 0.7 (1.2); the most common Agency for Health Care Research and Quality comorbidities were other disorders (73.4%). Patients initiated etanercept (48.1%), adalimumab (24.0%), infliximab (10.4%), golimumab (8.3%), ustekinumab (7.2%) or certolizumab (2.0%) as their index biologic. The mean (SD) duration of persistence with the index biologic was 246 (128) days; 44.5% of patients persisted on the index biologic for ≥ 12 months. Infliximab had the highest 12-month persistence rate (61.2%), and certolizumab had the lowest (32.0%). During the 12-month follow-up period, 22.9% of patients switched to a different biologic, 5.8% discontinued and restarted the index biologic and 26.8% discontinued without switching or restarting. The overall mean (SD) PDC was 0.59 (0.30).

CONCLUSIONS: In this descriptive, administrative claims-based study, the majority of patients with PsA discontinued their index biologic prior to 1 year, among those who discontinued, only 10.5% restarted the same biologic within that year. These findings provide a better understanding of real-world treatment patterns of biologics in PsA and unmet treatment needs of patients.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.
RESULTS: Of 34,780 narratives collected from 3,449 patients with AS, physical aspects of AS (e.g., pain and mobility) were by far the most commonly reported concept (87%), followed by emotional (33%), cognitive (24%), role activity (9%) and social (5%) concepts. About one-third of patients with AS (n=1,303) reported barriers to treatment access; coverage ineligibility (44%) and out-of-pocket costs (27%) were the most frequently reported barriers to treatment access, followed by doctors’ guidance (7%), limited access to assistance programs (6%), clinical ineligibility (5%) and formulary placement/sequence (2%). Among patients who reported coverage ineligibility as their main barrier to treatment access, 19% cited coverage discontinuation, 12% reported delayed access to coverage and 7% had reduced coverage (71% reported coverage ineligibility for unspecified reasons). As for the patients who reported out-of-pocket costs as their main barrier to treatment access, 93% reported inability to afford expensive medication, while 19% reported difficulties with copay/insurance affordability.

CONCLUSIONS: Analysis of patient narratives from online sources highlighted some functional impairment concepts that may be critical in understanding the burden of AS. In addition, recognizing barriers to treatment access and identifying means of improvement would be critical in providing optimal therapy for patients with AS.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.

M12 Patterns of Treatment Adherence, Persistence, and Discontinuation of Biologic Therapy Among Patients with Ankylosing Spondylitis in the United States: Descriptive Analyses from an Administrative Claims Database

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BACKGROUND: Adherence and persistence to biologic therapy in patients with ankylosing spondylitis (AS) is critical to achieve optimal outcomes by alleviating pain and delaying radiographic progression; however, the number of real-world studies examining biologic therapy use in patients with AS is limited.

OBJECTIVE: To examine adherence, persistence and discontinuation of biologic therapies in patients with AS.

METHODS: This study used administrative pharmacy and medical claims data from the Optum Research Database. Adult patients with AS who newly initiated (no evidence of use in the 12 months prior) a biologic between January 1, 2013 and January 31, 2015, and were continuously enrolled in a commercial or Medicare Advantage health plan 12 months before (baseline period) and 15 months following the index date, defined as the date of first pharmacy fill or medical infusion, were included. Outcomes included persistence and discontinuation (>90-day gap) of the index biologic; post-persistence treatment patterns (switching to a different biologic, discontinuing and restarting the index biologic or discontinuing without switching or restarting); and treatment adherence (proportion of days covered [PDC] by index medication).

RESULTS: Of the 426 patients included (45.8% female; mean [SD] age: 45.1 [15.1] years), approximately half of the patients (45.1%) initiated etanercept, followed by adalimumab (28.6%), golimumab (11.7%), infliximab (11.7%) and certolizumab (2.8%). The most common Agency for Health Care Research and Quality comorbidities were non-traumatic joint disorders (97.4%) and spondylosis/intervertebral disc disorders/other back problems (79.6%). The mean (SD) PDC (treatment adherence) and duration of persistence with the index biologic were 0.56 (0.29) and 236 (131) days, respectively; only 40.6% of patients persisted on the index biologic for ≥12 months. During the 12-month follow-up period, 24.4% of patients switched to a different biologic, 7.0% discontinued and restarted the index biologic and 31.0% discontinued without switching or restarting.

CONCLUSIONS: In this descriptive, administrative claims-based study, a high proportion (~39%) of patients with AS either switched or discontinued their biologic therapy in the 12 months of follow-up. Further research is needed to better understand the reasons for discontinuation and switching between biologic therapies in patients with AS.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.

M13 Real-World Use of Secukinumab Among Patients with Ankylosing Spondylitis in the United States: Patient Profile and Dosing

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BACKGROUND: Secukinumab is a fully human anti-interleukin-17 monoclonal antibody approved for the treatment of patients with moderate to severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis (AS). The use of secukinumab in a real-world setting of patients with AS has not been evaluated since its approval in the United States on January 15, 2016.

OBJECTIVE: To describe the demographic and clinical characteristics of patients with AS who were treated with secukinumab and to examine secukinumab dosage use in routine clinical practice in the United States.

METHODS: Retrospective data from the Symphomy Health Solutions Lx commercial claims database between January 15, 2016 and June 30, 2016 were included in the study. Patients eligible for inclusion were ≥18 years of age who had the diagnosis of AS and ≥1 pharmacy or medical claim in the 12 months prior (baseline period) to their index date (first secukinumab claim) and ≥1 secukinumab claim during the study period. Patient demographics and secukinumab dosage were examined at the index date. Clinical characteristics, comorbidities and treatment history were identified during the baseline period.

RESULTS: A total of 250 patients treated with secukinumab were included in the study. At the index date, 101 patients (40%) received secukinumab at the 300 mg dose and 149 patients (60%) received the 150 mg dose. The mean (SD) age was 45.5 (11.5) years and 54% of patients were female. The most prevalent comorbidities included hypertension (20%), hyperlipidemia (17%) and psoriatic arthritis (13%). The majority of patients (66%) received a biologic during the baseline period, the most common being adalimumab (22%) and etanercept (17%). Other prior treatments included conventional synthetic disease-modifying antirheumatic drugs (30%; including 19% methotrexate), oral corticosteroids (32%), targeted synthetic disease-modifying antirheumatic drugs (7%) and nonsteroidal anti-inflammatory drugs (25%).

CONCLUSIONS: In this retrospective, administrative claims-based study, the majority of patients received secukinumab at the 150 mg dose and had received a biologic prior to secukinumab. The most prevalent comorbidities among patients with AS who received secukinumab were hypertension, hyperlipidemia and psoriatic arthritis. The results of this study provide early insights into real-world use of secukinumab in patients with AS in the United States.

SPONSORSHIP: Sponsored by Novartis Pharmaceuticals.
**M18** A Budget Impact Analysis of Total Disc Replacement for Single-Level Lumbar Degenerative Disc Disease: A U.S. Private Health Insurer Perspective

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**BACKGROUND:** Evidence on the favorable efficacy, safety and cost-effectiveness of lumbar total disc replacement (TDR) compared with fusion surgeries for lumbar degenerative disc disease (LDDD) is mounting; however, U.S. health insurance plans have been slow to cover this technology. Concerns regarding the budget impact of lumbar TDR surgery may underlie such decisions.

**OBJECTIVE:** The study objective was to estimate the budget impact of single-level lumbar TDR coverage for LDDD for a typical U.S. private health plan.

**METHODS:** An economic model, with a one-year time horizon, was developed assuming a population size of 1,000,000 privately insured patients. Published sources were used to estimate the prevalence of LDDD and the proportion that failed conservative care annually. The number of lumbar fusions for this sub-population was estimated using national-level, observational data, adjusted to the analysis target population. Given current fusion surgery rates and published estimates that 5% of lumbar fusion patients may be eligible for TDR, the on-label TDR surgery rate is estimated at 1.4 per one million insured. Reoperation rates were taken from a recent network meta-analysis of TDR and fusion randomized trials. Procedure costs of TDR and fusion were informed by Medicare 2016 DRG payment rates. Ongoing medical management costs were also included for all treatment options.

**RESULTS:** In the absence of TDR coverage, the model predicts that the target insurance plan to incur annual costs of $18.56 million for LDDD and the proportion that failed conservative care annually. The number of lumbar fusions for this sub-population was estimated using national-level, observational data, adjusted to the analysis target population. Given current fusion surgery rates and published estimates that 5% of lumbar fusion patients may be eligible for TDR, the on-label TDR surgery rate is estimated at 1.4 per one million insured. Reoperation rates were taken from a recent network meta-analysis of TDR and fusion randomized trials. Procedure costs of TDR and fusion were informed by Medicare 2016 DRG payment rates. Ongoing medical management costs were also included for all treatment options.

**CONCLUSIONS:** Based on the available evidence, TDR is expected to be less costly than surgical fusion and result in minimal to no budget impact when coverage is aligned with well-studied patient populations.

**SPONSORSHIP:** This work was sponsored by Aesculap.

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**N00-N99** Diseases of the Genitourinary System (e.g., ESRD)

**N1 Economic Burden of Anemia in Patients with Nondialysis-Dependent Chronic Kidney Disease**

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**BACKGROUND:** Although the economic burden of anemia among dialysis-dependent chronic kidney disease (DD-CKD) patients is well-characterized, contemporary data characterizing the economic burden of anemia in non-DD-CKD (NDD-CKD) patients are very limited.

**OBJECTIVE:** To evaluate the association between hemoglobin (Hb) level and economic burden in NDD-CKD patients.

**METHODS:** This retrospective analysis used electronic health records from patients enrolled in the Health Care Partners managed care provider group between July 1, 2013 and June 30, 2015. Patients were ≥ 18 y/o, with ≥ 1 Hb measurement while eGFR < 60 mL/min/1.73m² and not receiving ESA: they were categorized by Hb level < 9.0, 9.0-9.9, 10.0-10.9, 11.0-11.9, and ≥ 12 g/dL, and also eGFR 45-59, 30-44, 15-29 and < 15 mL/min/1.73 m² (CKD stages 3a, 3b, 4 and 5, respectively). Total health care costs (inpatient, outpatient, and pharmacy) in older patients with OP. Secondary outcomes included clinical outcomes.

**RESULTS:** A total of 142,318 patients (OP and OAB = 5,527; OP and no OAB = 136,791) were eligible for inclusion. After matching, 11,052 (5,526 per cohort) were included in the analyses. Patients with OP and OAB had greater all-cause inpatient utilization (19.7% vs. 15.3%, P < 0.001), emergency room use (32.8% vs. 27.4%, P < 0.001), and physician office visits (10.8 (7.1 vs. 8.8 (7.0), P < 0.001). Mean OP-related outpatient visits were greater among patients with OAB (0.96 vs. 0.93, P = 0.009); however, no other OP-related HRU measures differed between groups. A greater proportion of patients with co-occurring OAB had a fall and/or fracture in the post-index as compared to the non-OAB controls (17.7% vs. 14.9%, P < 0.001). Patients with co-occurring OAB had total health care costs that were approximately 35% greater than non-OAB OP patients (P < 0.001).

**CONCLUSIONS:** Co-occurring OAB was associated with greater HRU and health care costs in patients with OP. Comorbid OAB was also associated with increased prevalence of falls and/or fractures in patients with OP.

**SPONSORSHIP:** Study was funded by Astellas and conducted as part of the Astellas-Humana Research Collaboration.

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**M20 Impact of Co-occurring Overactive Bladder in Medicare Patients with Osteoporosis**

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**BACKGROUND:** Osteoporosis (OP) is a common condition impacting older adults. Overactive bladder (OAB) is, similarly, a common condition in older adults and is associated with negative impacts on health-related problems, quality of life and costs. There is a paucity of evidence examining the impact of co-occurring OAB in patients with OP.

**OBJECTIVE:** The primary objective of the study was to examine the impact of co-occurring OAB on health care resource utilization (HRU) in older patients with OP. Secondary outcomes included clinical outcomes and costs.

**METHODS:** This historical cohort study compared patients with OP and co-occurring OAB to a comparison group of patients with OP but no OAB. Patients with a diagnosis of OP, enrolled in a Medicare plan, and aged ≥ 65 and < 90 years were eligible. Patients with OAB were required to have a diagnosis of OAB after OP diagnosis and the non-OAB comparison group could not have evidence of OAB during the study period. The date of diagnosis of OAB was considered the index date for the OAB group, the non-OAB comparison group was assigned an index date. Propensity score matching was used to balance the cohorts on baseline demographic and clinical characteristics. A 12-month post-index period was used to evaluate HRU, falls and/or fractures and costs. Analyses included bivariate comparisons and regression models. Ordinary least squares regression was used to examine the relationship between OAB and log-transformed total health care costs.

**RESULTS:** Patients with co-occurring OAB had total health care costs that were approximately 35% greater than non-OAB OP patients (P < 0.001).

**CONCLUSIONS:** Based on the available evidence, TDR is expected to be less costly than surgical fusion and result in minimal to no budget impact when coverage is aligned with well-studied patient populations.
RESULTS: Overall, 26,833 patients (CKD stage 3a, n = 17,559; 3b, n = 6,848; 4, n = 1,976; 5, n = 450) were included. Total health care costs (mean [SD], US$ per member/month) were significantly higher for patients with Hb < 10.0 g/dL compared with Hb 10.0-12.0 g/dL. This was also evident by CKD stage; the adjusted mean difference (AMD) in health care costs being significantly higher for patients with Hb 9.0-9.9 g/dL or < 9.0 g/dL versus Hb 10.0-12.0 g/dL: stage 3a, +$343 (P < 0.001) and +$998 (P < 0.001); stage 3b, +$275 (P < 0.001) and +$718 (P < 0.01); stage 4, +$263 (P < 0.05) and +$948 (P < 0.01), respectively. AMDs for stage 5 showed a similar but non-significant trend (+$931 and +$1,411), albeit patient numbers were relatively small. Hospitalization rates (incidence rate ratios [IRRs]) were similarly higher for Hb < 10.0 g/dL versus Hb 10.0-12.0 g/dL. This was similarly evident by CKD stage with IRRs for hospitalization being significantly higher for Hb 9.0-9.9 g/dL and < 9.0 g/dL versus Hb 10.0-12.0 g/dL: stage 3a, 2.87 (P < 0.001) and 5.06 (P < 0.001); stage 3b, 1.87 (P < 0.001) and 3.43 (P < 0.001); and stage 4, 2.14 (P < 0.001) and 3.49 (P < 0.001), respectively. Trends for stage 5 were similar but non-significant.

CONCLUSIONS: In patients with CKD stages 3/4 not treated for anemia, Hb levels < 10 g/dL were associated with higher health care costs and greater hospitalization rates compared with a higher Hb level of 10-12 g/dL. This suggests a need for better management of patients with anemia and NDD-CKD.

SPONSORSHIP: Study sponsored by AstraZeneca.

N3 The Economic Burden of Overactive Bladder Among Medicare Beneficiaries with Employer-Sponsored Supplemental Coverage

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BACKGROUND: While Medicare population, overactive bladder (OAB) is a prevalent chronic condition that significantly affects quality of life. However, recent published estimates of the economic burden of OAB in Medicare beneficiaries are limited.

OBJECTIVE: To quantify the direct cost burden of OAB within a population of Medicare beneficiaries with employer-sponsored supplemental coverage.

METHODS: Adults with an OAB diagnosis or OAB prescription therapy between 1/1/2008-12/31/2013 were identified from the MarketScan Medicare database (index date = qualifying claim date). Patients were required to have ≥ 12 months of pre- and ≥ 1 month of post-index continuous enrollment. Patients without OAB were propensity score-matched to the OAB case cohort. Log-transformed, total per patient per month (PPPM) direct health care costs were estimated using ordinary least squares regression, adjusting for patient demographic and clinical characteristics, as well as baseline health care costs. Values were transformed back to the original dollar scale by the use of smearing estimators. The level of statistical significance for all tests was set at 0.05.

RESULTS: 36,191 OAB patients were identified and propensity score-matched to the same number of non-OAB patients. Within the combined OAB and non-OAB study population, 81.1% were female and 56.9% were ≥ 75 years of age. The mean and median, multivariable-adjusted PPPM health care costs were $3,448 and $1,987 for OAB patients and $1,858 and $920 for non-OAB patients (P < 0.0001 for both differences in means and medians). Other factors associated with significantly higher costs were: age ≥ 75 years, males, greater comorbid burden as indicated by the Charlson Comorbidity Index score, and having comorbid diabetes, hypertension, multiple sclerosis, and osteoporosis (P < 0.0001 for all).

CONCLUSIONS: Within this Medicare population, the mean, multivariable-adjusted health care costs of OAB patients were 85.6% higher than those of similar patients without OAB.

SPONSORSHIP: Supported by Janssen Scientific Affairs.

N4 Refill Gaps and Dose Reductions in Patients with Prostate Cancer and Visceral Metastases Treated with Abiraterone Acetate Plus Prednisone or Enzalutamide

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BACKGROUND: The prognosis for men with metastatic castrate resistant prostate cancer (mCRPC) and visceral metastases is generally poorer when compared to those without visceral metastases. The two oral mCRPC therapies abiraterone acetate plus prednisone (AA + P) and enzalutamide (ENZ) have been shown to improve overall survival in this more severe population. However, dose reductions and refill gaps may be associated with lower drug effectiveness.

OBJECTIVE: To study identified refill gaps and a dose reduction in mCRPC patients with visceral metastases treated with AA + P or ENZ.

METHODS: The MarketScan databases (03/2012-10/2015) were used to conduct a retrospective analysis. Patients initiated on AA + P or ENZ (index date) after 09/2012 with ≥ 6 months of continuous eligibility prior to index date (baseline period), ≥ 1 diagnosis for prostate cancer, and ≥ 1 diagnosis for visceral metastases during the baseline period were included. Inverse probability-of-treatment weighting (IPTW) was used to adjust for observed baseline confounders between groups. Weighted Kaplan-Meier (KM) rates and Cox proportional hazard models were used to compare the occurrence of refill gaps (≥ 14, ≥ 30, or ≥ 60 days) or dose reductions (i.e., relative dose intensity [RDI] ≤ 80%, and ≤ 85%) between groups. RDI was calculated as the ratio of the delivered dose intensity (total delivered dose divided by the period over which the total dose was measured) to the standard dose intensity as recommended in the package insert for AA + P or ENZ.

RESULTS: A total of 2,540 AA + P and 1,265 ENZ patients were identified, of which 236 (9.3%) and 111 (8.8%) had baseline visceral metastases, respectively. IPTW resulted in balanced baseline demographic, comorbidities, and disease characteristics. At 12 months post-index, patients initiated on AA + P were 59-65% less likely to have an RDI ≤ 80% or ≤ 85% (all P < 0.05) and 50-73% less likely to have a refill gap ≥ 14, ≥ 30, or ≥ 60 days (all P < 0.05) when compared to patients initiated on ENZ.

CONCLUSIONS: This study showed that mCRPC patients with visceral metastases treated with AA + P were less likely to experience a refill gap and to reduce their treatment dose than patients treated with ENZ.

SPONSORSHIP: Supported by Janssen Scientific Affairs.

N5 Potential Drug-Drug Interaction Events in Patients Treated with Abiraterone Acetate Plus Prednisone or Enzalutamide

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BACKGROUND: The use of smearing estimators. The level of statistical significance for all
BACKGROUND: The treatment of patients with advanced cancer generally requires multiple medications and consideration of potential drug-drug interactions (DDIs) is important to avoid unintended consequences.

OBJECTIVE: This study assessed potential DDIs in patients treated with oral metastatic castrate resistant prostate cancer (mCRPC) therapies (abiraterone acetate plus prednisone [AA + P] and enzalutamide [ENZ]).

METHODS: The MarketScan databases from 03/2012 to 10/2015 were used to conduct a retrospective analysis, in which patients initiated on AA + P or ENZ after 09/2012 (index date) with ≥6 months of continuous eligibility prior to index date and ≥1 PC diagnosis were included. Inverse probability of treatment weighting (IPTW) was used to adjust for observed baseline confounders between groups. Weighted Kaplan-Meier (KM) rates and Cox proportional hazard models were used to compare the occurrence of potential DDIs. Potential DDI was defined as having a claim for a drug that can interact with the index drug (AA + P or ENZ) during the exposure to index treatment (i.e., the time between the first and last claim [plus days of supply] of the index treatment). Interaction drugs were selected based on the prescribing information for each drug and included strong CYP3A4 inducers and CYP2D6 substrates for AA + P and strong CYP3A4 inducers, CYP2C8 inhibitors, CYP2C9 substrates, CYP3A4 substrates, and CYP2C19 substrates for ENZ.

RESULTS: A total of 2,540 AA + P and 1,265 ENZ patients were identified. IPTW resulted in balanced baseline demographic, comorbidities, and disease characteristics. At 3, 6, 9, and 12 months post-index, patients initiated on ENZ were more likely to have a potential DDI during their exposure to ENZ treatment when compared to patients initiated on AA + P (ENZ vs. AA + P, KM rates at 12 months: 30.3% vs. 1.5%, hazard ratio [95% confidence interval]: 28.9 [14.5, 57.4], P < 0.0001).

CONCLUSIONS: This study showed that mCRPC patients treated with ENZ were more likely to be exposed to a potential DDI during their treatment than those treated with AA + P.

SPONSORSHIP: Supported by Janssen Scientific Affairs.

R00-R99 Symptoms, Signs, and Abnormal Clinical and Laboratory Findings Not Elsewhere Classified (e.g., Pain, Opioids, Vasomotor, Urticaria, Nausea & Vomiting)

R1 Prophylactic Antiemetic Use Reduces Opioid-Induced Nausea and Vomiting and Improves Patient Recovery in the Outpatient Setting

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BACKGROUND: Nausea and vomiting (NV) are common opioid-related side effects often associated with the early treatment of acute pain. Co-prescribing of antiemetic (AntiE) medications with opioids may reduce patient risk and improve recovery, however, little is known about the effectiveness of such an approach in the outpatient setting.

OBJECTIVE: Assess the frequency and effectiveness of AntiE and opioid co-prescribing in the outpatient setting.

METHODS: A cross-sectional survey of adults who received an oral opioid-containing product (≤14 days’ supply) for treatment of acute pain resulting from injury or surgery in the prior 90-days, and with no recent prior opioid use, or cancer/chemotherapy was conducted. Opioid induced nausea and vomiting (OINV), overall effectiveness in daily activities (0-100%) and difficulties in activities of daily living (ADLs) (attend school/work, care of self/others, consume meals/liquids/medicines, perform usual household tasks) for the first week of opioid treatment were assessed. Chi-square tests for categorical and t-tests for continuous variables were used to test for significant differences.

RESULTS: Of 512 respondents, mean (SD) age was 42.9 (15.2) years and 73.4% were female. Twenty-four percent (n = 125) received concurrent opioid and AntiE prescriptions (Rx) from their health care provider. Among these patients, 49.6% (n = 62) took the AntiE prophylactically (either before or with their opioid), and 50.4% (n = 63) did not [breakdown: 14.4% (n = 18) did not fill Rx, 17.6% (n = 22) filled but did not take Rx, and 18.4% (n = 23) took after experiencing NV symptoms]. The incidence of OINV was lower in patients who took their AntiE prophylactically compared to patients who did not (29.0% vs. 47.6%, P = 0.03). Mean (SD) percent effectiveness in performing daily activities was significantly greater in patients with prophylactic AntiE use compared to no prophylactic use [54.9 (29.4% vs. 41.9 (28.3), P = 0.01]. Overall, proportions of patients indicating difficulties with ADLs trended higher with no prophylactic AntiE use compared to prophylactic AntiE use, with the greatest differences in “care of self” (90.8% vs. 33.9%, P = 0.06) and “care of others” (52.4% vs. 32.3%; P = 0.023), respectively.

CONCLUSIONS: Use of prophylactic AntiE with opioid therapy was associated with significantly lowered risk of OINV and functional impairment. However, concurrent opioid and AntiE Rx were not common and only half of patients who received AntiE Rx concurrently with an opioid took the AntiE prophylactically. A more proactive approach to prevent OINV may improve patient recovery.

SPONSORSHIP: Daiichi Sankyo.

R2 How Pricing Changes and Dose Optimization Affected Compound Pharmaceutical Use in the Missouri Medicaid Population

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BACKGROUND: Compounded pharmaceuticals are prescribed at high rates despite limited efficacy data and high cost when compared to commercial formulations. As a result, Medicaid programs have had to evaluate and implement cost containment methods.

OBJECTIVE: Describe trends in compound pharmaceutical utilization among recipients after implementation of Maximum Allowable Cost (MAC) pricing and clinical dose optimization.

METHODS: MO HealthNet pharmacies and recipients continuously eligible from 1/1/15 to 12/31/15 were identified via claims data. Recipients with a history of at least one compound medication were the target group. After implementing MAC pricing and clinical dose optimization, we compared trends in total spend pre-rebate and total scripts per month from CY15 to those from January-June 2016 as well as per member per month (PMPM). We also evaluated trends in non-compound pharmaceuticals for comparison. As many compounds are for pain, we did sub-analysis of opioids, pregabalin, duloxetine, and gabapentin to determine if recipients shifted from using compounds to commercial formulations.

RESULTS: A total of 13,079 recipients were eligible for the study. Prior to cost containment methods, recipients filled an average of 4.401 compound scripts per month at an average cost of $638.590. The PMPM averages were 0.34 and $30.35 respectively. After MAC pricing and dose optimization the target group filled an average of 3,550 com-
CONCLUSIONS: Results indicate a vast decline in utilization and cost of compound pharmaceuticals after MAC pricing and clinical dose optimization without a significant increase in commercial formulation utilization. Medicaid programs should evaluate and implement cost containment methods to decrease the utilization and cost of compound medications considering the limited efficacy data and substantial cost.

SPONSORSHIP: This research was funded internally by Conduent and used data from MO HealthNet.

T00-T98 Injury Poisoning and Certain Other Consequences of External Causes (e.g., Adverse Events, Side Effects)

Characteristics Associated with Opioid Overdose in a Medicaid Population

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Conduent

BACKGROUND: Medicaid beneficiaries are prescribed opioids at twice the rate of the rest of the population and are three to six times more likely to overdose. Based on pain guidelines and data analysis, state programs can implement utilization management programs that promote safe use of opioids.

OBJECTIVE: Describe the characteristics and opioid drug use patterns of recipients who experienced an opioid overdose.

METHODS: Using a claims database, 746 consecutive recipients who had a diagnosis of opioid overdose between January 2015 and June 2016 were identified. Opioid use patterns, coordination of care concerns, history of substance abuse and pain-related diagnoses (acute pain, chronic pain and cancer) of the target group six months prior to overdose were compared to a control group of 140,129 consecutive recipients with opioid utilization during the same period who did not experience an opioid overdose.

RESULTS: The average morphine milligram equivalent (MME) in the target group was 67.7, compared to 58.4 in the control group. The target group had larger percentages of recipients receiving MME $\geq$90 (32.8%), long-acting products (23.3%), and $\geq$5 opioid prescriptions (50.5%) compared to the control group (8.3%, 12.7% and 27.4%, respectively). Coordination of care issues, while low in incidence, were more prevalent in the target group as well. 3.0% of the target group had prescriptions from $\geq$3 physicians per month (1.1% control group); 1.7% of the target group used $\geq$3 pharmacies per month (0.6% control group). History of substance abuse was over four times more prevalent in the target group (29.1%) compared to the control group (7.0%). Over 87% of the target group had chronic pain, either alone (38.1%) or in addition to other pain-related diagnoses (49.6%). Half of the target group had 2 or more pain-related diagnoses. 23.3% of the target group experienced 2 or more overdoses within the study period.

CONCLUSIONS: The data indicates opioid overdose is more likely with MME $\geq$90, long-acting opioids, higher prescription counts and a history of abuse, prior overdose, chronic pain and multiple pain-related diagnoses. Medicaid programs should consider utilization management strategies addressing these issues to help reduce the incidence of opioid overdose in prescription opioid users. Patient education addressing the purpose, use and dosing of long acting opioids and alternative pain management strategies should also be considered.

SPONSORSHIP: This research was funded internally by Conduent.
U0-U99 Codes for Special Purposes and AMCP Unclassified Abstracts
(e.g., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)

U1 Systematic Literature Review of Performance-Based Risk-Sharing Arrangements in the United States

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BACKGROUND: Value for money is a growing necessity in today’s United States (U.S.) health care system in which drug spending is expected to increase by 5% yearly through 2024. In response to uncertainty about real-world outcomes for drugs, health insurers and pharmacy benefit managers (PBMs) have implemented various contracts and arrangements with drug manufacturers that can collectively be described as performance-based risk-sharing arrangements (PBRSAs).

OBJECTIVE: To conduct a systematic literature review of PBRSAs in the U.S.

METHODS: A systematic literature review was conducted in MEDLINE (1946-present), Embase (1988-present), and the grey literature to identify PBRSAs for drugs. Articles/congress abstracts written in English that described a U.S.-specific PBRSA for a drug were included. Articles/congress abstracts were excluded if the arrangements were with the Centers for Medicare & Medicaid Services, 4 (17%) were with large multi-state insurers, 5 (22%) involved oncology indications, and 6 (26%) involved indications—44% members of P&T committees making listing recommendations, 9% involved with manufacturer pricing negotiations; Use of 46% ICER, 36% ASCO, 36% NCCN. 44% members of P&T committees making listing recommendations, 9% involved with manufacturer pricing negotiations; Use of U.S. frameworks: 46% ICER, 36% ASCO, 36% NCCN.

RESULTS: We identified 23 PBRSAs. Among them, 11 (48%) were initiated between 2015-2016, 10 (43%) were initiated between 1997-2012, and 2 (9%) were initiated no earlier than 2009 and 2011. In relation to disease state, 12 (52%) involved cardio-metabolic indications, 5 (22%) involved oncology indications, and 6 (26%) involved other indications. Regarding the health insurer or PBVM involved with the PBRSA, 10 (43%) were with large multi-state insurers, 5 (22%) were with the Centers for Medicare & Medicaid Services, 4 (17%) were with regional insurers, 3 (13%) were with PBMs, and 1 (4%) was with multiple unspecified insurers. Relative to the initial approval of a treatment, 14 (61%) PBRSAs occurred within 5 years, 7 (30%) occurred more than 5 years later, and 2 (9%) occurred within 5-7 years. For data collection methods required to implement PBRSAs, 13 (57%) required electronic medical record (EMR) data, 8 (35%) could utilize claims data, 1 (4%) required EMR data for one outcome but could also utilize claims data for another outcome, and 1 (4%) was not specific in its requirements.

CONCLUSIONS: The number of PBRSAs for drugs in the U.S. has increased over the years as the desire to demonstrate value for money has become more important in paying for health care. These study findings are likely an underestimate of the total number of U.S.-specific PBRSAs for drugs, but nevertheless offer insights into increased willingness among stakeholders to engage in them, confidence in the use of the selected measures, and the focus on value for money where drugs are costly and/or treat a large patient population.

SPONSORSHIP: No funding was provided for this study.

U2 A Global Context for Drug Value

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PROBLEM DESCRIPTION: Government mandated health technology assessment (HTA) agencies such as the U.K.’s NICE, Germany’s G-BA, and Canada’s CADTH have been conducting efficacy and cost-effectiveness assessments of drugs for years. The U.S. lacks a formal HTA policy but frameworks used by payers for assessing the value and fairness of prices of drugs and how they align with decision-making goals are a hot topic of discussion.

GOAL: Compare the purpose, intended and current use of various value frameworks for U.S. payer decision-making and identify factors in global HTA frameworks that may add value to a U.S. approach.

PROGRAM DESCRIPTION: A comparative analysis of methodologies from the U.S.-based ICER, ASCO, and NCCN along with frameworks from NICE, G-BA, and CADTH, identified the purpose, audience, scope and implications for decision-making of each framework. An online survey of U.S. payers assessed awareness and use of U.S.-based frameworks.

OBSERVATIONS: The US frameworks are diverse in audience, scope, and purpose. For example, Perspective: NCCN and ASCO: patient and physician; ICER: payer and policy maker; Goals: ASCO: help patients and physicians achieve affordable care through better understanding of relative efficacy, toxicity, and cost specific to oncologic drugs; NCCN: provide patients and physicians with a score and visual representation of cancer drug performance to aid in decision-making; ICER evaluate the efficacy, value, and affordability of drugs to help payers and policy makers’ decision-making with focus on payers and policy at a larger level; Global Comparison: CER’s framework most closely aligns with NICE, G-BA and CADTH; no mandate to follow ICERs decisions; Current Payer Use of U.S. frameworks: of 99 respondents—44% members of P&T committees making listing recommendations, 9% involved with manufacturer pricing negotiations; Use of U.S. frameworks: 46% ICER, 36% ASCO, 36% NCCN.

FINDINGS/RECOMMENDATIONS: Each U.S. framework has a different purpose and intended audience, potentially influencing conclusions regarding efficacy and affordability of drugs. Though not mandated, payers are considering these frameworks, even when not designed toward their decision-making. The U.S. frameworks lack the health care system integration that HTA agencies hold. The U.S. may benefit from the unified identification of stakeholders and value lexicon demonstrated by HTA agencies to successfully navigate a transparent path to implementation. Future study is needed to determine how U.S. payers make listing decisions using these frameworks.

SPONSORSHIP: Context Matters and Dymaxium.

U3 Relative Versus Absolute Risk Framing in Health Care Decision Making: A Survey of U.S. Payers

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BACKGROUND: Cognitive biases are psychological tendencies that systematically lead people to make decisions that deviate from rational convention. The framing effect is a cognitive bias in which decision-making is influenced by how information is framed or presented. This effect has been demonstrated across a wide variety of decision-makers and contexts.

GOAL: To conduct a systematic literature review of PBRSAs in the United States.
OBJECTIVE: The aim of this study was to assess whether health care payer decision-making is influenced by information presented in terms of relative versus absolute risks.

METHODS: An online survey was conducted with Xcenda's Managed Care Network (MCN), a research panel of U.S. managed care professionals. Participants included in the survey were pharmacy and medical directors who worked at a managed care organization and served as active members of an organization's pharmacy and therapeutics committee. Participants were presented with two near-identical scenarios, summarizing the number of adverse events observed in clinical trials with two fictitious drugs for breast cancer. Adverse events were presented in terms of relative risks in one scenario and absolute risks in the other. In each scenario, one of the drugs had objectively fewer adverse events based on calculations, despite being masked by framing. Participants were prompted to choose the preferred drug, based on the adverse event profile presented. Survey results were collected and analyzed using a chi-square test of independence to assess if the likelihood of choosing the optimal drug depended on question framing.

RESULTS: The survey was sent to 76 medical and pharmacy directors within the MCN panel and yielded 54 (71%) responses in total. In the relative risk scenario, 43 (80%) of the 54 participants chose the less optimal drug with a riskier adverse events profile. In contrast, in the absolute risk scenario, only 21 (39%) of the 54 participants chose the less optimal drug. Decision-makers were more likely to choose the drug with more adverse events when the rates were presented in terms of relative risks than when the rates were presented in terms of absolute risks ($\chi^2(1) = 18.56, P < 0.0001$).

CONCLUSIONS: Health Care payers, like other decision-makers, are susceptible to the cognitive bias of the framing effect when information is presented in terms of relative risks. Presenting information in absolute risks may result in better communication of clinical information and help to improve health care decision-making.

SPONSORSHIP: Xcenda.

U6 How Do Payers Utilize the AMCP eDossier System for Preapproval Information and Could It Qualify as a Safe Harbor?

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PROBLEM DESCRIPTION: Currently there is no accepted FDA sanctioned safe harbor mechanism for the exchange of truthful and non-misleading information for payers. Payers are reviewing products up to 18-24 months in advance of approval to meet budget/formulary approval timelines. The AMCP eDossier System (System) is a secure, web-based system within the Formulary Decisions.com platform supporting the exchange of manufacturer-provided approved information since 2009. Supported in partnership with AMCP and participating life sciences organizations, it is designed to support reimbursement decisions for qualified U.S. health care decision makers via a FDA-compliant unsolicited request process. The need for pre-approval information is apparent, as indicated during recent FDA hearings.

GOAL: To investigate how U.S. payers are utilizing the AMCP eDossier System for pre-approval information and whether this System could be a potential safe harbor mechanism for pre-approval information and support the decision-making process.

PROGRAM DESCRIPTION: In November 2016, 172 registered users of the AMCP eDossier System, a secure, web-based system to support P&T recommendations and formulary decision making, participated in an online survey detailing their use of the System for pre-approval information.

OBSERVATIONS: Payer respondents actively involved or part of the exchange of pre-approval product information indicated (62%) the System’s unsolicited request process supports the information exchange between manufacturers and payers. 80% indicated the System’s ease of use, and 67% responded that manufacturers participating in the System respond better or the same than those not participating in the System. Also, the System can better support the information exchange with more manufacturer participation and by making it easier to understand what manufacturer information is currently available to the System payer. The System provides sufficient tools/information for pre-approval product review, and 85% felt the System met

BACKGROUND: Section 114 of the Food and Drug Administration (FDA) Modernization Act of 1997 (FDAMA 114) was intended to allow the sharing of health care economic information (HCEI) with formulary decision makers. However, its use in practice has been limited and the evolving health care environment has spawned renewed interest in the sharing of health care economic information (HCEI) with formulary decision makers. However, its use in practice has been limited and the evolving health care environment has spawned renewed interest in the need for legislative and regulatory updates.

OBJECTIVE: To understand manufacturer experiences, attitudes, and perceptions of FDAMA 114 and help shape future regulatory guidance on the proactive dissemination of HCEI.

METHODS: Manufacturer stakeholders completed a survey assessing the interpretation and application of FDAMA 114 as well as limitations of, and proposed changes to, current legislation.

RESULTS: Respondents (N = 73) represented small to large sized companies, with representation primarily from Health Economics and Outcomes Research (HEOR) (38%), Medical Affairs (23%), and Managed Markets/Market Access (18%) functions. Respondents were primarily Associate Director level or above (79%). Of the 73% who had a specific process for approval of FDAMA 114 materials, most (68%) rated that process as somewhat or not very clear, with a typical (57%) review duration of 1-3 months. Legal and regulatory (both 88%), followed by medical (62%) and HEOR (60%) departments were required to provide final approval of FDAMA 114 materials. Many respondents (41%) found gaining approval of HCEI materials under FDAMA 114 to be very or extremely difficult and largely noted that decisions were somewhat (56%), not very (15%), or not at all (7%) consistent across brands, with only 18% agreeing very much or completely that their organization utilizes FDAMA 114 effectively to support product value. Specifically, the FDAMA 114 terms “competent and reliable scientific evidence” and “directly relates to an approved indication” have very much or extremely limited the ability to convey HCEI according to 36 and 41% of respondents, respectively. With regard to the changes proposed in a recent AMCP Partnership Forum to add clarity to FDAMA 114, the majority (62 to 84%) very much or completely agreed that the suggested changes would be helpful in improving their organization’s ability to effectively communicate HCEI.

CONCLUSIONS: Unclear processes, inconsistent approval of materials, and current legislative terms are substantially impacting the exchange of HCEI under FDAMA 114, according to manufacturer stakeholders. While the 21st Century Cures Act has provided clarity, FDA guidance on FDAMA 114 and reviews of manufacturer’s own policies and procedures is warranted.

SPONSORSHIP: None.
or exceeded the needs. All payers asked indicated that having ready access to manufacturer curated information within the System would be helpful.

**FINDINGS/RECOMMENDATIONS:** The research indicates the System could be a safe harbor mechanism for the exchange of pre-approval information between payers and manufacturers. Overall, payers indicated System usage for this purpose and believe the System supports the process. There may be opportunities to increase manufacturer participation, provided identified barriers could be overcome.

**SPONSORSHIP:** None.

**U7** Targeted Prescriber Office Outreach to Grow Adoption of Electronic Prior Authorizations

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**PROBLEM DESCRIPTION:** Electronic prior authorizations (ePAs) enable rapid, streamlined processing of prior authorizations (PAs) resulting in decreased prescription turnaround time for prescribers, pharmacies, and patients. Few factors challenge ePA system implementation such as delegation of support staff duties and potential workflow transition and interruption. These surmountable issues take time, focus and resources away from providing patient care due to the use of traditional, lengthy methods of PA submissions. Targeted outreach could help overcome these challenges.

**GOAL:** Explore the capacity of targeted outreach to prescriber offices in driving growth of ePA submissions.

**PROGRAM DESCRIPTION:** We conducted a retrospective study using a pre-post case-control analysis. A pharmacy technician experienced in communicating with physician offices gathered feedback on the ePA process from prescribers (case group) associated with three clients of a national pharmacy benefits manager between March and May 2016. Brief one-on-one discussions addressing any concerns that might prevent use of the ePA process were held with those responsible for submitting ePAs in each setting. Prescribers associated with the same three clients that received no outreach from the pharmacy technician constituted the control group. For each prescriber, total ePA submission counts were compared before and after the technician outreach. Monthly rates of ePA utilization were calculated and compared between the two groups to obtain the difference in ePA adoption with and without targeted outreach.

**OBSERVATIONS:** Based on quarter 1 of 2016 data (prior to outreach), baseline rates of ePA use for case and control groups were 26.8% (n = 1,687) and 27.3% (n = 1,947), respectively. The case group resulted in a 6.5% increase of ePA submissions over two months (to 33.3%) while the control group experienced an increase of 3.6% (to 30.9%). Overall, this pattern indicates a +2.9 percentage point increase in ePA while the control group experienced an increase of 3.6% (to 30.9%).

**FINDINGS/RECOMMENDATIONS:** The rise in opioid abuse and dependence is a problem for all stakeholders involved in health care. Published research shows that providers report concerns surrounding the misuse of opioid pain medications, patient addiction and insufficient training in prescribing opioids. The rise in the number of opioid related overdoses and deaths, combined with the apprehension associated with prescribing opioids, underscores the need to identify gaps in provider education.

**GOAL:** The objective was to evaluate providers’ training and awareness of chronic opioid therapy, abuse, and universal precautions as well as their practices for managing patients on these therapies.

**PROGRAM DESCRIPTION:** A retrospective claims data analysis identified providers with the highest opioid prescribing patterns compared to peers. Providers were invited to complete a brief anonymous survey, via fax or SurveyMonkey, regarding their demographics, training, awareness, and management practices.

**OBSERVATIONS:** Of 49 responses, the majority were family practice and internal medicine providers. Results show nearly 87% of providers recognize opioid abuse as a priority for their practice and used an average of 6.3 tools or interventions to mitigate risk. Nearly half (n = 23) of providers responded with a low level of comfort treating patients on opioids for an extended period of time. Furthermore, 60.8% of providers did not receive training on universal precautions for the assessment and management of chronic pain. This is demonstrated with greater than half (n = 30) of the providers requesting more education on universal precautions, approaches to the treatment of chronic pain and use of long-term opioid therapy. The survey revealed a disparity between provider practices and the level of opioid training. This emphasizes the need for additional education to increase the provider’s comfort level regarding patients on chronic opioid therapy.

**FINDINGS/RECOMMENDATIONS:** Increased understanding of provider’s practices and their needs allows U.S. to offer targeted educational resources to improve management of patient care and their practices. Areas of opportunity include providing educational materials, assessment and prescribing tools and logistical support. Future initiatives will include provider education related to universal precautions, treatment of chronic pain and use of long-term opioid therapy. An assessment of the impact education has on a provider’s level of comfort and practice management will follow.

**SPONSORSHIP:** None.

**U8** Assessment of Health Care Providers’ Training, Awareness, and Management Practices for Chronic Opioid Therapy

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**PROBLEM DESCRIPTION:** The rise in opioid abuse and dependence is a problem for all stakeholders involved in health care. Published research shows that providers report concerns surrounding the misuse of opioid pain medications, patient addiction and insufficient training in prescribing opioids. The rise in the number of opioid related overdoses and deaths, combined with the apprehension associated with prescribing opioids, underscores the need to identify gaps in provider education.

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**SPONSORSHIP:** None.

**U9** Creating a Quality Audit Process to Identify Fraud, Waste, and Abuse

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Physicians Health Plan

**PROBLEM DESCRIPTION:** Physicians Health Plan (PHP), serving 60,000 commercial and self-funded members in the mid-Michigan region, maintains a custom drug formulary. Evidence of fraud, waste, and abuse was discovered at point-of-service pharmacy claims as well as overpayment errors on medical side drug billing. Areas of focus include payment of non-FDA approved prescription drug products, days' supply fraud, medications filled for excessive quantities, stockpiling of as-needed medications, inappropriate prescribing activities, and pharmacy benefit manager (PBM) errors in formulary
implementation and processing. Errors were also found with incorrect billing for the number of units on medications with HCPCS codes. At the time, there were limited in-house quality checks and auditing of non-specialty medication utilization.

**GOAL:** Identify fraud, waste, and abuse in pharmacy claims processing as well as develop and implement prevention methods and correction through post-payment recovery audits.

**PROGRAM DESCRIPTION:** Formulary assessment and development of scheduled audits started in the first quarter of 2016. Audits were conducted based on past known incidences of similar errors and issues. PHP’s Analytics department developed algorithms for identification of outlier claims billed, based upon units, volume, quantity, and cost. Clinical assessment was done by a pharmacist on all audit findings which were then reported to various departments to either recover funds or implement coding changes.

**OBSERVATIONS:** An in-house quality control process overseeing additions and changes to the custom formulary likely would have lead to discovery of PBM implementation errors at an earlier stage, possibly preventing member impact. Potential fraudulent activity was uncovered based on detecting outliers using standard deviation auditing, where it appeared that prescriptions were billed as 30 day supply for clinically excessive quantities and only filled every 3 months. This was especially prevalent with topical formulations of medications. Improper payments were discovered in the form of excessive over-payments on medications billed by HCPCS coding, generally from out-of-network providers. High-cost pharmacy claims were found on a frequent basis for non-FDA approved drug products mostly in the form of topical products and drug kits, and were subsequently blocked from the formulary.

**FINDINGS/RECOMMENDATIONS:** After finding over $600,000 in recovered and potential savings over the course of 10 months with minimal adverse impact to members and the formulary, PHP plans to expand the operational and quality components of the pharmacy department.

**SPONSORSHIP:** Physicians Health Plan.

**U10 Impact of Motivational Interviewing on Medication Adherence**

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**OBSERVATIONS:** Evaluating all patients combined, 68% of patients who talked to a pharmacist had improved PDC rates compared to 60% of patients who could not be reached (P < 0.05). Evaluating each drug class separately, the results were as follows: diabetes 64% vs. 58%, RASA 68% vs. 61%, and statins 69% vs. 59% (P < 0.05). To determine the impact on the star rating, the percentage of patients who achieved a PDC of 80% or greater at year-end was evaluated. Sixty four percent of patients who talked to a pharmacist reached 80% or greater PDC compared to 54% of patients who could not be reached.

**FINDINGS/RECOMMENDATIONS:** As cut-points to achieve 4- and 5-stars become more challenging each year, health plans should consider implementing motivational interviewing to continually improve their results.

**SPONSORSHIP:** None.

**U11 Early Integrated Scientific Advice as a Tactic to Support Successful Regulatory Approval, Reimbursement, and Patient Access**

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**Mapi Group**

**PROBLEM DESCRIPTION:** A successful global market access strategy requires an understanding of a variety of stakeholders’ value demonstration requirements. Recent asset failures show this has been a key hurdle for manufacturers. Focusing on regulatory requirements in the clinical development plan (CDP) may result in the failure to obtain reimbursement. Seeking early regulatory and HTA Integrated Scientific Advice can have a significant impact on the ability to meet marketing authorization and reimbursement requirements.

**GOAL:** To gain clinical and economic advice early in a CDP to identify unmet need, define the value proposition, minimize approval and reimbursement risk, manage the complexity of evidence requirements, and optimize patient access.

**PROGRAM DESCRIPTION:** A shifting global reimbursement landscape requires a proactive approach. Seeking non-binding, confidential, integrated Scientific Advice to ensure the demonstration of clinical efficacy and cost effectiveness provides manufacturers with feedback for both regulatory approval and reimbursement. Whether this advice is formal (e.g. scientific advice engagements in the EU or Canada), or informal (eg advisory board meetings in the U.S.) input, as early as Phase 1 and particularly in areas of great uncertainty (eg rare diseases, new drug classes), is critical to successfully demonstrate the added value and optimal positioning of an asset. A robust formal Integrated Scientific Advice program allows manufacturers to obtain critical advice and proactively shape the CDP. The advice obtained helps identify potential data gaps early and adjust accordingly. Furthermore, the current environment makes real world evidence (RWE) a critical part of regulatory and reimbursement decisions. Early Integrated Scientific Advice enables a manufacturer to discuss appropriate sources and utilization of RWE in the CDP in order to obtain marketing authorization and reimbursement, thus giving patients timely access to promising new treatments.
**OBSERVATIONS:** 7 years of European experience with Integrated Scientific Advice shows great value for manufacturers and patients. Results of assessments by the EMA and NICE show that companies complying with the advice given were more likely to gain marketing authorization and reimbursement.

**FINDINGS/RECOMMENDATIONS:** Integrated Scientific Advice allows manufacturers to adjust their CDPs to better demonstrate clinical and economic value to obtain marketing authorization and reimbursement. Integrated Scientific Advice should become a routine part of CDPs as a stepping stone to minimize risk and maximize patient access to promising new treatments.

**SPONSORSHIP:** None.

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**U12 Validation of a Budget Impact Model for a Clinical Management Program for Zarxio**

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**BACKGROUND:** In March 2015, Zarxio became the first biosimilar to be approved in the U.S. Zarxio is currently the third filgrastim product available in the U.S. market, besides Granix and its reference product Neupogen. In 2015, a large commercial insurer used a clinical management program (CMP) to encourage providers to switch from Neupogen to Zarxio. A budget impact model (BIM) was developed to predict one year cost savings from the CMP. One year post the CMP’s implementation, we want to compare predicted savings to realized costs.

**OBJECTIVE:** To validate a previously built budget impact model predicting one-year cost savings from implementing a clinical management program from the payer perspective.

**METHODS:** There were three phases to validating this BIM. Phase 1: Updating key assumptions for the BIM. Two key assumptions in the original BIM were: Zarxio’s price would be 30% off of Neupogen’s price, 30% of the utilization would switch from Neupogen to Zarxio with the CMP. What we actually saw was: Zarxio’s price was 15% off of Neupogen’s price, 9% of utilization shifted from Neupogen to Zarxio and 26% shifted from Neupogen to Granix. Phase 2: Building an additional component into the BIM. The CMP encouraged not only a utilization shift from Neupogen to Zarxio, but also from Neupogen to Granix. Since the original BIM predicted savings based only on the shift from Neupogen to Zarxio, we added into the BIM cost savings from switching from Neupogen to Granix. Phase 3: Replacing with actual utilization and costs. We updated drug utilization and costs with pharmacy claims data from 9/18/15 to 9/17/16. We also updated realized program review costs and waived copays associated with switches.

**RESULTS:** The predicted cost savings from the original BIM was $56.94 per utilizing member per month (PUMPM). Phase 1: The predicted cost savings after updating key assumptions was $3.28 PUMPM. Phase 2: The predicted cost savings after adding cost savings from the Neupogen to Granix utilization shift was $20.74 PUMPM. Phase 3: The predicted cost savings after updating drug utilization and costs from pharmacy claims, as well as actual program review costs and waived copays, was $29.45 PUMPM.

**CONCLUSIONS:** The original predicted cost savings was higher than what was realized primarily due to a smaller reduction in price for Zarxio versus Neupogen. Future BIMs should be validated by updating key assumptions, building in additional components as needed, and comparing against claims data.

**SPONSORSHIP:** No external sponsorship provided.

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**U13 Improving Patient Care One Consult at a Time Through Our Clinical Quality Oversight of Medication Therapy Management**

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OptumRx

**PROBLEM DESCRIPTION:** The Medicare Modernization Act of 2003 requires that medication therapy management (MTM) services be offered to all eligible Medicare Part D program participants. MTM’s intent is to help patients understand their medications, avoid adverse outcomes, improve adherence, and to help health care providers improve patient care. Beginning in 2017, an enhanced MTM offering will roll out, allowing for more flexibility while providing incentive payments to prescription drug plans (PDP) that are enrolled. The enhanced MTM program (MTMP) will allow plans to overcome the shortcomings of the current MTMP.

**GOAL:** The goal of our quality program is to support our organization’s approach to provide high quality, clinically appropriate recommendations to members and providers through comprehensive medication reviews. Our MTMP is designed to follow the guidance set forth by CMS, NCQA, and URAC.

**PROGRAM DESCRIPTION:** Cases are randomly selected and audited for clinical quality. Our program is designed to meet 10 key performance indicators (KPIs) that assess clinical quality while following the guidance set by regulatory and accreditation entities. A quality improvement plan is implemented to remediate any KPI that falls below the 95% benchmark for two consecutive quarters. Our collaborative efforts with the MTM team foster discussions that lead to continuous improvements.

**OBSERVATIONS:** Our quarterly assessments show that 70% of our KPIs are at or above the 95% benchmark. Through our clinical oversight program we have identified three key areas of focus. These include better documentation with a KPI of 83%, addressing gaps in care with a KPI of 90%, and enhancing the identification of drug interactions with a KPI of 90%. Our dynamic clinical oversight program will continue to monitor the KPIs and allow for continuous quality improvements.

**FINDINGS/RECOMMENDATIONS:** Our program will continue to evaluate the MTM staff’s ability to deliver appropriate consultations, ensure consistent clinical performance by all staff, and promote future enhancements that address over and undertreatment, adherence, and better disease state management. The improvements brought about by our clinical quality program allow U.S. to enhance our MTM program while delivering overall cost savings and improving patient care.

**SPONSORSHIP:** None.

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**U14 Wearable Health Technologies to Treat Chronic Pain: Establishing Baseline Treatment Effects in a Multidisciplinary Pain Program**

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Geisinger Health System; 2Purdue Pharma

**PROBLEM DESCRIPTION:** About 100 million chronic pain patients in the U.S. account for >$560 billion in annual costs. Wearable health technologies (WHT) may allow health care providers to monitor patients in real time, improving outcomes at reduced cost.

**GOAL:** To evaluate the Geisinger Multidisciplinary Pain Program (MPP).
Program Description: The Geisinger Multidisciplinary Pain Program (MPP) takes a bio-psycho-social approach to improve function and quality of life for chronic pain patients. Patients take an educational class (3d) and develop measurable goals with pain specialists, who follow up over 12 months in coordination with primary care providers. This study of electronic health records compares outcomes from the first 91 MPP patients to those of chronic pain patients treated in a primary care (PC) setting. The goal was to establish current treatment effects of the MPP so the incremental value of WHT could be measured in the future. Paired t-tests were used to compare changes over 6 months for pain scale and the PHQ8 depression index. Lower scores indicated improvements.

Observations: At enrollment MPP patients (36% male, 99% Caucasian, mean age 51) had mean (SD) scores of 6.1 (2.0) for pain (n = 91) and 91.7 (7.6) for PHQ8 (n = 86). 49% of patients met or exceeded the depression cutpoint of ≥ 10 (n = 86). Of patients with outcomes measured at 6 months, mean (SD) changes were -0.48 (2.3) for pain (n = 62) and -2.1 (7.7) for PHQ8 (n = 58), with 36% ≥ 10 (n = 61). In the same timeframe, PC patients (38% male, 98% Caucasian, mean age 53) had baseline mean (SD) scores of 6.1 (2.4) for pain (n = 1,741) and 5.9 (7.1) for PHQ8 (n = 1,609), with 31% ≥ 10 (n = 1,609). PC patients with outcomes measured at 6 months had mean (SD) changes of -0.28 (2.4) for pain (n = 487) and -0.3 (5.6) for PHQ8 (n = 387), with 26% ≥ 10 (n = 407). No differences reached statistical significance.

Findings/Recommendations: MPP patients showed moderately greater improvement in pain and depression than controls. With mean scores and level of improvement suggesting no clear ceiling effect, there is a potential for further improvement with WHT use. A prospective study investigating WHT into MPP is planned to provide real-time feedback, support physical activity and medication adherence, and integrate treatment data into new patient/provider dashboards.

Sponsorship: This research was funded by Purdue Pharma.

Results: A total of 20,252 patients met the study criteria. Rheumatoid arthritis (RA; 37.6%) was most prevalent, followed by plaque psoriasis (PP; 21.1%), Crohn’s disease (CD; 15.8%), psoriatic arthritis (PA; 4.8%), and ankylosing spondylitis (AS; 4.3%). Approximately 58.0% of patients discontinued adalimumab treatment (range: 62.8% RA to 43.3% CD). Mean (SD) time to discontinuation was longest for patients with PP [132.5 (88.4) days] and shortest for patients with PP [119.9 (95.7) days]. Among patients who discontinued adalimumab, 30% switched to another biologic, 27.6% restarted adalimumab, and 39.0% neither switched nor restarted their treatment. Among patients with a restart, mean (SD) days between medication discontinuation and restart was 82.7 (51.3) days.

Conclusions: The 1-year treatment discontinuation rate for adalimumab treatment is high. A significant proportion of patients discontinuing adalimumab treatment either restart adalimumab treatment or switch to another biologic. Further research is needed to understand why patients on adalimumab interrupt, switch, or discontinue treatment altogether.

Sponsorship: This study was sponsored by Boehringer Ingelheim Pharmaceuticals.

Clinical Quality Oversight of Fast-Tracking Utilization Management Strategies

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Problem Description: In recent years, a number of factors may have led to a rise in drug cost such as novel specialty drugs, industry mergers, and development of non-inferior “Me-too” drugs. Pharmacy benefit managers, health plan sponsors, and retail pharmacies struggle to keep up with the increase in cost. Our First Movers program for blockbuster drugs provides clients with a process to contain cost, improve outcomes, and ensure appropriate use of medication by implementing utilization management (UM) strategies.

Goal: As part of the post launch evaluation of the effectiveness of our expedited clinical strategy, our quality program provides targeted prior authorization (PA) reviews of clinical criteria developed for high profile drugs.

Program Description: Our program allows for a comprehensive review of the development and enforcement of clinical criteria for specialty and non-specialty drugs. Prior to product launch, clinical guidelines are developed and ready for immediate implementation. Each quarter, we analyze 120 random PA cases of 2 targeted products for clinical review. Our program retrospectively evaluates each case based on 5 key performance indicators (KPIs); clinical decision making, documentation of clinical decision and rationale, correspondence language, UM criteria and system programming. Each parameter is set at a 95% benchmark accuracy level.

Observations: Starting 2016, we have reviewed over 300 PA cases inclusive of 6 targeted products. Overall, each product scored above the benchmark of 95% for 4 of the 5 KPIs. The correspondence language KPI dropped below 95% for 83% of the products. We have demonstrated appropriateness of clinical criteria, decision making, and consistency of implementation amongst our reviewers. We have observed that our clinicians’ ability to follow guidelines and procedures helps enhance the quality of cases reviewed by ensuring safe and effective use of medications. Meeting with clinical staff shows improved accountability by giving feedback in a timely manner to target specific areas in need of improvement.
**U17 Utilization of Geriatric Care Among Medicare Beneficiaries**

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**Trinity Partners**

**BACKGROUND:** Geriatric care is often critical for many in the Medicare population, given that two-thirds of all people 65+ experience multiple chronic conditions. However, many beneficiaries who could benefit from geriatric care do not receive it. This could lead to downstream effects such as higher costs and decreased patient quality of life due to preventable health care use and uncontrolled chronic disease.

**OBJECTIVE:** To assess the use of geriatric care among Medicare beneficiaries and identify the patient factors most strongly associated with receiving geriatric care

**METHODS:** A case-control claims analysis was performed, comparing patients with and without geriatrician visits. The study cohorts were from a random 5% sample of Medicare FFS beneficiaries that were aged 65+ in 2010. Cases were beneficiaries with an initial geriatric claim in 2011 and 2+ geriatric claims from 2011-2014. Controls were beneficiaries that did not have a geriatric claim from 2011-2014. Overall and regional geriatric care use rates were determined. A subset of patients were then used in a classification tree (CRT) analysis to determine which demographic factors and medical conditions prior to the initial geriatrician visit were most associated with receiving geriatric care.

**RESULTS:** Overall, 3% of Medicare patients utilized geriatrician care (24,664 geriatrician case patients and 845,584 non-geriatrician control patients). On average, cases were three years older than controls (P<0.05) and cases had a higher number of claims in 2010 (43 vs. 31 in controls, P<0.05). The CRT analysis suggested that state of residence was the most important factor associated with receiving geriatric care; the states/districts having the highest rates of geriatric care were DC, MI, NH, CT and HI, while the lowest use rates were found in AK, SD, ND, ID and WY.

**CONCLUSIONS:** The proportion of Medicare beneficiaries receiving geriatric care is very low even though the majority are elderly and suffer from multiple chronic conditions. This proportion varies by state, which likely reflects an access-to-care issue as well as a shortage of geriatricians. Patients who received geriatric care tended to be older and required more resources prior to their first visit. This suggests that when access to geriatrician care is limited, only the sickest patients are provided access, possibly excluding many patients that would benefit. Additional studies are needed to understand whether access to geriatric care reduces overall health care resource utilization and costs among this population.

**SPONSORSHIP:** Trinity Partners conducted this research without external funding.
non-pharmacy expenditures. Little is known about the impact to treatment and costs associated with access restrictions on extended-release opioids (ER opioid) in the management of chronic pain across different types of health plans.

**OBJECTIVE:** This study evaluated the ER opioid dispensing patterns, health care resource utilization and costs following prior authorization (PA), non-formulary (NF) and step therapy (ST) restrictions for branded oxycodone hydrochloride extended release (OER) in national and regional commercial/Medicare plans.

**METHODS:** This retrospective, longitudinal case-control study analyzed pharmacy and medical claims data (2012 to 2015) for adult patients with chronic ER opioid use from U.S. plans that instituted formulary restrictions for OER. Cases (PA, NF or ST plans) and controls (no restriction plans) were matched on key clinical and demographic characteristics and were followed for 6 months. Study groups were segmented by health plan type (commercial/Medicare), and geography (national/regional). ER opioid market share, health care utilization, and costs were evaluated for the 6-month periods before and after the restrictions. A difference-in-difference (DiD) approach was utilized to evaluate the total per patient per month (PPPM) health care utilization and costs.

**RESULTS:** The final sample comprised 1,622 (national commercial PA), 2,020 (regional commercial PA), 34,703 (national commercial ST), and 4,372 (national Medicare NF) chronic ER opioid users, and equivalent number of controls from no restriction plans. Market share for OER decreased after the formulary restrictions, with the national Medicare NF plan showing the greatest decrease (from 23.5% to 14.3%). DiD analyses indicated non-significant decreases in PPPM office visits of 0.12 and 0.16 ($P > 0.05$) in the PA and NF plans, respectively, and a significant increase ($PPPM = 0.07, P < 0.001$) in the ST plan. No significant total monthly cost changes were observed: PPPM decreased by $48.74$ and $59.87$ in the ST and NF plans, and increased by $37.90$ in regional commercial the PA plan ($P > 0.05$).

**CONCLUSIONS:** The results of this study found that formulary restrictions reduced the market share of OER, but did not result in net cost changes. This effect appears to be consistent across national and regional commercial/Medicare plans.

**SPONSORSHIP:** This research was supported by funding from Purdue Pharma.

**U20 Assessing the Impact of Community-Based Overdose Prevention in Rural North Carolina**

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**PROBLEM DESCRIPTION:** To address the opioid overdose epidemic from prescription pain medications the North Carolina (NC) Division of Public Health task force recommended community-based overdose prevention programs in 2002.

**GOAL:** Develop and assess the impact of community based prevention programs on the opioid-related overdose, abuse and diversion epidemic.

**PROGRAM DESCRIPTION:** Project Lazarus is a community based overdose prevention program started in 2008 in Wilkes County, NC in response to high unintentional poisoning mortality rates due to prescription opioids. By 2010, all health care providers who prescribed opioids had been trained using the Project Lazarus Medical Care Provider Toolkit, prepared in collaboration with the NW Community Care Network Chronic Pain Pilot. The Project Lazarus intervention model consists of best practices for addressing overdose, abuse and diversion of opioids, including (1) community education, (2) provider education, (3) hospital ED policies to address drug seeking behavior, (4) reducing the presence of unused medications, (5) pain patient support, (6) prevention of overdose by naloxone use and (7) addiction treatment. In addition to provider training, Project Lazarus has supported goals of Safe Kids NC and Operation Medicine Drop by organizing a series of medicine take-back events (starting in 2008) and arranging 5 permanent disposal receptacles installed in police stations and pharmacies across the county.

**OBSERVATIONS:** The Project Lazarus initiative may have had a positive impact on both hospitalization and death rates. The prescription opioid poisoning hospitalization rate per 100,000 persons in Wilkes County declined from 36.1 in 2009 to 18.7 in 2010. The prescription opioid poisoning death rate per 100,000 persons in Wilkes County was 42.1 in 2009, which was 4 times that of the state. The death rate declined to 20.2 in 2010 and 13.0 in 2011. Furthermore, in 2008, 82% of the people in Wilkes County who experienced a fatal overdose received a prescription for an opioid from a Wilkes county prescriber, which decreased to 10% in 2010. The most recent data, from 2015, shows the opioid poisoning death rate in Wilkes County climbed to 33.6 per 100,000.

**FINDINGS/RECOMMENDATIONS:** Early impacts of Project Lazarus on public health outcomes in Wilkes County are encouraging but may not be permanent. Further research on borderline retrenchment rates and drug take back programs are recommended to help communities design statewide initiatives.

**SPONSORSHIP:** This research abstract was supported by funding from Purdue Pharma.

**U21 Adverse Drug Event Reporting Rates: Comparing FAERS to Clinical Trials**

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**BACKGROUND:** Adverse drug events lead to 700,000 annual emergency room visits and are the fourth leading cause of death in the U.S. However, a large number of serious adverse drug events are not reported to FDA’s Adverse Event Reporting System (FAERS), making the incidence rates of adverse drug events impossible to calculate from FAERS.

**OBJECTIVE:** This study provides a methodology to calculate adverse drug event reporting rates and examine whether reporting rates differ by indications.

**METHODS:** Reported adverse drug event rates in clinical trials were compared to FAERS data for 54 drugs in four indications—Multiple Sclerosis (n = 6), Chronic Hepatitis C (n = 5), Diabetes Mellitus, Type 2 (n = 30), Breast Cancer (n = 13). We examined: (1) the rate of serious adverse drug events in treatment arms of phase II and III trials; (2) the reported post-approval adverse drug events in FAERS; and (3) patient usage data from Evaluate Pharma. Focus was limited to EudraVigilance Important Medical Event Serious adverse drug events and “primary suspect” adverse drug event reports in FAERS. Chemotherapy drugs, drugs approved for multiple indications, and drugs approved prior to 1997 were excluded. To calculate reporting rate, the FAERS serious adverse drug event rate was divided by the pooled clinical trial serious adverse drug event rate.

**RESULTS:** The final analysis provided a methodology for calculating a “real world” reporting rate of post-approval adverse drug events and demonstrated differential reporting between indications. The analysis showed that Multiple Sclerosis drugs had a 49.8% adverse drug event reporting rate in FAERS, Chronic Hepatitis C had a 27.1% adverse drug event reporting rate, Breast Cancer had a 4.7% adverse drug event reporting rate, and Diabetes Mellitus had a 0.2% adverse drug event reporting rate.
U22 Helping Seniors in the Denver Community: Medicare Part D Outreach and Plan Optimization

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BACKGROUND: Medicare Part D is a prescription drug benefit program implemented in 2003 and administered by Centers for Medicare and Medicaid Services to subsidize the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries.

OBJECTIVE: Medicare Part D (MPD) open enrollment occurs every year from mid-October through early December providing a limited window for many beneficiaries to update or alter their drug coverage. Finding a MPD prescription drug plan can be overwhelming for many beneficiaries due to the number of plans and complexity of the Medicare.gov Plan Finder. Since 2013 the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences AMCP student chapter (CU AMCP) has helped Colorado residents navigate the Plan Finder site to find the most appropriate prescription drug plan to suit each beneficiary’s needs.

METHODS: For 2017 open enrollment, a grant from Advera Health Analytics in partnership with CU AMCP and the Colorado Gerontological Society (CGS), a grant funded State Health Insurance Assistance Program was implemented. Beneficiaries’ information such as demographics, a current medication list, plan preferences, and additional benefit eligible information was gathered by CGS and volunteer student pharmacists. Then using the Medicare.gov Plan Finder online, students identified a range of possible Part D preferences, and additional benefit eligible information was gathered during sessions. Students also received experiential credit through the CU for outreach efforts served to introduce student volunteers to challenges and necessary skills to assist beneficiaries in finding appropriate drug coverage.

RESULTS: A total of 6 events with 25 student pharmacist volunteers (8 P1, 8 P2, 9 P3) were held at CGS during the 2017 MPD outreach season. Students also received experiential credit through the CU for attending these events. A total of 41 plan finders and 1 MTM counseling session were completed during the 2017 MPD open enrollment. Approximately 100 hours of outreach services, and 40 hours in administration were provided by 25 CU students and 1 faculty preceptor. Outreach services were provided to Colorado residents with 73% living within Denver Metro area, 24% rural, and 3% undisclosed. The age span of members was 62-90 years, with 2.5% needing extra financial help. Of the 41 plan finders, 78% members were Caucasian, 15% Hispanic, and 7% unspecified race, 65% female. And, 61% members were previously enrolled in an original MPD prescription plan.

CONCLUSIONS: Medicare Part D outreach is essential to the community due to the complexity for seniors trying to enroll and the limited window in which to complete enrollment. Outreach efforts served to introduce student volunteers to challenges and necessary skills to assist beneficiaries in finding appropriate drug coverage.

SPONSORSHIP: No funding was used in conducting this study.
**PROGRAM DESCRIPTION:** The Pharmacy’s Medication Therapy Management (MTM) clinical outreach team is made up of pharmacy technicians and a pharmacist who are responsible for reaching out to providers, pharmacists, and members. The objective was to improve Medicaid member’s medication adherence in four disease states including Asthma, Diabetes, Inflammatory Bowel Disease and Multiple Sclerosis. Outbound telephone calls were conducted on a daily basis to members. Successful live member calls were transferred to the pharmacist for further clinical consultation. Targeted members were chosen based on lack of 35 or more consecutive calendar days of adherence to medication(s). Medication adherence for each member was confirmed prior to each call based on review real-time claims adjudication. During the phone call contact with the members the disease state along with medication adherence and barriers to adherence are addressed. The goal of each call is to have the member take ownership of their disease state.

**OBSERVATIONS:** Observations of this process showed that members were overall satisfied. Observations of the process for the treating provider clinical care team revealed appreciation for the additional information the health plan provided.

**FINDINGS/RECOMMENDATIONS:** Over the last six months, medications and member fills were tracked by the health plan on a monthly basis from June 2016 through the end of November 2016. The year to date (YTD) savings amounted to more than $750,000. The baseline metric was defined as a rolling 12 month period prior to initial outreach. The total per member per month (PMPM) savings was analyzed for each of the four above stated disease states. The YTD savings was defined as a rolling 12 month period after the member telephonic outreach. The total savings was calculated for both medical and pharmacy PMPM.

**SPONSORSHIP:** This study was not sponsored.

**RESULTS:** The final sample included 63,648 beneficiaries. The median age was 44 and 58% were female. Of these beneficiaries, 14,115 (22.18%) filled at least one opioid prescription and 4,315 (6.78%) filled at least one BZD prescription during the study period. A total of 2,198 (3.45%) individuals filled at least one opioid and one BZD during the year. Of those who filled both an opioid and BZD prescription, a significantly higher proportion were female compared to those who did not fill both (73% vs. 58%, P < 0.0001). The proportion of males vs. females in each of the four subgroups was significantly different (P < 0.0001). The age distribution was significantly different in the four subgroups (P < 0.0001).

**CONCLUSIONS:** These findings suggest that many patients fill prescriptions for at least one opioid and BZD in the same year, despite warnings against concomitant use, and that a higher proportion of female patients may be at risk. Further research may serve as the basis for employer and managed care programs to ensure appropriate utilization of these potentially dangerous medications.

**SPONSORSHIP:** None.
CONCLUSIONS: Among current or recent Medicaid enrollees, opioid death rates are high, especially among the middle-aged. An opportunity exists to identify members at risk of overdose death and apply early intervention strategies based on member characteristics and utilization patterns.

SPONSORSHIP: Purdue Pharma.

U27 Medicaid Brand and Generic Drug Utilization Trends: A Quantitative Analysis of Uptake Dynamics Within the First Year of Introducing Generic Competition

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BACKGROUND: For commercial payers, launch of generics leads to a fast loss of total prescription share; however, the impact on Medicaid expenditures may be different, given different formulary approaches. With biosimilars poised to become widely available in the United States, we sought to understand the market dynamics between generic and branded drugs in the Medicaid program as a baseline for future evaluation of biosimilar market dynamics.

OBJECTIVE: To establish a quantitative understanding of market dynamics under Medicaid coverage resulting from introduction of generics.

METHODS: Quarterly Medicaid State Drug Utilization data were obtained for Q1 2013 through Q2 2016. Monthly data for the National Average Drug Acquisition Cost (NADAC) between October 2013 and October 2016 were retrieved as benchmark pricing. For each generic launched in this window, the average price and volume were calculated for the corresponding branded drug in the quarter prior to launch, and price and volume changes were evaluated during the 4 quarters after launch. Branded drug utilization over the entire time window was analyzed using the Cochran-Armitage trend test, and the relationship between pricing and uptake patterns among generic products and their corresponding branded drugs was explored using descriptive statistics and pairwise t-tests.

RESULTS: From Q1 2013 to Q2 2016, a statistically significant trend was observed for increasing generic product use with each quarter after launch in the Medicaid population (P<0.001). Total prescription share for branded products decreased from 15.08% to 12.42% in this timeframe (P<0.001), but the percentage of drug spending on branded drugs significantly increased (61.98% to 64.89%, P<0.001). Between Q1 2014 and Q2 2015, first generics were launched for 167 National Drug Codes. Over the 4-quarter period post-launch of generics, branded product pricing significantly increased (4% to 12% vs. pre-generic), generic drug prices significantly decreased (76% to 63% of pre-generic brand price), and brand utilization adjusted for population growth decreased (59% to 35% of pre-generic levels).

CONCLUSIONS: Results from this analysis demonstrate that branded drug utilization in the Medicaid program decreases significantly after launch of generics, but this decrease is relatively gradual and brand utilization is 35% at 1 year post-generics. Once sufficient data become available, future analyses will evaluate market dynamics associated with biosimilar introduction in this population.

SPONSORSHIP: None.

U28 Payer Viewpoints on, and Use of, Real-World Evidence

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BACKGROUND: As health care management evolves, managed care organizations are seeking more evidence to support product differentiation. Real world evidence (RWE) has become trending tool for establishing product differentiation. Manufacturers need to understand what evidence is relevant to payers as they consider designing their phase III and late stage clinical development programs.

OBJECTIVE: To understand role of RWE in payer organizations across relevant therapeutic areas, when stakeholders are using RWE in product management decisions, and which RWE data payers view as the most, and the least, valuable when making product management decisions.

METHODS: An online survey was conducted with a mix of 20 managed care pharmacy and medical decision makers from national and regional managed care organizations. The survey was designed to obtain quantitative and qualitative data regarding payer views of RWE for diabetes, rheumatoid arthritis (RA), oncology and treatment with PCSK-9 inhibitors.

RESULTS: Analysis of the survey data with 20 managed care decision makers representing 172 million covered lives reveal that when making management decisions payers are currently primarily influenced by RWE from claims data (55% of respondents) and database studies (35%). Respondents indicate that RWE is more influential for management decisions regarding diabetes (ave. rating 5.2 on a scale of 1-7) compared to RA (4.4), PCSK-9 inhibitors (4.35) or oncology (4.0) and indicate that RWE is most suited to influence access decisions in diabetes (5.85) compared to RA (5.15), PCSK-9 inhibitors (5.0), or oncology (4.4). Respondents views on RWE is dependent on therapeutic category with the top RWE mentioned for each category being meeting treatment goals (diabetes), overall treatment costs (RA), cost effectiveness (PCSK-9 inhibitors), and overall survival (oncology).

CONCLUSIONS: Payers are focused on managing high cost and chronic disease categories and welcome RWE that can provide perspective on how to best control cost while maintaining positive clinical outcomes. For chronic care products, MCOs are looking for RWE that can help understand how to best to manage the drug to maximize its clinical value while controlling costs. For oncology, payers are focused on RWE that helps the plan understand overall survival impact. When considering phase III and late stage evidence development, manufacturers must understand which type of RWE best resonates with future payer needs to justify product value.

SPONSORSHIP: This research was funded by inVentiv Health.

U29 ICER Reports: The Role of Cost/QALY Evaluations in the Evolving U.S. Reimbursement Landscape

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PROBLEM DESCRIPTION: The Institute for Clinical and Economic Review (ICER) conducts comparative value assessments of medical technologies in the U.S. ICER reports include economic evaluations in terms of cost-effectiveness and budget impact and have gained increasing attention for concluding many innovative therapies are priced too high. The reports are purely advisory and not formally used for
which costs can be benchmarked, alongside the ICER organization reform. Recent developments include clinical value scorecards against pharmaceuticals but escalating costs have spurred discussions on additional benefit, qualifying for price negotiations. 77% had a price negotiation.

OBSERVATIONS: Of 112 G-BA benefit assessments, 45% offered no additional benefit with automatic reference pricing. 55% offered additional benefit with automatic reference pricing. 44% were clearly clinically effective ≥ 80% positive votes), with 11% clearly not clinically effective. Five votes on whether therapies within a given class could be clinically differentiated were all overwhelmingly negative. Clinical ratings were provided for 22 drugs: 31% achieved ≥ B rating, 42% C or D and 27% I or P. A cost-utility assessment was undertaken and compared to WTP thresholds for 21 drugs. Even at the highest WTP threshold of 150,000/QALY, only 23% of therapies were deemed cost-effective, with a 14% mean discount deemed necessary. Of 22 votes on the “care value” of a product, based on their clinical and cost-effectiveness, 41% were rated as low value, 5% low/intermediate, 45% intermediate, 5% intermediate/high, and 5% high. Of 11 votes on the “health system value” of products, based upon their anticipated budget impact and affordability, 100% were deemed low value.

FINDINGS/RECOMMENDATIONS: ICER reports have generally concluded that assessed therapies offer important clinical benefits but generally do not justify their economic impact. These reports currently do not influence coverage decisions. However, there is anecdotal evidence of insurers using these in negotiations, and they are cited in recent CMS reform propositions, indicating ICER reports may play a key role in future reforms to U.S. drug reimbursement as payers struggle to manage increasing costs. Nevertheless, significant legislative changes would be required and the recent Trump presidential election victory casts uncertainty on future direction of policy.

SPONSORSHIP: None.

U30 The Future of U.S. Pharmaceutical Pricing and Reimbursement: What Can We Learn from Europe?

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1PAREXEL Access; 2PAREXEL International

PROBLEM DESCRIPTION: The U.S. is largely a free pricing market for pharmaceuticals but escalating costs have spurred discussions on reform. Recent developments include clinical value-based scorecards against which costs can be benchmarked, alongside the ICER organization that promotes and conducts cost-utility economic evaluations. These do not formally influence price or coverage in the U.S., with substantial legislative barriers precluding this. Several EU HTA bodies have methodological parallels with the clinical value scorecard (G-BA [Germany]) and cost-utility approaches (NICE and SMC [UK]).

GOAL: This research explores the impact of EU HTA bodies on market access and discusses their potential impact if used as hypothetical analogues for U.S. reform.

PROGRAM DESCRIPTION: Publicly available reports for three major EU HTA bodies: the G-BA/GKV, NICE and SMC were analyzed (01/01/2011-31/12/2015).

OBSERVATIONS: Of 112 G-BA benefit assessments, 45% offered no additional benefit with automatic reference pricing. 55% offered additional benefit, qualifying for price negotiations. 77% had a price negotiated, 14% had price fixed by court, 8% withdrew from market. Of 156 NICE STAs: 51% recommended, 17% restricted, 20% not recommended, and 12% non-submissions. Positive appraisals were an average of 10.5 months post-launch and 48% were associated with a PAS, 86% being simple discounts schemes. Of 497 SMC appraisals; 35% accepted, 28% restricted, 17% not recommended and 19% non-submissions. Positive appraisals were an average of 12.7 months post-launch, 24% were associated with a PAS, 88% being simple discount schemes.

FINDINGS/RECOMMENDATIONS: HTA bodies issue guidance on whether health technologies should be adopted by their respective public health systems. NICE and SMC exert downwards price pressure but many therapies are denied reimbursement with recommendations following a substantial delay. In Germany, medicines can launch with free pricing post-EC approval; price controls only come into effect after the benefit assessment. Despite a strict definition of additional benefit that just 55% of medicines attained, only 8% were withdrawn from market. In the absence of price control mechanisms in the U.S. such approaches cannot influence price but ICER guidance and the scorecards do stimulate discussion on the value of medicines. Even if the legislative framework existed for price control in the U.S. (and the recent presidential election outcome casts uncertainty over future changes), it could threaten its position as the first launch country and largest revenue market, impacting the ROI and underlying capital supporting future innovations.

SPONSORSHIP: None.
controls, $P<0.05$). Mean daily hospital charges were significantly higher for patients who did not experience any VTE ($\$14,682$ controls vs. $\$11,014$ cases, $P<0.05$). Mean length of stay was significantly higher for VTE cases than controls ($7.2$ cases days vs. $4.0$ days controls, $P<0.05$).

**CONCLUSIONS:** Patients undergoing planned surgery with overnight hospital stay who experience a VTE during their surgery are associated with a longer length of stay and higher total hospital charge compared to those who do not experience a VTE, with lower incidence rates versus those found in literature for the general population. Further study should be encouraged to investigate potential genetic associations to VTE.

**SPONSORSHIP:** Millennium Health.

**U32** Risk of Emergency Department Use and Hospitalization in Patients Without Access to Medications in the United States

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**BACKGROUND:** Medication nonadherence has been shown to increase medical health costs by $290$ billion a year. Up to half of the U.S. adult population report not taking medication as prescribed.

**OBJECTIVE:** Our goal was to quantify the failure to access necessary medications and the risk of emergency department (ED) visits and hospitalization in the U.S. population.

**METHODS:** We performed a cohort study using the latest 2013 and 2014 Medical Expenditure Panel Survey (MEPS)-Panel 18 longitudinal data. MEPS is an annual, nationally representative survey containing information on health care utilization in the U.S. Our primary analysis was a survey-weighted Poisson regression to quantify the association between inability to receive necessary medication in 2013 to outcomes of ED visits (1) and hospitalization (2) in 2013 and 2014. Secondary analyses included subpopulation analyses by insurance type (uninsured, private insurance, public insurance). Adjustment was performed for age category, race, income, insurance, marital status, health, education, and census division of the appropriate year. Additional adjustment for 2013 ED visits and 2013 hospitalization was included in our sensitivity analysis for 2014 outcomes. Analyses were conducted using Stata/SE 14 (College Station, TX) with alpha = 0.05.

**RESULTS:** Inability to get necessary prescribed medications was reported by 2% (6 million weighted lives) of respondents. Of those unable to get medication, 56.7%, reported that they could not afford the medication, 21% reported that the insurance did not approve/cover/pay for their medication. Compared to those able to get medication, inability to get medication in 2013 was associated with increased risk of 2013 ED visit (IRR = 1.32, CI: 1.07-1.63) and 2014 ED visit (IRR = 1.36, CI: 1.15-1.62). There was no statistically significant association between medication access and 2013 or 2014 hospitalizations (IRR = 0.97, CI: 0.66-1.42, IRR = 1.20, CI: 0.88-1.64, respectively). Sensitivity analyses revealed that the risk of ED in 2014 was still prominent (IRR = 1.28, CI: 1.10-1.49). For the secondary outcomes, failure to access necessary medications was associated with increased risk of 2013 ED visits (IRR = 1.46; CI: 1.09-1.94), 2014 ED visits (IRR = 1.63; CI: 1.25-2.13), and 2014 hospitalization (IRR = 1.51; 1.02-2.24) in the public insurance subpopulation.

**CONCLUSIONS:** Inability to get necessary medication increased risk of ER visits in the same and following years. Our findings suggest that improving medication access to necessary medication may reduce catastrophic health utilization.

**SPONSORSHIP:** There was no sponsorship for this study.

**U33** The U.S. Payor Landscape: Results from a Survey of Medical and Pharmacy Directors on Formulary Management

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The JeSTARx Group and National Payor Roundtable

**BACKGROUND:** Payors use a variety of formulary management tools to control health care costs and ensure appropriate product use.

**OBJECTIVE:** To understand the P&T decision-making process to determine the types of approaches used for formulary reviews/coverage and changes and opportunities.

**METHODS:** Online survey of U.S. Medical and Pharmacy Directors (MDs+PDs) from public/private health plans, insurers, and pharmacy-benefit managers. Topics included: advisor+plan information; member types; formulary decisions, coverage, restrictions and desired changes; Affordable-Care-Act (ACA) coverage; and their top concerns.

**RESULTS:** Invitations were sent to 210 subjects and received 61 responses (29%) with 59% of respondents MDs from National = 41.1%; local = 38.6%; and regional = 30.4% plans. Clinician-administered products (CAPS) always covered under the medical-benefit (MB = 64.3%), always under the pharmacy-benefit (PB = 5.4%), the remaining 32.7% based on thresholds or plan-design. Changes were: not anticipated (70.9%); being implemented (5.4%), expected by 12/16 (14.5%) or by 12/18 (3.6%). Mental health (MH) products were carved-out by 25.9%, conditions with multiple MH-therapies required: generics-first (50%), step-therapy (31.5%) or specialist care (18.5%). Respondents involved in decisions for: prescription-drugs (All = 66.5%, Some = 22.4%, None = 12.1%) and Medical-devices (All = 53.7%, Threshold-based = 5.6%, None = 40.7%). MH parity policies were in place for: All = 31.2%, None = 20.8%; Mandated-states = 20.8%, Commercial-plans = 14.6%, Select-plans = 10.4%, Medicaid-plans = 4.2%. ACA plans are being eliminated by 21.3% (6.4% = Currently, 8.3% By 12/17) and current ACA family-deductibles were: $<1,000$ (7.9%); $1,000-$2,499$ (26.3%); $2,500-$4,999$ (28.9%); $5,000-$9,999$ (15.8%); $10,000$ (5.3%). Most were happy with their PB design, the most requested changes were: Formulary changes (17.1%); Tiering (17.1%); Benefit-approval (11.4%); and tied at 8.6% Biosimilars, Clinician-involvement, and Evidence-based Medicine (EBM). Cost-Effectiveness Research (CER) results will be used for: Care Value = 34.6%; Care appropriateness = 17.3%; Guideline optimization/improvement = 11.5%; R&D = 1.9%; MB/PB management = 23.1%; Other = 0%; Unsure/None of the above = 11.5%. The most desired P&T process change was no-change and better EBM data (both 31.6%). The most requested MB change was moving all drugs to the PB. Top concerns included Oncology; Diabetes and Cardiovascular diseases (present and future).

**CONCLUSIONS:** Formulary management will continue as the cornerstone of pharmacy benefit management. P&T committees, PBMs and health plans are increasingly raising co-pays and co-insurance to control the use of newer agents and specialty pharmaceuticals.

**SPONSORSHIP:** TPG-National Payor Roundtable.

**U34** Covered California’s Specialty Drug Cap Regulation: Impact on Cost and Utilization

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BACKGROUND: On January 1, 2016, Covered California became the first health insurance marketplace in the nation to adopt regulations mandating a maximum-per-prescription consumer cost-share for specialty outpatient prescription drugs, henceforth referred to as the Specialty Drug Cap. Specialty drugs are novel or biologic drugs, whose utilization is growing by >15% annually despite only about 1% of the U.S. population's use of specialty drugs. In 2015, these drugs accounted for $151b of the total $425b U.S. prescription drug spend. Specialty drugs offer tremendous promise, as many provide highly sophisticated treatment for conditions such as Hepatitis C, Rheumatoid Arthritis and Multiple Sclerosis, which have few other viable treatment options. However, significantly higher consumer cost-sharing threatens consumer access and availability of affordable care. At the time of the Specialty Drug Cap regulation finalization in May 2015, Covered California projected premium impact of would be less than 1% in 2016 and less than 3% through 2018. With barely 12 months since implementation of this regulation, little to no data is available on its impact.

OBJECTIVE: This study’s objective is to identify the short term impact of the Specialty Drug Cap on utilization and overall health care costs; and provide a perspective on how the impact can be leveraged to influence future Covered California and state wide legislative or regulatory changes related to outpatient prescription drugs.

METHODS: This retrospective observational study analyzed a Covered California Individual Family Plan sample population of 3,117 enrollees. Study participants were adults 18 to 64 years old with at least one paid claim for a newly started specialty drug; and active continuous enrollment in an eligible Covered California Individual family plan (IFP) for at least 6 months in 2014, through 2016. Data was collected from a health insurers pharmacy claims database for 12 months in 2015 and 9 months in 2016. An analysis of changes in specialty drug utilization and consumer cost sharing changes from 2015 to 2016 was performed.

RESULTS: Consumer cost-sharing decreased from 17.2% to 6.6%. Specialty drug utilization increased 25%, 8% higher than Express Scripts Drug Trend Report’s 17% forecast; and higher than United Health Group’s forecast of 14-20%.

CONCLUSIONS: The Specialty Drug Cap achieved its consumer out-of-pocket cost-sharing reduction goal. However with an increase in utilization that far exceeds industry predicted benchmarks, its impact to consumer premiums in 2018 and beyond requires further analysis.

SPONSORSHIP: Internally sponsored by Blue Shield of California.

U36 Understanding Factors that Contribute to Opioid Misuse and Diversion
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BACKGROUND: Each incident case of opioid abuse incurs approximately $14,000 in cost for commercial health plans. Prior research has shown that two-thirds of opioids diverted for non-medical use come from family members and friends, including intentional and unintentional diversion.

OBJECTIVE: The goal of this study was to better understand the conditions contributing to opioid misuse and potential diversion.

METHODS: We conducted interviews with 152 chronic pain patients prescribed opioid medicines in the past 2 years and asked them about behaviors, beliefs and motivations regarding disposal of unused medication.

RESULTS: Among respondents 59% reported both acute and chronic pain, 31% chronic only and 10% acute only. 60% reported only short-acting opioid use, 10% long-acting only, 15% both and 15% were unsure. The most commonly reported opioids were acetaminophen combined with short-acting hydrocodone (52%) or with oxycodone (35%). More than three-quarters (78%) of patients reported having leftover opioid tablets. Of those with leftover medication, 65% reported keeping them, with 63% reporting they kept them in the event they required pain treatment in the future, and 3% in the event friends or family required future pain treatment. Among patients who disposed of unused opioids, nearly half (47%) reported doing so through disposal kiosks or drug takeback programs. Most patients believed that kiosks (64%) and takeback programs (49%) were the most appropriate ways to dispose of unused opioids, and most preferred that disposal take place at a local or chain pharmacy. Only 26% of patients reported that their health care provider discussed the importance of disposing unused opioids.
CONCLUSIONS: These results reinforce the need to educate patients about the importance of disposing unused opioid medications, and for providing easy access to disposal through kiosks and drug take back programs. Health Care providers may help by taking the time to discuss disposal with all patients prescribed opioids, including the significant risks associated with inappropriate self-medication and sharing medications with others, as well as the diversion risks of retaining unused medicine.

SPONSORSHIP: This research was supported by funding from Purdue Pharma.

U37 A Four-State Assessment of Patient-Centered Medical Home Elements at Physician Practices

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BACKGROUND: Patient-Centered Medical Home (PCMH) has been hailed by some as the solution to the many challenges faced by the U.S. health care system.

OBJECTIVE: To assess the presence of key PCMH features within physician practices, and to understand physician beliefs regarding physician-patient orientation.

METHODS: A mixed method (paper, internet, and telephone) survey design was utilized to survey practicing physicians in 4 states (NY, MS, TX, CO). The 48 question survey instrument was developed following a thorough literature review and pilot testing. A survey was sent to practicing physicians via mail, non-responders received 3 additional surveys and 2 post card reminders. Following this, 2 attempts were made to contact non-responding physicians via phone.

RESULTS: A total of 248 surveys were completed, providing an adjusted response rate of 24%. Respondents represented all geographic locations (32% rural, 31% suburban, 36% urban) and indicated they devote 83% of their work time to patient care and 13% to administrative responsibilities. Many elements of PCMH were present in this sample; 62% of practices employed ancillary care providers (most frequently nurses, nurse practitioners, and physician assistants); 56% offer programs or services to increase patient self-management skills beyond traditional physician counseling (most frequently for diabetes and obesity management); and 92% provide a variety of patient care scheduling options. Electronic medical records and nationally recognized evidence-based practice guidelines are utilized by 76% and 79% of practices, respectively. Physician performance is measured at 57% of practices via a variety of methods (outcomes data, results of quality improvement projects, or adherence to evidence based guidelines), though performance feedback was reported to physicians at a lower rate (35%). Patient satisfaction surveys are utilized by 46% of practices. Measurements of physician-patient orientation found that 86% of physicians viewed patients as an equal partner regarding health decisions, and that 88% believed that treatment plans cannot succeed when conflicting with a patient’s lifestyle or values. Only 5% of physicians believed that proficiency in diagnosis and treatment was more important than relating to patients.

CONCLUSIONS: Elements of PCMH are present in the majority of surveyed physician practices. These findings, in addition to the results demonstrating alignment between physician and patient interests, indicate an environment fertile for continued expansion of PCMH services in the United States.

SPONSORSHIP: None.
BACKGROUND: Tuberous sclerosis complex (TSC) is a rare multi-organ disease, often with neurologic and renal complications. Everolimus is the only FDA approved drug for treatment of adults with renal angiomyolipoma and TSC, not requiring immediate surgery, and pediatric and adult patients with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. There are potential differences on everolimus use between patients with commercial and Medicaid insurance. However, information on real-world use of everolimus is limited.

OBJECTIVE: To compare compliance and persistence of everolimus among TSC patients with renal angiomyolipoma or SEGA between those with commercial insurance and Medicaid using most recent claims data from U.S.

METHODS: This retrospective study used MarketScan databases to select patients with ≥1 claim of TSC diagnosis with renal angiomyolipoma or SEGA in commercial (1/1/09-8/31/16) and Medicaid (1/1/09-6/30/15) databases. Patients were followed from index date (earliest date of TSC, renal angiomyolipoma, or SEGA diagnosis) to inpatient death or end of data. Non-persistence was defined as a ≥60-day gap without everolimus during the entire follow up period. Medication possession ratio (MPR) was calculated for the subset of patients with at least one year of follow up from the first everolimus use.

RESULTS: A total of 1,497 TSC patients met the study criteria (896 renal angiomyolipoma only, 411 SEGA only, and 190 both). Compared to Medicaid patients (N = 513), commercial patients (N = 984) had the same ages (22 years), a lower proportion of males (42.9% vs. 50.0%, \( P = 0.006 \)), and a shorter length of follow up period (38 vs. 48 months, \( P < 0.001 \)). Medicaid and commercial patients had similar rates of being treated with everolimus (14.4% vs. 13.6%, \( P = 0.668 \)), but it took Medicaid patients a longer time to start everolimus (871 vs. 704 days, \( P < 0.001 \)). Although the non-persistence rate was not significantly different between commercial and Medicaid patients (42.5% vs. 35.1%, \( P = 0.561 \)), the number of days from everolimus initiation to non-persistence was significantly lower for commercial patients (945 vs. 1132, \( P < 0.001 \)). During the first year post everolimus initiation, commercial patients had a significantly higher MPR (0.81 vs. 0.74, \( P < 0.001 \)) and higher percentage of patients with MPR ≥ 0.80 (67.8% vs. 58.1%, \( P < 0.001 \)).

CONCLUSIONS: This claims analysis demonstrated that among TSC patients with renal angiomyolipoma or SEGA, everolimus MPR was between 0.74-0.81. Medicaid patients had lower MPR than commercial patients but better persistence rate.

SPONSORSHIP: Novartis Pharmaceuticals.

PROGRAM DESCRIPTION: The health system partnered with pharmacy services to ensure successful implementation of new requirements across the system’s roughly 75 primary care and specialty clinics, 6 hospitals, 30 retail pharmacies and specialty pharmacy. As part of this process, a central team was created, consisting of 10 employees with varying pharmacy, clinic and referral management background responsible for processing all PAs for the health system. Centralization and transition to the ePA process began with 6 clinics in December 2015, then system-wide in three phases starting January 2016. The ePA process largely shifted all PA work from the pharmacy and providers to the central PA team. To evaluate the impact of the program, performance metrics, such as enabled prescribers, active prescribers, and PA processing time, were summarized almost a year after ePA implementation.

OBSERVATIONS: The health system processes about 2,700 prior authorization requests per month. Prior to ePA initiation, processing times took an average of 72 hours. As of November 2016, 63% of providers had ePA enabled systems, however, only 25% are active users. As a result, only about 30% of PA requests are completed via the ePA process but the processing time for the ePA prescriptions was an average of 2 hours, a 97% reduction.

FINDINGS/RECOMMENDATIONS: Implementation of an ePA system can decrease PA processing time from days to hours. This process provided several benefits to our health system including (1) removing the responsibility of individual clinics to complete prior authorization requests, (2) removing the prior authorization workflow from the pharmacy workflow, and (3) increasing the proportion of patients that are able to obtain PA-required medications the same day the prescription was written. Regular provider education, increased pharmacy benefit manager connectivity, and EMR system upgrades will help expand use of ePA across the health system.

SPONSORSHIP: None.

U41 Retrospective Analysis of Pregabalin and Gabapentin Concomitant Utilization in a Medicaid Population

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BACKGROUND: Pregabalin (Lyrica) is indicated for the management of neuropathic pain, fibromyalgia, and partial onset seizure. Gabapentin, a generic drug that has a similar mechanism of action and biological effects, is commonly used as an alternative to Lyrica. However, Lyrica and gabapentin should not be taken concurrently due to therapeutic duplication and aggravating adverse effects. On September 1, 2016, Passport Health Plan, a Kentucky Managed Medicaid Plan, removed the grandfathering policy for Lyrica which allowed members to receive it without prior authorization (PA) if the member has a historical paid claim within the past 180 days. Impacted members required a PA to continue Lyrica. The issue of concurrent Lyrica and gabapentin use was identified after the policy changes.

OBJECTIVE: The objectives of this study are to (1) analyze the concomitant utilization data of Lyrica and gabapentin, and (2) identify the clinical and financial impact of grandfathering policy changes.

METHODS: The claims data between June 1, 2016 and November 30, 2016 were retrieved from Passport Health Plan claims database. Members who received at least one fill of either gabapentin or Lyrica were included in the analysis. Members with at least two overlapping fills (refill within 30 days) between Lyrica and gabapentin were identified as ‘concomitant users’. Utilization data for concomitant users, including average daily dose, prescriber information, and drug
expenses, were calculated and compared 3 months before and after the policy changes. The impact from the policy change was analyzed in the overall population as well as concomitant users.

RESULTS: There were 194 concomitant users identified before policy changes, which decreased by 41% to 114 after the policy changes. Prescription fills of concomitant users for Lyrica and gabapentin also dropped from 479 to 253 and 555 to 333, respectively. However, the average daily dose of Lyrica significantly increased from 296 mg to 329 mg (P = 0.0145) while gabapentin dose remained the same, from 2,126 mg to 2,156 mg (P = 0.6827). Within the concomitant users, 42% received both Lyrica and gabapentin prescriptions from the same prescriber and 49% from different prescribers. There is an average cost savings of $1,777 for every concomitant user that discontinued Lyrica and/or gabapentin. A 49% decrease in pharmacy costs for Lyrica among concomitant users, and 38% decrease overall, was observed.

CONCLUSIONS: Removal of grandfathering policy significantly decreased the concurrent use rate of Lyrica and gabapentin. The changes also reduced pharmacy cost and promoted medication safety.

SPONSORSHIP: None.

**U42 Recent Trends in Payer Perception and Use of Value Frameworks in the United States**

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BACKGROUND: The increasingly high cost of specialty and oncology drugs has resulted in greater focus on value. In the U.S., this has given rise to private sector organizations developing value assessment frameworks (VAFs) to guide decision-making. How payers view and utilize VAFs remains unclear.

OBJECTIVE: To assess payer familiarity with and perceptions of VAFs.

METHODS: A blinded electronic survey was conducted with current U.S. pharmacy and medical directors across national and regional health plans in July 2016. Respondents were asked about knowledge, use, and perceptions of the American Society of Clinical Oncology (ASCO) Net Health Benefit, Institute for Clinical and Economic Review (ICER), Memorial Sloan Kettering Cancer Center (MSKCC) Drug Abacus, and National Comprehensive Cancer Network (NCCN) Evidence Blocks VAFs.

RESULTS: Over half (63%) of the 56 respondents were pharmacy directors, 34% medical directors, and 4% (n = 2) noted another role. Respondents had the highest level of familiarity with NCCN Evidence Blocks (43% very familiar) and lowest with MSKCC Drug Abacus (25% not familiar). Self-reported comparison of current familiarity versus 12 months prior shows an increase in familiarity across all VAFs. Frameworks were referenced most often for major clinical evidence (NCCN, 55%; ASCO, 24%; ICER, 20%; MSKCC, 12%), economic support data (ICER, 24%; NCCN, 9%; ASCO, 9%; MSKCC, 8%), and context to support decision making (NCCN, 46%; ICER, 31%; ASCO, 25%; MSKCC, 10%). Among those who have not used VAFs, the most common reasons included insufficient validation, too difficult to use, or waiting for a revised/better version. With regard to how useful VAFs are perceived to be, most (45%) rated them as “somewhat useful” (4 on 7-point Likert scale). Viewing each VAF separately, 38% of payers projected they are more likely to use ASCO in the next 6-12 months, and 60% anticipated no change (ICER, 40%; 50%; NCCN, 50%, 48%; MSKCC, 27%, 65%). A vast majority (77%) indicated a desire for more emphasis on the payer perspective in future VAFs.

CONCLUSIONS: Compared with similar research conducted in 2015, payers are increasingly familiar with VAFs and are beginning to utilize them in decision-making, yet still in a limited capacity. VAFs are primarily being used (most commonly NCCN, ASCO, and ICER) as supporting information in a clinical and/or economic capacity or contextually to support proprietary assessment processes. As VAFs evolve, continued research is needed to gauge changing attitudes and payer application of VAFs in decision-making.

SPONSORSHIP: Research conducted by Xcenda without external funding.

**U43 Formulary Change Notification: A Two-Tiered Approach**

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BACKGROUND: To manage medication expenses and ensure coverage of appropriate therapies for their members, health plans actively manage drug formularies. Formularies typically change on an annual basis with additional updates made throughout the year. Timely notification is important for assisting members and prescribers in implementing conversions to covered formulary alternatives without experiencing an interruption to drug therapy. Previous studies suggest that multimodal interventions can result in successful formulary conversions. In 2015, WellCare Health Plans was contracted with the University of Florida Medication Management center for the provision of telephonic formulary change notification outreach to prescribers and plan members.

OBJECTIVE: To evaluate the effectiveness of a two-tiered approach of notifying members and prescribers of upcoming year over year formulary changes for a Medicare-Advantage Prescription Drug Plan (MA-PD) for three specific medications: fenofibrate tablet, Dulera (formoterol/mometasone), and Tudorza (aclidinium).

METHODS: A retrospective analysis of claims was conducted to evaluate the percent of members that successfully switched to a recommended formulary alternatives within the first 120 days of 2016 for the following medications: fenofibrate 54 mg and 160 mg tablets, formoterol/mometasone, and aclidinium. Members and prescribers were contacted and notified of the upcoming formulary changes starting in November 2015 until January 2016. Prescription claims were analyzed for successful conversion 90 days past the last member contact in 2016.

RESULTS: There were 19,773 total members that met criteria for needing to convert to a formulary alternatives in 2016. Overall 44.9% (8,887/19,773) of prescribers and members were contacted, with a conversion rate of 24.8% (2,208/8,887). For the fenofibrate conversion, 45.3% (3712/8179) of prescribers and members were contacted, with 19.3% (718/3712) of members successfully filling the alternative fenofibrate formulations. There were 4,256 members needing a formoterol/mometasone conversion and 48.8% (2,081/4,256) of prescribers and members were contacted, with 16.6% (345/2,081) of members successfully converting to a formulary alternative. Finally, there were 7,338 members filling aclidinium and 42.1% (3,094/7,338) of prescribers and members were contacted, with a 37% (1,145/3,094) successful conversion rate to the formulary alternative.

CONCLUSIONS: Contacting prescribers regarding formulary changes followed by member notification of the changes resulted in successful formulary conversions.

SPONSORSHIP: None.
U44 Patient Perceptions of a Posthospitalization Transitions-of-Care Program

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BACKGROUND: Most hospital-related medication errors occur at these transition-of-care points: admission, transfer, discharge and in outpatient settings. Medication reconciliation is a Joint Commission National Patient Safety Goal and a vital component of optimal care transitions; it is also a key element of medication therapy management (MTM), a comprehensive service available to eligible Medicare Part D beneficiaries. For this project, a university-based MTM provider developed the Discharge Companion Program (DCP) to help patients transition from hospital to home, with the overall goal of reducing medication errors and readmissions. A local hospital contracted with the MTM provider to implement and evaluate the DCP, including assessing patients’ perceptions about the program.

OBJECTIVE: To evaluate patient experiences with the DCP, and analyze the optimal timeframe to administer a feedback survey to maximize patient response rate, following program completion.

METHODS: A 17-item survey developed for the DCP, using items from two published questionnaires, measured: medication knowledge, self-management, patient concerns, and overall patient experience. A 4-point scale measured item response options (‘strongly agree’ to ‘strongly disagree’). Telephonic surveys were administered to patients completing the DCP. The timeframe for survey completion after last follow-up phone call was categorized as: < 50 days; 50-99 days; ≥ 100 days; a chi-square test was used to determine the optimal timeframe for survey administration after program completion. Survey data were collected from January to March 2016; data were input into Qualtrics for survey administration after program completion. Survey data were analyzed using statistical methods (SPSS and Excel).

RESULTS: Of the 295 eligible patients, 153 were reached and 72 consented to participate (24% response rate). Most patients (n = 68; 94%) ‘agreed’ or ‘strongly agreed’ that they were satisfied with the pharmacists’ overall care and valued the information provided. Nearly all (n = 66; 92%) agreed that the service would improve their overall health. No significant differences were observed in the number of patients reached in the follow-up timeframe for survey administration (P = 0.14) or those consenting to participate (P = 0.44).

CONCLUSIONS: Overall, patients were satisfied with the DCP. No difference in patient response rate relative to time since last follow up with pharmacist was observed. These results are promising, yet more investigation is needed to define the optimal timeframe for patient feedback survey administration.

SPONSORSHIP: University of Arizona College of Pharmacy and SionfiaRx.

U45 Impact of Cash Prescriptions and Use of Affiliate Provider Identifiers on Measures of Opioid Use from Multiple Providers

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BACKGROUND: The Pharmacy Quality Alliance (PQA) measure for use of opioids from multiple providers can be used as a quality measure for comparing data from different programs. Also it can be a quality improvement tool to identify substance use disorder (SUD) high risk beneficiaries for potential intervention efforts. For both purposes, underestimates can occur when only administrative claims are available and beneficiaries pay cash for opioid prescriptions. Overestimates can also occur due to counting providers in the same practice site as multiple providers when individual provider IDs are used.

OBJECTIVE: The objectives of this study were to estimate the impact of including cash paid prescriptions and using affiliate provider identifiers (IDs) to identify beneficiaries using multiple providers for opioids.

METHODS: A retrospective analysis was conducted using Mississippi Medicaid pharmacy administrative claims, linked with Mississippi Prescription Monitoring Program (MPMP) data for the period July 1, 2015-June 30, 2016. MPMP data were obtained through a memorandum of agreement between Mississippi Medicaid and the Board of Pharmacy. Affiliate provider IDs were created linking prescribers in the same physical practice setting to a single ID and pharmacies in networked chains in the same zip code to a single ID. The PQA measure for use of opioids from multiple providers was calculated according to the measure specifications. Beneficiaries were identified as “provider shopping” (using + prescribers and pharmacies), both with and without the inclusion of cash prescriptions and affiliate provider IDs.

RESULTS: A total of 26,796 beneficiaries were identified as having 2 or more opioid prescriptions for greater than 15 days supply. Using only administrative claims, 1,390 (5.2%) beneficiaries were classified as provider shopping. Including cash payments added 148 (0.6%, P < 0.001) more beneficiaries. When using only administrative claims, affiliate provider IDs reduced the number of beneficiaries identified as provider shopping by 269 (1.0%, P < 0.001).

CONCLUSIONS: Inclusion of cash paid prescriptions and use of affiliate provider IDs makes a statistically significant, although very small difference when identifying opioid provider shopping. Although the impact when used as a quality measure will be minimal, the additional beneficiaries identified using cash payments should enhance quality improvement efforts since these beneficiaries are probably at higher risk than others. The use of affiliate provider IDs also will reduce the number of false positives identified for possible intervention.

SPONSORSHIP: Mississippi Division of Medicaid.

U46 Preparing Pharmacy Students to Meet Challenges in Managed Care Pharmacy from a U.S. Pharmacy School

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BACKGROUND: Integration of managed care courses in pharmacy school curricula is mostly inadequate, despite a pivotal role the pharmacist plays in the delivery of managed care product and services to the general public. There is dearth of information regarding student perceptions of managed care pharmacy, evidence of successful learning, and student desire to pursue a career in this area.

OBJECTIVE: (1) To assess pharmacy students’ knowledge of managed care pharmacy (MCP) concepts and understanding of the role of the managed care pharmacist. (2) To measure student attitudes toward and perceptions regarding a career in MCP.

METHODS: A pre-post survey research design utilizing a self-administered paper-pencil questionnaire technique was adopted in a pharmacy classroom setting at a private New York university. Students in multiple sections entering the first professional year of pharmacy program (between 2006-2015), and enrolled in a semester-long, two-credit introductory elective MCP course, completed a 20-item questionnaire pre- and post-course instruction (Pretest, P1, n = 280; Post-test, P2, n = 234). A knowledge component score (KCS) was developed specifically to assess student improvement in knowledge.

Survey items also assessed students’ understanding and knowledge of MC concepts, both pre- and post-instruction, and perceptions towards the course content and prospects for a career in MCP post-graduation.
RESULTS: About 30% (P1) of the students surveyed stated they had heard of or had some knowledge of MCP before course enrollment. The proportion of students who reported an improved understanding of MCP rose from 22% to 68% post-test. Overall, 208 students (88.9%, P2 vs. 72.1%, P1) had favorable impressions of the course, and a clear majority (91.4% vs. 49%) reported having developed a better understanding of the pharmacist’s role in MCP. Nearly half of the students expressed favorable opinions regarding MCP, more than three-fourths of the sample (76%) also identified correctly five or more (out of 8) role functions of the pharmacist in managed care. A t-test performed to test the difference in KCS revealed a statistically significant difference in learning about MCP between pre- & post groups (t=16.6, P=0.001). Percentage of students wanting to consider a career in MCP rose from 6.6% to 67.9%.

CONCLUSIONS: Early and repeated exposure to MC training would lead to a better understanding of MCP and improved learning outcomes. Pharmacy school curricula across the country must adopt courses geared towards managed care to increase awareness and opportunities for students to manage early in the program.

SPONSORSHIP: None.

Effect of AbbVie’s Patient Support Program on Patient Adherence and Work Productivity in Patients Initiating Adalimumab Therapy

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BACKGROUND: AbbVie’s Patient Support Program (PSP) assists adalimumab (ADA)-treated patients with medication costs, nurse support, injection training, and medication reminders. Improved adherence to ADA and reduced health care costs have been demonstrated for patients enrolled in PSP compared with those who were not. The effect of PSP on absenteeism has not been studied.

OBJECTIVE: To compare various outcomes in ADA-treated patients based on PSP-enrollment.

METHODS: A longitudinal study was conducted using patient-level data from AbbVie’s PSP combined with health care claims and workplace absence data from the 2008-2014 MarketScan databases. Patients (≥18 years) with ≥1 claim for rheumatoid arthritis, Crohn’s disease, ulcerative colitis, psoriasis, psoriatic arthritis, or ankylosing spondylitis were included. Medical and pharmacy coverage ≥6 months before and ≥12 months after index date (date of first ADA claim) was required. Multivariate regression analysis was used to compare outcomes over 12 months for PSP (patients enrolled in PSP within 90 days of initiating ADA) and non-PSP (patients not enrolled in PSP but who initiated ADA) groups. Adherence was defined as the proportion of days covered during follow-up. Persistence was assessed using Kaplan-Meyer analysis of discontinuation rates. Absenteeism was based on work days lost for employed patients with available absence data.

RESULTS: For PSP (n = 19,171) vs. non-PSP groups (n = 41,151), respectively, significant differences (all P < 0.0001) were seen at baseline for mean age (47 vs. 46 years), women (64% vs. 58%) and patients with prior anti-tumor necrosis factor therapy (71% vs. 66%). After adjusting for baseline characteristics, adherence was 64.9% vs. 39.6% (Δ = 25.3%, 95% CI: 22.3% to 28.3%) and risk of discontinuing ADA was 29% lower (hazard ratio = 0.71, 95% CI: 0.69 to 0.73) in the PSP vs. non-PSP groups, respectively. For patients with absence data (PSP, n = 236; non-PSP, n = 418), a significantly smaller proportion of patients in the PSP group incurred any absence days than patients in the non-PSP group (74% vs. 85%; odds ratio = 0.56, 95% CI: 0.36 to 0.85). On average, the PSP group gained ~5 work days per patient per year (25.4 vs. 29.9 work days lost, Δ = 4.5 days, 95% CI: 3.0 to 5.8 days).

CONCLUSIONS: Enrollment in AbbVie’s PSP was associated with significantly higher adherence and persistence to ADA therapy and reduction in absenteeism.

SPONSORSHIP: For this study was provided by AbbVie.
Examining Pharmacy Quality Among Medicare Patients with Hypertension: Implications of Pharmacy Impact on Star Ratings

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BACKGROUND: Nearly three out of five Medicare beneficiaries have hypertension. Pharmacists employing pharmacists that frequently interact with patients present tremendous opportunities to positively impact patients’ medication adherence. However, financial arrangements have not been adequately leveraged to incentivize pharmacists to provide high quality care and improve patient safety and adherence.

OBJECTIVE: To define, quantify and evaluate pharmacy quality improvement vis-à-vis adherence to antihypertensives among Medicare patients, when pharmacies participate in financial risk and reward agreements.

METHODS: A retrospective study of community-based retail pharmacies participating in a pay-for-performance program from January 1, 2013 to December 31, 2013, and dispensing antihypertensives to Medicare patients aged 65 and above. Data included pharmacy (using National Association of Board of Pharmacy identifier) and patient level information from a large, nationally representative pharmacy benefit manager. Eligible patients and the days’ supply of their prescriptions were used as proxy to assess pharmacy quality. The control group consisted of pharmacies matched on patient demographics and not contracted for the program. Medication adherence was measured for each pharmacy as a percent of members with proportion of days covered (PDC). Average percentage of adherent (PDC>80.0%) patients for case and control pharmacies was used to assess differences in pharmacy quality. Descriptive analyses (one tailed t-test with α = 0.01) was used to examine improvement in quality of care over control group.

RESULTS: The final study sample consisted of 366 pharmacies in each group with a similar demographic mix of patients. Case pharmacies had a significantly higher proportion of Medicare patients adherent on antihypertensives compared to control pharmacies (72.5% vs. 66.4%, P<0.01). Case pharmacies on average had more than six percentage point higher proportion of adherent patients that translated to a higher star rating, per the Centers of Medicare and Medicaid Services (CMS) cut-offs.

CONCLUSIONS: Findings indicate an improvement as a result of financial risk and reward contract with pharmacies. As star ratings are tied to higher financial remuneration from CMS, improved patient adherence translates to better clinical outcomes for patients and financial outcomes for plans. Continued collaboration between CMS, payers, benefit managers and pharmacies can result in value-based networks that lead to better patient outcomes.

SPONSORSHIP: Financial support is provided by Florida Blue and Prime Therapeutics.

Z9 Preemptive Pharmacogenetic Testing: Exploring the Knowledge and Perspectives of U.S. Payers

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BACKGROUND: Preemptive pharmacogenetic testing aims to improve the safety and efficacy of medications by using genetic information to inform drug prescribing. Further investigation is needed to describe the position of the payer stakeholder on preemptive pharmacogenetics, as their coverage and reimbursement decisions will impact the adoption of this technology.

OBJECTIVE: The purpose of this study was to investigate payer’s knowledge, awareness, and perspectives on preemptive pharmacogenetic testing.

METHODS: We conducted a qualitative study using semi-structured, in-depth interviews. Participants were screened for eligibility using an online survey. A blended inductive and directed approach was used to analyze the transcripts. Two authors conducted an iterative reading process, the constant comparative methodology, to code and categorize meaning units, which were aggregated to develop major themes and subthemes.
Z10

The Impact of Medication Therapy Management and Text Message Reminders on Medication Adherence and Health Care Utilization in a Disabled Medicaid Population

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Molina Health Care

BACKGROUND: Medication non-adherence contributes to poor health outcomes and is a primary driver of avoidable medical expense.

OBJECTIVE: To describe a novel approach to improve medication adherence and reduce utilization through coordinated interventions with an in-house, medication therapy management (MTM) model and text message reminders in a Medicaid population.

METHODS: Patients were identified from an MTM-eligible, ABD (aged, blind and disabled) Medicaid population across 3 states. Recruitment occurred over 3 months. After consent, all patients received an interactive, telephonic MTM consult with an in-house pharmacist. The pharmacist coordinated appropriate care and enrolled the patient in a 2-way text messaging program. Text messages were personalized and delivered at requested times of the day to assist patients in medication administration. Upon receipt of the message, patients acknowledged medication administration with a response text. In addition, the patient could also interact with the health plan pharmacist. Patients were evaluated for chronic medication adherence with baseline proportion of days covered (PDC), then followed forward after program enrollment. Change in health care utilization per member per month (PMPM) was assessed using claims data to evaluate the change from baseline for emergency and inpatient utilization. Reasons for program refusal were also captured.

RESULTS: Out of 12,303 eligible patients, 503 were enrolled and 1,559 declined participation. A belief in lack of benefit (38%) and failure to know how to text (14%) were top reasons for declining participation. Among enrollees, the average age was 54.4 years; 70% were female; disease and medication burden was heavy (average 7.6 conditions/13.6 medications monthly). Patient engagement with text message reminders was high, with over 70% of patients (n = 354) responding to more than half of delivered texts. In addition, patient/pharmacist interaction via text was ongoing and enhanced collaboration. Results for the first 205 patients enrolled was assessed after 60 days and compared with a 4.5 month average baseline value. The PDC for statin, antihypertensive, and oral diabetes medications improved by 5.1%, 7.1%, and 7.3%, respectively, from baseline. Total cost of care was reduced by $183.83 PMPM; with a subsequent reduction by $102.18 PMPM for inpatient costs, and $81.65 PMPM for ED utilization.

CONCLUSIONS: Preliminary results indicate a MTM intervention combined with interactive mobile phone text messaging improves medication adherence and reduces health care utilization for a Medicaid population with high disease burden.

SPONSORSHIP: None.

Z13

Comparing Adherence to Treatment Guidelines After an Opioid Dependence Hospitalization in Medicaid and Commercially Insured Populations

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Avalere Health

BACKGROUND: There is an unprecedented opioid epidemic in the U.S. leading to health care and social costs estimated at $55 billion annually. Each day on average more than 650,000 opioid prescriptions are dispensed and 78 people die from overdose. The DHHS has made prevention, treatment and research a top priority, and expanding use of medication-assisted treatment is a key initiative. However, recent studies found privately insured patients receive limited or no services after an opioid related hospitalization.

OBJECTIVE: To evaluate adherence to treatment guidelines and differences in receipt of FDA-approved opioid dependence medications shown to reduce addictive behaviors in Medicaid and commercial patients within 30-days of discharge from an opioid hospitalization.

METHODS: We used claims data from Inovalon's MORE2 Registry. Methods followed a recent study by Naeger, et al (2016) of a commercially insured population in order to provide comparable analyses of Medicaid beneficiaries. Our cohort included members aged 18-64 between January 1, 2010 and September 30, 2014 who were hospitalized for opioid abuse, dependence or overdose and continuously enrolled at least 90-days prior to hospitalization and at least 30-days post-discharge. Use of FDA-approved medication was defined as receipt of buprenorphine, naltrexone or methadone. We also evaluated use of benzodiazepines (contraindicated), antipsychotics and antidepressants (prevalent use).

RESULTS: We identified 76,611 patients with an opioid misuse hospitalization; 16,859 (22%) with commercial insurance and 59,752 (78%) with Medicaid. Medicaid members were more likely to be female (57% vs. 44%) and older on average. A similar proportion filled an opioid prescription following hospitalization (20%). The percent receiving recommended treatment post-discharge is low for both cohorts, but significantly smaller for Medicaid members (8.6% vs. 18.5%). Overall, a higher proportion of Medicaid patients did not fill a prescription for any of the medications evaluated (41% vs. 28%).

CONCLUSIONS: This study found more than 90% of Medicaid beneficiaries do not receive recommended opioid dependence medications and found disparities in treatment between Medicaid and commercial patients. Further research is needed to adjust for socioeconomic and clinical risk factors to identify the most at-risk patients to better target interventions and treatment, but these findings point to the need for greater awareness and effort to increase use of evidence-based guidelines and reduce treatment disparities to reduce opioid overdoses and deaths in the U.S.

SPONSORSHIP: This study was funded by Inovalon.
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