Abstract Submission Process

Abstracts provide 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 & Specialty Pharmacy (JMCP). Of the abstracts accepted for publication, most are presented as posters, so interested AMCP meeting attendees can review the findings and query authors. The main poster presentation is Thursday, April 9, 2015; posters are also displayed on Friday, April 10, 2015.

The AMCP 2015 Annual Meeting & Expo in San Diego, California, is expected to attract more than 3,500 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 the specific steps taken to 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. These abstracts describe a course of events; they do not test a hypothesis, but they may include data.

- The content of poster abstracts submitted for consideration should not have been published previously as an abstract or article or presented in another forum.

**Abstract Submission Timeline**: This table gives an approximate timeline for abstract submission.

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<td>5 months</td>
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**Abstract Authorship**: Abstracts are classified by the status of the first author.

- **Student/Resident/Fellow**: Abstracts may be submitted by students enrolled in a Doctor of Pharmacy degree program or a pharmacy-related graduate program (MS or PhD), pharmacy residents, and pharmacists completing postdoctoral fellowships. Students, residents, and fellows who have results and conclusions are strongly encouraged to submit their abstracts for review and publication.

- **Professional abstracts** are submitted by nonstudents.

- **Nonreviewed Student Abstracts**: Students, residents, and fellows are eligible to submit "work in progress" poster abstracts that do not undergo peer review. Results and conclusions are not required. These abstracts are not published in JMCP and they are not indexed in PubMed.

- At least 1 author of each accepted poster (preferably the primary author) must register for and attend the meeting to present the poster during the time designated for poster presentations.

**Abstract Review Process**

131 reviewers and 4 JMCP editors were involved in the review process for the 2015 San Diego meeting. Each abstract (with author name and affiliation blinded) was reviewed by reviewers and scored using a 1-5 scale on the following 5 criteria (15 rating scores per abstract) used by JMCP to evaluate manuscripts for publication:

- Relevance to managed care
- Originality
- Quality of the work
- Clarity
- Bias

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 editor, 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 score was used to award Gold, Silver, and Bronze ratings for the best abstracts submitted.

**Reviewers**

- Chris Bell, MS, GlaxoSmithKline
- Martin Bradley, PharmD, PhD, University of Arkansas for Medical Sciences, College of Pharmacy
- Doug Burgyone, PharmD, RPh, VRx Pharmacy Services
- Jongwa Chang, PhD, Samford University
- Mike Durkin, PhD, Janisien Scientific Affairs
- Abimbola Farinde, PharmD, PhD, Bayshore Medical Center
- Sarah Kachur, PharmD, MBA, BCACP, Johns Hopkins HealthCare
- Denise Kehoe, MBA, RPh, FAPhA, University of New Mexico, College of Pharmacy
- Donald Klepser, PhD, MBA, University of Nebraska Medical Center, College of Pharmacy
- Alexandra Lin, PharmD, BlueCross BlueShield of Michigan
- Greg Low, RPh, PhD, Massachusetts General Hospital
- Uche Anadu Ndolo, PharmD, BCPS, Texas Southern University, Department of Pharmacy Practice
- Gene Reeder, RPh, PhD, Xcenda
- Terry Richardson, PharmD, BCACP, Express-Scripts
- Matthew Remo, PharmD, MTMcare
- Cynthia Sanoski, PharmD, Jefferson School of Pharmacy
- Kim Shaffer-Weaver, PhD, Health Analytics
- Sean Sullivan, PhD, University of Washington, School of Pharmacy
- Andy Szczotka, PharmD, Endo
- Patty Taddei-Arlen, PharmD, WellDyne

**JMCP Editors**

- John Mackowiak, PhD, Academy of Managed Care Pharmacy: Center for Outcomes Research
- Laura E. Happe, PharmD, MPH, Humana, Inc.
- Eleanor M. Perfetto, MS, PhD, University of Maryland School of Pharmacy
- Karen L. Rascati, PhD, The University of Texas College of Pharmacy
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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, or Bronze medals.

**Medal Winning Abstracts**

- Nicole Hancy, PharmD; [U27] Application of Pharmacogenomics Screening into a Specialty Drug Management Program
  
  - Daniel Hilleman, PharmD; [I9] Utilization of Daigibran in Patients with Atrial Fibrillation: Impact of the ACCP Guidelines and the SAE-T2R2 Score
  
  - Leanne Lai, PhD; [F23] Off-Label Use of Antidepressants for Children with Attention-Deficit Hyperactivity Disorder (ADHD)
  
  - Folashade Naku, PharmD; [K11] Budget Impact Analysis of Hepatitis C Treatment for Medi-Cal

- Margaret K. Pasquale, PhD; [M14] Patient Preferences Associated with Therapies for Rheumatoid Arthritis Among Humana Medicare Members: A Conjoint Analysis

- Jason Shafrin, PhD; [I7] Physician and Patient Preferences for Nonvalvular Atrial Fibrillation Therapies

- Libiu Zhang, MD, PhD; [U37] Medication Adherence Among Mail-Order Pharmacy Users Versus Retail Pharmacy Users with 90-Day Supply Prescription Fills

- Aylin Altan, PhD; [I4] Rethinking Costs of Psoriasis: 10% of Patients Account for Nearly 40% of Health Care Expenditures Among Enrollees with Psoriasis in a U.S. Health Plan

- Tony Amos, PharmD; [U28] Prescription Patterns of Patients Meeting Opioid Overutilization Criteria

- Evgeniya Antonova, MS, PhD; [J7] Health Care Use and Costs Associated with High Versus Low HEDIS Asthma Medication Ratio

- Onur Basar, MS, PhD; [M2] Impact of Switching Among Tumor Necrosis Factor Inhibitors (TNF) on Health Care Resource Utilization and Costs in Patients with Rheumatoid Arthritis (RA)

- Michael Bellano, PharmD Candidate; [U12] Predicting the U.S. Market on Biosimilars Based on Sales Figures for the European Union

- Nella Bieszk, PharmD; [E13] Evaluating the Effect of a Randomized Controlled Educational Intervention Targeting Improved Glycemic Control: "Act on Threes" Paradigm for Treatment Escalation of Type 2 Diabetes Mellitus (T2DM) in Managed Care

- Machaoon Bonafede, PhD, MPH; [M5] Variation in Disease-Modifying Antirheumatic Drug (DMARD) Initiation Among Newly Diagnosed Rheumatoid Arthritis (RA) Patients by State and Drug Plan

- Sue Cammarata, MD; [L1] Evaluation of Signs and Symptoms and Health-Related Quality of Life in Cured Versus Improved Patients in an Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Phase 3 Trial

- Shelly Chun, PharmD; [I1] The Use of an Interactive Voice Response Refill Reminder Program to Complement a Medication Adherence Intervention

- Mark Conklin, PharmD, MS; [U31] Differences in the Quality of Medication Use: Evaluating Environmental Factors—An Insight for the Medicare Star Rating System

- Terrance Coyne, MD; [J3] U.S. Grass Pollen Seasons: Influence of Latitude and Longitude

- Alexander DeRuiter, PharmD; [F24] Impact Analysis of an Implemented ADD/ADHD Clinical Edit in a Medicaid Population

- Stefan DiMario, PharmD; [E4] Adding Insulin to T2DM Treatment Versus Other Antidiabetic Medications: Implications on Cost and HbA1c

- Michael Durkin, MSc; [G33] Cost of Opioid Overutilization in a Medicare Population Under Alternative Definitions of Overutilization

- Komal Gupte, MS; [U27] Prescription Patterns of Patients Meeting Opioid Overutilization Criteria

- Michael Bellano, PharmD Candidate; [U12] Predicting the U.S. Market on Biosimilars Based on Sales Figures for the European Union

- Cheryl Hankin, PhD; [J3] Allergy Immunotherapy for Childhood Allergic Rhinitis Is Associated with Significant Reductions in the Frequency and Costs of Inpatient Care: Detailed Case Analyses from Large-Scale, Retrospective Claims Research

- Aniket Kawatkar, PhD, MS; [U2] Out-of-Pocket Cost, Expenditures, and Health-Related Quality of Life in Managed Care Plan Members

- Elizabeth Kelly, PharmD; [B11] Evaluation of Prescribers’ Adherence to Hepatitis C Treatment Guidelines Within a Commercial Health Plan

- John Knispel, MD; [I13] Patients with Cardiorenal Comorbidities on Submaximum Doses or Who Discontinued Renin-Angiotensin-Aldosterone System Inhibitors Manifested Significantly Worse Cardiorenal Outcomes than Patients on Maximum Doses of RAASi

- Yuqian Liu, PharmD; [U4] Utilization of Specialty Pharmacy Versus Nonspecialty Pharmacy in the Medicare Population: An Analysis on Adherence and Cost-Effectiveness

- Kimmie McLaurin, MS; [J17] Respiratory Syncytial Virus Hospitalization Costs of Full-Term and Preterm Infants

- Radhika Nair, PhD; [E1] Patient and Provider Care Quality Factors Associated with the Incidence of Diabetes-Related Vascular Events in a Large Cohort of Health Plan Members

- Chelsey Poquette, PharmD; [D8] Hereditary Angioedema Drug Utilization and Spend: A Medical and Pharmacy Integrated Analysis

- Simon Rodriguez, BS; [I21] Cost Impact of Adopting ACC/AHA Cholesterol Guidelines in an Employer-Based Primary Care Clinic

- Philip Schwab, PhD; [J10] Association Between Comorbidities and Hospitalizations Among Patients with Chronic Obstructive Pulmonary Disease (COPD)

- Philip Schwab, PhD; [J9] Association Between Nonadherence to Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and Medications for Other Chronic Conditions

- Martha Skup, PhD; [U8] Comparison of Annual Treatment Costs for Patients Treated with Infusion Versus Injectable Biologics
Catherine Starner, PharmD; [F9] A Controlled Substance Score: Is It Related to Health Care Utilization and Total Cost of Care?

Chia-Chen Teng, MS; [M4] Identification of Infliximab Infusions Using Veterans Affairs Structured Pharmacy and Procedure Data and Unstructured Clinical Notes

Josephine Tran, PharmD, MS; [B18] Comparison of Population Treatment Policies for Chronic Hepatitis C: A Short-term Budget Impact Model Based on the U.S. Population

Ming Zhang, PhD; [L2] Potential Predictors of Using Ustekinumab 90 mg Versus Other Biologic Treatments in Patients with Moderate-to-Severe Plaque Psoriasis

Jill Bell, PhD; [U38] Characterizing Health Care Resource Utilization and Costs Following Patterns of Immediate-Release Hydrocodone Use

Beilei Cai, PhD; [E20] Hypoglycemia Rates and Health Care Costs in Patients with Type 2 Diabetes Mellitus (T2DM) Treated with Second-Line Linagliptin or Sulfonylurea After Metformin

Dilesh Doshi, PharmD; [B12] Analyzing the Burden of Hepatitis C Using an Outcomes Evaluation Tool Within an Integrated Delivery Network

Henry Henk, PhD; [E40] Health Care Costs and Resource Utilization Related to Cardiovascular Events Among Commercially Insured Patients with Hyperlipidemia

Radhiya Hussain, PharmD; [B6] A Retrospective Analysis of Patients Enrolled in Commcare’s Hepatitis C Disease Management Program


Tom Karagiannis, PharmD; [L16] The Burden of Chronic Hives from the Patient’s Perspective as Compared with Psoriasis

Alice Koh, Pharm D Candidate; [U78] Medication Adherence Using Informatics Reminders

Andreas Kuznik, PhD; [L3] Frequency of Increased Maintenance Doses of Adalimumab, Etanercept, and Ustekinumab

Terrie Livingston, PharmD; [G7] Multiple Sclerosis (MS) Patient Adherence to Delayed-Release Dimethyl Fumarate and Patient-Reported Side Effects from a Specialty Pharmacy Program.

Gregory Maglinte, PhD; [C2] Economic Analysis of Panitumumab Versus Cetuximab in Chemorefractory Patients with Wild-Type KRAS Metastatic Colorectal Cancer

Sagar Makanji, PharmD; [M6] Impact of a Clinical Outreach Program on CMS Star Rating for Rheumatoid Arthritis Treatment

Mark Matusik, PharmD; [E12] Benchmarking Insulin Treatment Persistence Among Patients with Type 2 Diabetes Mellitus (T2DM) Across Different U.S. Payer Segments

Shivani Mhatre, MS; [E35] Development of Prescription Medication Adherence Prediction Tool (RxAPT) to Predict Nonadherence to Oral Antidiabetic Drugs

Daojun Mo, MD, MSc; [E3] Suboptimal Glycemic Control, Obesity, and Hypoglycemia in Insulin-Treated Diabetes Mellitus Patients: Estimates from Physicians’ Electronic Health Records in the United States, 2010-2012

Elvin Montanez, PharmD; [B17] Innovative Specialty Pharmacy Hepatitis C Management Plan Reduces Wasted Drug Spend and Inappropriate Utilization While Maintaining Optimal Patient Outcomes

Thomas Power, MD, FACC, MRCP; [I3] Health Care Resource Utilization and Costs Among Patients with Atherosclerotic Cardiovascular Disease

David Rubin, MD; [U7] Impact of AbbVie’s Patient Support Program on Resource Costs in Crohn’s Disease, Ulcerative Colitis, Rheumatoid Arthritis, Psoriasis, Psoriatic Arthritis, and Ankylosing Spondylitis

Jason Shafrin, PhD; [M1] Regional Variation in Rheumatoid Arthritis Quality Measures

James Signorovitch, PhD; [C13] Real-World Dosing and Drug Costs with Everolimus (EVE) and Axitinib (AXI) as Second Targeted Therapies (TTs) for Metastatic Renal Cell Carcinoma (mRCC): A Retrospective Chart Review

Patty Taddei-Allen, PharmD; [U72] Prescriber-Oriented Comprehensive Medication Therapy Management Outreach in a Medicaid Managed Care Organization Population

Brent Tambourine, PharmD; [B15] Analysis of Member Characteristics and Prescribing Patterns Associated with Sofosbuvir Treatment

Douglas Taylor, MBA; [K8] Health Care Resource Use (HCRU) and Costs Among Commercial and Medicare Advantage Health Plan Patients Initiating Treatment with Linacotide for Irritable Bowel Syndrome with Constipation and Chronic Idiopathic Constipation

Christie Teigland, PhD; [Z10] Decomposing the Impact of Clinical, Demographic, Socioeconomic, and Community Resource Availability Factors on Performance Measure Rates for Dual Eligible and Nondual Eligible Medicare Advantage Beneficiaries

Krista Trivieri, PharmD, MPH; [F6] State-by-State Comparisons of Prescription Drug Monitoring Program Components and Opioid Overdose Death Rates

Tao Wang, PhD; [B28] Patterns of H. pylori Treatment and Testing for Patients in a Commercially Insured Population

Michele Wilson, MSPH; [K4] The Budgetary Impact of Vedolizumab in the Management of Moderately to Severely Active Ulcerative Colitis and Crohn’s Disease in the United States

H. Keri Yang, PhD, MPH, MA, BSpPharm; [U30] Pneumococcal Vaccination Coverage in Adults with Chronic Medical Conditions in the United States

Winnie Yang, PharmD; [B5] Utilization Patterns of Sofosbuvir-Based Regimens for Hepatitis C in Managed Care Setting
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Charles Altman, MD, MBA; [J1] Postmarketing Survey of Satisfaction with Needle-Free Administration of Afluria Influenza Vaccine Using Novel Jet Injection Technology

Carl Asche, PhD; [M18] The Economic Benefit of Bupivacaine Liposome Injectable Suspension in the Management of Total Knee Arthroplasty (TKA) Patients

Kevin Bowen, MD, MBA; [E42] Cystic Fibrosis Prevalence and Total Cost of Care in a Commercially Insured Population

Adam Bress, PharmD, MS; [U26] Characterization of an Elderly Population with Potential for Drug-Gene Interactions to Determine the Value of Pharmacogenetic Risk Screening

HungChing Chan, MPH; [E14] Impact of Continuous Glucose Monitoring (CGM) on Diabetes Control and High Cost Events for Type 1 Diabetic Patients

Ashley Choi, PharmD; [Z3] Mobile Applications in Advanced Managed Care: Medication Adherence, Quality of Life, Existing Health Care Apps, and Privacy

I-Chen Fong, PharmD Candidate; [U76] Medication-Related Issues Uncovered Posthospital Discharge Using Automated Callbacks and Follow-Up Calls by Nurses and Pharmacists

Simone Jiandani, BS; [U24] Education and Training in U.S. Pharmacy Schools: Meeting the Needs of the Pain Population

Pravin Kamble, RPh, PhD; [B1] Real-World Medication Adherence in Hepatitis C Patients on Recently Approved Direct-Acting Antivirals

Andreas Kuznik, PhD; [L5] Recent Cost Trends Among Patients Using Biologic Agents for the Treatment of Psoriatic Arthritis

Nanxin Li, PhD; [C5] Treatment Patterns and Predictors of Everolimus Use Among Postmenopausal Women with HR+/HER2- Metastatic Breast Cancer in the United States: A Retrospective Chart Review Study

Julie Locklear, PharmD, MBA; [G12] An Assessment of Adherence Among Multiple Sclerosis Patients Newly Initiating Treatment with a Self-Injectable Versus Oral Disease-Modifying Drug

Lisa Mostovoy, PharmD, MBA; [B10] Retrospective Analysis of Overall Health Care Costs Pre- and Post-Treatment with Sofosbuvir Using Administrative Claims Data


Bimal Patel, PharmD, MS; [U3] Improving Medication Adherence by Addressing Member Convenience: Year Three of an Ongoing Dual-Eligible Medicare Plan's Efforts

Ron Preblick, PharmD, MPH; [I24] Cost-Effectiveness of Edoxaban Versus Warfarin for the Treatment of Venous Thromboembolism: Results Based on the Hokusai-VTE Study

Digisha Shah, PhD; [E41] Cardiovascular Risk of Patients with Lysosomal Acid Lipase (LAL) Deficiency

Yan Song, PhD, MBBS; [C7] Overall Survival Following Initiation of First-Line Treatment with a Non-Steroidal Aromatase Inhibitor or Fulvestrant Among Postmenopausal Women with Recurrent HR+/HER2- Metastatic Breast Cancer

Daniel Sussman, MD; [K1] Comparing Direct Costs and Health Utilization Among Patients Using Adalimumab or Infliximab for Ulcerative Colitis (UC): A Retrospective Study

Ann Taylor, MPH; [U82] Patients' Perceptions of and Beliefs About Medication Therapy Management (MTM) Services

Fulton Velez, MD, MS, MBA; [G28] Cost Analyses Among U.S. Veterans Diagnosed with Epilepsy and Treated with Antiepileptic Drug Monotherapy or Adjunctive Therapy

Adam Wilson, PharmD; [U69] Comparison of Generic Doxycycline and Minocycline Pricing and Utilization Trends Using a Co-Insurance Benefit Design

Amanda Winters, PharmD; [U33] Physician Perception of Medication Adherence in a Cohort of Medicare Advantage Plans in Texas

Edward Wolin, MD; [C14] Burden of Disease in Patients with Neuroendocrine Tumors (NETs): U.S. Results from the First Global NET Patient Survey—A Collaboration Between the International Neuroendocrine Cancer Alliance (INCA) and Novartis Pharmaceuticals

Real-World Medication Adherence in Hepatitis C Patients on Recently Approved Direct-Acting Antivirals

Kamble P1, Walker D2, Marx S2, Uribe C1, Bunniran S1, Collins J1. 515 W. Market St., 7th Fl., Louisville, KY 40202; pkamble2@humana.com; 502.476.2117
1Comprehensive Health Insights; 2AbbVie

BACKGROUND: Chronic hepatitis C virus (HCV) infection is a common blood-borne infection that affects 3.2 million Americans. HCV, if left untreated, may lead to liver transplant or death. Past treatments for HCV had low treatment success rates often due to poor adherence and high discontinuation rates. Treatments approved in 2013 have higher treatment success rates and lower side effects. It is unknown whether the new direct acting antivirals (DAA) have better adherence rates in a real-world setting.

OBJECTIVE: The objective is to assess medication adherence to recently approved DAs in HCV commercial and Medicare populations from a large health benefits organization.

METHODS: This was a retrospective cohort study using administrative claims data from a large managed care organization from May 2013 to September 2014. The health plan types included were Medicare Advantage Prescription Drug Plan (MAPD), commercial (COM) plan, and Medicare Prescription Drug Plan (PDP). PDP includes only pharmacy benefits whereas MAPD and COM include both medical and pharmacy benefits. The study cohort included patients who initiated HCV treatment using DAA (sofosbuvir or simeprevir). The index date was defined as the date of initial prescription fill for a DAA identified between November 2013 through May 2014, with follow-up periods for both 12-week and 24-week treatments. Continuous enrollment for 4 months or 6 months post index date was required for inclusion into the study. Adherence was calculated using proportion of days covered (PDC), and patients with at least 85% PDC were categorized as adherent. Regression analyses were conducted to identify baseline covariates associated with adherence in the MAPD and COM plan members only. Covariates included age, gender, risk score, plan type, and healthcare use and costs.

RESULTS: The sample sizes for MAPD, COM and PDP members who initiated HCV treatment with DAA were 829, 225 and 1431 respectively. Patients were 60% male and had a mean age of 59 years. Overall, the percent of patients considered adherent was 85.0%. COM patients were significantly more adherent than PDP patients (89.3% vs. 83.9%, P<0.05) but similar to MAPD (85.8%). Based on the regression analysis, only younger age and lower comorbidity risk score were significantly associated with better adherence after controlling for other covariates.

CONCLUSIONS: In a real-world setting, 15% of patients on a new DAA were not adherent (defined as 85% PDC). Sicker and older patients were less likely to be adherent. Additional patient support may be required to optimize adherence in these patients.

SPONSORSHIP: AbbVie was the source of funding for this study.

Retrospective Analysis of the Medication Utilization and Clinical Outcomes of Patients Treated with Various Regimens for Hepatitis C Infection

Trombatt W1, Coerper P2, Cuzi Z1, Miller R1. 304 Jamisonville Rd., Butler, PA 16001; william.trombatt@walgreens.com; 724.822.7366
1Walgreens Specialty Pharmacy; 2Duquesne University Mylan School of Pharmacy

BACKGROUND: In the United States, the hepatitis C virus (HCV) is the most common chronic blood borne infection and the leading cause of liver transplantation. According to the United States Centers for Disease Control and Prevention, there is an estimated 3.2 million people infected with HCV in the United States. The last reported surveillance of HCV in 2010 approximated 17,000 new cases and 15,000 deaths due to complications. Although there is no vaccine to prevent transmission, the virus can be treated once infection has occurred. According to American Association for the Study of Liver Disease guidelines, the surrogate marker of sustained virologic response (SVR) defines successful treatment, or cure, 12 weeks after treatment has ended. SVR indicates that the virus has been suppressed to an undetectable level. Maintaining SVR is associated with a decreased risk of liver complications.

The first medication approved by the FDA for the treatment of HCV was interferon alfa in 1991. Later, in 2001 and 2002, pegylated interferons were approved and used in combination with ribavirin with about 40% of patients achieving SVR. Since the 2011 approval of the protease inhibitors, boceprevir and telaprevir, each used in combination with peg-interferon alfa and ribavirin, 66-72% of patients achieved SVR. However, the use of the protease inhibitors has decreased with the approval of the newest medications. Clinical trials for simprevir (in combination with sofosbuvir or peg-interferon alfa and ribavirin) and sofosbuvir (in combination with ribavirin with or without peg-interferon alfa) have shown up to 90% of patients achieving SVR.

OBJECTIVE: The purpose of the study is to evaluate medication utilization and clinical outcomes (SVR, side effects, adherence rates, reasons for discontinuation, etc.) of patients being treated for HCV with any approved combination of ribavirin, interferon products, simprevir, and sofosbuvir.

METHODS: Patients of Walgreens Specialty Pharmacy—Central Specialty locations who start therapy for HCV and are eligible for SVR between January 1, 2014 and December 31, 2014 will be retrospectively reviewed. Data will be collected from Walgreens prescription processing and clinical assessment software. Data will include demographic information, genotypes, SVR, patient reported side effects, discontinuations, adherence markers such as medication possession ratio, and therapy costs. Patient responses in assessments will be obtained and evaluated using descriptive statistics.

RESULTS: SVR rates were higher or equal in all but one subgroup for treatment-naïve patients compared to treatment-experienced patients. The most common genotype was genotype 1 and the most common regimens were sofosbuvir plus simprevir or sofosbuvir, ribavirin, plus peginterferon.

CONCLUSIONS: The observed results were similar to clinical trials. However, due to the small sample sizes, no conclusions can be made in regards to superiority of different regimens, warranting future research in this area.

SPONSORSHIP: None.
B3 An Assessment of the Clinical Relevance of Serum IL-21 Level After Discontinuation of Nucleos(t)ide Analogue Therapy in a Small Cohort of Chronic Hepatitis B Patients

Yu T. State Key Laboratory of Organ Failure Research, Guangdong Provincial Key Laboratory of Viral Hepatitis Research, Department of Infectious Diseases, Nanfang Hospital, Southern Medical University, Guangzhou, China, Guangzhou 510515; 1005004354@qq.com; 86+020 6278 7426
Department of Infectious Diseases, Nanfang Hospital, Southern Medical University

BACKGROUND: Interleukin-21 (IL-21) stimulates T cell and B cell responses and plays a role in control of chronic viral infections. The role of IL-21 after discontinuation of nucleos(t)ide analogue therapy in chronic hepatitis B virus (HBV) infection is not understood.

OBJECTIVE: To evaluate serum levels of IL-21 in the chronic hepatitis B (CHB) patients treating by nucleos(t)ide analogue (NAs) after discontinuation of therapy and its relationship with HBsAg and HBVDNA, working on the role of IL-21 in maintaining sustained response after coming off the NAs.

METHODS: Serum IL-21 levels were measured by enzyme immunoassay in 20 patients with CHB undergoing NAs treatment after discontinuation of therapy during the follow-up process, analyzing the correlation between serum IL-21 and HBVDNA and HBsAg.

RESULTS: The HBsAg titres in baseline in the sustained responses group were significantly lower than those in the virological relapse group (P = 0.039). Serum IL-21 in all the patients in the 24th week, the 48th week coming off the medication are significantly higher than the discontinuation of baseline (P = 0.028, P = 0.019). Serum IL-21 levels in the sustained responses group after 12th, 48th week coming off the medication were significantly higher than the discontinuation of baseline (P = 0.009, P = 0.016). The levels of IL-21 in virological relapse group and sustained response group were not significantly related with the titers of HBVDNA and HBsAg levels.

CONCLUSIONS: HBsAg titers in the discontinuation of baseline can be used as a better predictor of sustained response. Although HBsAg and serum IL-21 levels, HBV DNA and serum IL-21 levels are not significantly correlated, serum IL-21 levels in sustained response patients are in fluctuated status. IL-21 as a kind of inflammatory factor in patients with CHB after the discontinuation of immune control plays an important role.

SPONSORSHIP: Internally sponsored by BSC and no external funding was solicited for this study.

B6 A Retrospective Analysis of Patients Enrolled in Commcare’s Hepatitis C Disease Management Program

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BACKGROUND: Major changes have emerged in the treatment of chronic hepatitis C with newer medications receiving FDA approval within the past year, favoring less adverse effects and higher sustained virologic response (SVR) rates than the older treatment options which included interferon and ribavirin. Adherence to these newer medications is important to obtain the desired clinical outcome of achieving SVR and eradicating the virus. Multiple studies have shown an association between poor adherence and not achieving SVR. Reasons for non-adherence include undesirable side effects, high medication costs and lack of patient education. Commcare’s Hepatitis C disease management program addresses a broad spectrum of detailed patient care that empowers patients to adhere to these medications and thus optimize clinical outcomes.

OBJECTIVE: To review the role of clinical pharmacist in optimizing clinical outcomes of Hepatitis C patients in a specialty pharmacy.

METHODS: A retrospective, observational study was conducted using data collected from patients enrolled in the program from January 2014 to November 2014. The study outcome aimed to show the clinical pharmacists role with ensuring medication adherence through patient management and included documenting all clinical interventions of those enrolled in the program. The medication possession ratio (MPR) score was calculated to ensure adherence. Viral loads were collected from the prescriber’s office after the patient completed the treatment to calculate the percentage who achieved SVR.

RESULTS: The final study sample consisted of 79 genotypes one, 21 genotypes two, 13 genotypes three and 2 genotypes four. The clinical pharmacist documented more than 250 interventions/consultations that included adverse effect management, dose/regimen clarification, and prevention of drug-drug interactions. These patients were further...
subdivided into three treatment groups (sofosbuvir/peg/ribavirin; sofosbuvir/ribavirin; sofosbuvir/simeprevir plus or minus ribavirin). The MPR score was measured at greater than 95% for all treatment arms. SVR rates were 74% (95% confidence interval [CI], 73 to 75) in the interferon treated group; 93% (95% CI: 90 to 95) in the group treated with sofosbuvir/ribavirin and 88% (95% CI: 86 to 90) in the group treated with sofosbuvir/simeprevir plus or minus ribavirin.

CONCLUSIONS: Clinical pharmacists were significantly instrumental with ensuring patient adherence and providing side effect management for patients enrolled in the Hepatitis C program. Additionally, the clinical interventions resulted in a cost avoidance amount of about $175,000.

SPONSORSHIP: None.

B8 Health Care Resource Utilization and Costs in Patients Treated with Sofosbuvir in a Managed Medicaid Population

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BACKGROUND: The total healthcare cost related to chronic hepatitis C (HCV) in the U.S. is estimated to be as high as $9 billion annually. Direct-acting antivirals, like sofosbuvir, have revolutionized the treatment of HCV with higher rates of sustained viral response (SVR), better tolerability, and significant treatment costs. With a greater number of patients with HCV qualifying for Medicaid, the new treatments can present an economic strain for Managed Medicaid Plans. However, studies suggest treatment may reduce healthcare resource utilization post-therapy.

OBJECTIVE: To evaluate utilization and costs of healthcare resources in members enrolled in a Medicaid Managed Care plan that have completed treatment with sofosbuvir.

METHODS: A retrospective analysis of administrative pharmacy and medical claims data was conducted from June 2013-November 2014. Pharmacy claims data were reviewed to identify members who had > 3 prescription claims for sofosbuvir between December 2013-April 2014, and no sofosbuvir claims after April 2014. Treatment with sofosbuvir was the index period. Members were required to have 6 months pre- and 6 months post-index continuous enrollment. Six months pre- and post-index healthcare service utilization (hospitalizations, emergency department (ED), home health, office, other outpatient visit, and prescription fills) and costs (pharmacy, medical, and total) were compared using descriptive statistics.

RESULTS: A total of 19 members were included in the analysis. There were no differences in HCV related inpatient, ED, and home health utilization pre- and post-index. HCV related office and outpatient service utilization was 18.52% lower post-index compared to pre-index. There were also fewer HCV related prescriptions per member post-index compared to pre-index. All-cause medical service utilization was 2.86% higher post-index whereas all-cause prescriptions per member decreased by 14.4%. For HCV healthcare costs (medical and pharmacy combined), the mean cost per member per month decreased by 42.8% ($990.53 pre-index to $566.93 post-index). Overall, all-cause healthcare costs per member per month decreased by 4% ($1,023.33 to $983.22).

CONCLUSIONS: Our analysis showed healthcare costs decreased post-treatment with sofosbuvir for HCV and all-cause healthcare services. Whereas a decrease in all-cause prescription claims was observed, there was a slight increase in all-cause medical services utilized post-index period. Continued evaluation is needed to assess the impact of direct acting antivirals on long-term healthcare service utilization, clinical outcomes and costs.

SPONSORSHIP: This research was conducted by Passport Health Plan without external funding.

B9 Evaluation of Prescribing Trends of Sofosbuvir-Containing Products Using Pharmacy Paid Claims Data in 2014

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BACKGROUND: Over the past two years, the Food and Drug Administration has approved several new medications for the treatment of chronic Hepatitis C virus (HCV) that have changed treatment guidelines and prescribing practices. Of particular interest are the once-a-day oral regimens containing sofosbuvir (e.g., Sovaldi, Harvoni). Treatment of HCV was revolutionized with the approval of Sovaldi and Harvoni, which demonstrated sustained virologic response (SVR) rates up to 96%. The high costs of these regimens are a concern for patients and payers prompting for a prior authorization process at the payer level.

OBJECTIVE: To identify and characterize Sovaldi and Harvoni prescribing practices over a one year period based on patient disease severity and prescriber specialization.

METHODS: A retrospective analysis using paid claims data Sovaldi and Harvoni from December 2013-December 2014 was performed to identify prescribing and approval trends for patients with HCV for all clients. Prior authorization requests were evaluated for hepatic fibrosis stage, prescriber specialization, and date of claim based on all available data.

RESULTS: A total of 96 paid claims from all clients were evaluated; 10 Harvoni, 86 Sovaldi. Using chi-square analysis, patients with less severe hepatic fibrosis (Stages 1, 2, or unknown) comprised a higher proportion of paid claims, 40 out of 56, over the first two quarters and 14 out of 38 paid claims over the last two quarters (P<0.001). Claims for Sovaldi during the third and fourth quarter dropped significantly compared to the first and second quarters (P<0.001). Claims for Harvoni were approved only for patients with hepatic fibrosis Stage 3 or 4. Approved sofosbuvir-containing products were prescribed most commonly by gastroenterologists (62), physician assistants (13), and internists (6).

CONCLUSIONS: The significant decrease of paid claims for patients with evidence of less severe hepatic fibrosis from the first two quarters (71%) and the last two quarters (37%) may be due to more stringent prior authorization requirements. These strengthened prior authorization requirements also applied to Harvoni at the time of its FDA approval. The decrease in the number of Sovaldi claims during the third quarter may be due to prescribers and/or patients delaying treatment until the approval of Harvoni. While most pharmacy benefit managers require that prescribers of sofosbuvir-containing products be specialists (e.g., hepatologist, gastroenterologist), this was not evidenced in the data. Payers may want to consider requiring a specialized physician be involved in patient care for future drug approval.

SPONSORSHIP: None.

B10 Retrospective Analysis of Overall Health Care Costs Pre- and Post-Treatment with Sofosbuvir Using Administrative Claims Data

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BACKGROUND: Sofosbuvir, approved by the FDA in late 2013 as part of a treatment combination for chronic hepatitis C virus (HCV)
infection, is one of the revolutionary new medications which promise to drastically improve the health of patients with HCV. However, sofosbuvir typically costs over $90,000 per regimen, which when combined with the estimated 3.2 million people in the U.S. who have chronic HCV and may benefit from treatment, poses a substantial financial burden to payers and provokes value-of-treatment questions.

**OBJECTIVE:** To determine the short-term impact on overall healthcare costs for patients with chronic HCV following treatment with sofosbuvir.

**METHODS:** Retrospective analysis of administrative claims data from a large commercial insurer in the Federal Employees Health Benefits Program (FEHBP) including Medicare claims between January 1, 2013 and October 31, 2014. Eligible patients had a diagnosis for chronic HCV (ICD-10-CM B18.20), at least 18 months of continuous enrollment and completed at least 12 weeks of treatment with sofosbuvir between January 1 and June 30, 2014. The change in overall healthcare costs for chronic HCV patients were compared for the 120-day period pre-sofosbuvir treatment and the 120-day period post-sofosbuvir treatment.

**RESULTS:** A total of 402 patients met all study criteria and were included in the analysis. The overall healthcare costs for patients with chronic HCV were averaged $8,341 and mean post-treatment costs of $5,153. The $3,189 decrease in overall healthcare costs was statistically significant (P < 0.01).

**CONCLUSIONS:** This analysis of real-world data from a large U.S. commercial insurer showed a significant decrease in overall healthcare costs during the 120-day period following treatment with sofosbuvir for chronic HCV. The cost savings included medical and pharmacy claims across multiple chronic conditions beyond HCV, suggesting that there may be layered advantages of overall health improvement associated with sofosbuvir treatment. Further research is needed to extend these findings and help decision-makers understand the broader value of treatment with novel HCV agents that are highly efficacious yet expensive.

**SPONSORSHIP:** BlueCross BlueShield Association; no external funding provided for this analysis.

**B11 Evaluation of Prescribers’ Adherence to Hepatitis C Treatment Guidelines Within a Commercial Health Plan**

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**BACKGROUND:** In late 2013, sofosbuvir (SOF) and simeprevir (SMV) were approved to treat hepatitis C virus (HCV). The high cost of these medications has been of great interest to health care payers, the United States government, and the national media. In January 2014, guidelines were updated describing appropriate parameters around the treatment of HCV by the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) in collaboration with the International Antiviral Society-USA (IAS-USA). Due to the complexity and high cost of treatment, adherence to HCV guidelines and package labeling is essential, warranting clinical pharmacist interventions.

**OBJECTIVE:** To determine the impact of clinical pharmacist interventions in addressing prescribing which deviated from the AASLD/IDSA/IAS-USA HCV treatment guidelines.

**METHODS:** Commercially insured members with Blue Cross Blue Shield of Michigan pharmacy benefit from February 1, 2014 to October 31, 2014 with a prior authorization (PA) request for SOF were analyzed. The frequency of requests were categorized as follows: (a) deviation from AASLD/IDSA/IAS-USA guidelines, (b) deviation from SOF/SMV package labeling, (c) combination of SOF/SMV, (d) non-peg interferon (PEG) regimen among PEG eligible members, (e) treatment duration exceeding package labeling and AASLD/IDSA/IAS-USA guideline recommendations, (f) SOF/ribavirin (RBV) together for 24 weeks when SOF/SMV combination for 12 weeks was more appropriate, and (g) successful intervention by clinical pharmacist on appeal. Members could fall under multiple categories.

**RESULTS:** In the sample of 353 PA requests for SOF combinations, 85 (24%) were initially denied. The total number of cases that deviated from AASLD/IDSA/IAS-USA guidelines was 74 (21%) and 73 (21%) deviated from package labeling. There were 48 (13.3%) denied requests for SOF/SMV combination and among these denied requests, 30 (68.8%) were PEG eligible. A total of 13 (3.7%) requests went beyond recommended treatment duration, and 3 (0.9%) requests for SOF/RBV combination for 24 weeks when SOF/SMV combination for 12 weeks was more appropriate. Among the 33 appealed cases, 15 (45.4%) cases had a successful intervention.

**CONCLUSIONS:** Many physicians have deviated from the AASLD/IDSA/IAS-USA recommendations and package labeling for SOF and SMV. Potential interventions for health plans include targeted physician outreach, increased education, and clear denial language to ensure appropriate and cost effective use of newer HCV medications in correlation with the new December 2014 AASLD/IDSA/IAS-USA guidelines.

**SPONSORSHIP:** This research was conducted by Blue Cross Blue Shield of Michigan with no external funding.

**B12 Analyzing the Burden of Hepatitis C Using an Outcomes Evaluation Tool Within an Integrated Delivery Network**

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**BACKGROUND:** Hepatitis C virus (HCV) is a liver disease that can result in long-term illness with serious liver complications such as cirrhosis, liver failure, or hepatocellular carcinoma. Approximately 2.7 million people in the United States have chronic HCV, of which up to 75% are unaware of their infection. Total costs for chronic HCV are projected to increase by 60% by 2032.

**OBJECTIVE:** The objective of this study was to understand characteristics, treatment patterns, healthcare utilization and costs of patients at risk for or diagnosed with HCV within an integrated healthcare delivery system (IHDS) setting using an HCV claims analyzer software tool.

**METHODS:** Deidentified pharmacy and medical claims from a mid-size IHDS were imported into the HCV analyzer tool. Patients at risk for HCV and patients diagnosed with HCV were identified between October 1, 2011 and September 30, 2014 based on criteria of risk (with date of birth January 1, 1945-December 31, 1965 and ≥1 additional risk factor) or diagnosis (age ≥18 with a primary diagnosis of HCV during follow-up time frame). Follow-up timeframe was 6 months. Demographics were evaluated for both populations. In the diagnosed population, vaccinations, recent treatment status, treatment regimen/duration, healthcare resource utilization, and costs were evaluated.

**RESULTS:** Of 652,911 members in the plan, a total of 2,158 (0.3%) patients were identified as at risk for HCV and 3,072 (0.5%) patients were diagnosed with HCV. Approximately 29% of the at-risk population had evidence of HCV screening. Of the diagnosed population, 69%, 11%, and 20% of patients had non-cirrhotic disease,
Sustained Virologic Response Among HealthPartners Members Receiving Sovaldi-Containing Hepatitis C Treatment

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BACKGROUND: Six key studies have led to current recommendations for using Sovaldi (sofosbuvir) in the treatment of hepatitis C virus (HCV) infection. Treatment guidelines have been published by the American Association for the Study of Liver Diseases (AASLD), in cooperation with the Infectious Diseases Society of America (IDSA). These studies were each conducted on <500 patients with varying degrees of similarity in baseline patient characteristics. There is a lack of information on the effectiveness of Sovaldi-containing regimens across all genotypes, and in a “real-world” patient population. This study intends to fill this knowledge gap.

OBJECTIVE: This study will evaluate sustained virologic response at 12 weeks (SVR12) following the completion of treatment among HealthPartners members. We will compare SVR12 results with those reported in the primary literature.

METHODS: Using a retrospective study design, we described the rate of SVR12 among HealthPartners members treated for HCV infection using any Sovaldi-containing treatment regimen. Subjects were identified via prior authorization approval by HealthPartners. Adherence was encouraged and monitored throughout the course of treatment through refill coordination and drug delivery setup, the use of the HealthPartners MyMeds adherence application, a mid-treatment HCV assay, and provider & patient attestation. SVR12 outcome data was obtained through provider outreach to external providers, and through EPIC chart review from internal providers. The primary outcome measure was achievement of SVR12, defined as having an undetectable viral load 12 weeks after the completion of a Sovaldi-containing HCV treatment regimen. Outcome data was also described in the following sub-groups: genotypes 1-3, Metavir fibrosis score.

RESULTS: The results of this study will evaluate the effectiveness of all Sovaldi-containing regimens across a diverse, complex patient population that is more reflective of “real-world” populations compared with those described in the literature.

CONCLUSIONS: The results have the potential to heavily influence drug utilization decisions, prior authorization criteria, and adherence measures implemented by HealthPartners drug coverage plans.

SPONSORSHIP: HealthPartners Pharmacy Administration.

Analysis of Member Characteristics and Prescribing Patterns Associated with Sofosbuvir Treatment

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BACKGROUND: In December 2013, the FDA approved sofosbuvir (SOF) for the treatment of chronic hepatitis C (CHC). Compared to previous CHC treatments, SOF-based therapy has several advantages such as higher cure rates, fewer side effects, and shorter treatment durations. Despite these advantages, the high cost of SOF has resulted in payers implementing utilization management tools to ensure appropriate use and to minimize waste. Consequently, it is important to understand who is prescribing and who is receiving prescriptions for SOF.

OBJECTIVE: To describe the demographics, clinical characteristics, and prescribing patterns associated with SOF treatment in commercial populations.

METHODS: A retrospective analysis was conducted using a random sample of commercial members who were identified as having a prior authorization (PA) request for SOF between March and June 2014. Member and provider characteristics were collected from a PA database for a national pharmacy benefit manager and the results were assessed using descriptive statistics.

RESULTS: A total of 338 members were included in the analysis. Members had a mean age of 55.4 years, were predominantly male (65.1%), and most often resided in the Southern U.S. (38.2%). Genotype (GT) 1 CHC was present in 74.3% of members followed by GT 2, 3, and 4 in 13.9%, 9.5%, and 1.2%, respectively. Among GT 1 members, 19.1% had the equivalent of F0-F2 liver fibrosis, 24.7% F3-F4 fibrosis, and the remaining 56.2% did not have documentation indicating their degree of fibrosis. Of GT 1 members with fibrosis staging documented, 49.6% had undergone liver biopsy. Gastroenterologists or hepatologists accounted for 90% of providers while 3.8% were infectious disease specialists and 6.2% were other or unknown specialties. A total of 149 of 251 GT 1 members were prescribed interferon (IFN)-free regimens, with SOF plus simeprevir (SIM) accounting for 86.6%. The most common reasons for not prescribing IFN included the patient having a history of or active depression (17.4%), prior intolerance or hypersensitivity to IFN (12.8%), and a low platelet count (6.7%); however, a medical reason for not prescribing IFN was not clear or not provided for 51% of members.

CONCLUSIONS: Members who were prescribed SOF had characteristics that were consistent with expectations based on literature and epidemiological data. In addition, providers in the analysis were most likely to submit results of a liver biopsy when providing documentation of liver fibrosis status and were quick to adopt the IFN-free regimen of SOF plus SIM, despite the regimen lacking FDA approval during the study period.

SPONSORSHIP: This research was conducted by OptumRx, a pharmacy benefits management company based in Irvine, CA.

Innovative Specialty Pharmacy Hepatitis C Management Plan Reduces Wasted Drug Spend and Inappropriate Utilization While Maintaining Optimal Patient Outcomes

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BioPlus Specialty Pharmacy

BACKGROUND: Healthcare costs for hepatitis C virus (HCV) infection-related morbidity now exceed $13 billion per year. New antivirals such as ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir/daclatasvir,
simeprevir, and sofosbuvir bring high cure rates, but come at a high price point. Millions of dollars in HCV drug waste continues to accumulate by many health plans during the prior authorization process. Yet significant savings can be uncovered by leveraging the expertise of pharmacists with the application of technology.

**OBJECTIVE:** BioPlus Specialty Pharmacy developed RxSteward, an innovative intervention program in which our pharmacy collaborates with the prescriber to reduce cost.

**METHODS:** One way that RxSteward reduces unnecessary drug utilization while maintaining excellent clinical outcomes is by using a real-time data analysis called IRIS INSIGHTSSM, which allows the payer to see aggregate and individual outcomes (both financial and clinical). IRIS INSIGHTS identifies and corrects medication errors, contraindication, drug allergy, inappropriate indication, incomplete prescription, incomplete regimen, incorrect administration, incorrect drug duration, incorrect drug frequency, wrong dose, and wrong drug. In addition, IRIS INSIGHTS compares drug orders against American Association for the Study of Liver Diseases (AASLD) guidelines.

**RESULTS:** Internal research found that 18% of prior authorizations for HCV therapy did not meet AASLD recommendations. In one sample of interventions by IRIS INSIGHTS (n = 410), the most common error in prescription was incorrect drug duration (49.2%), with the duration not matching AASLD guidelines. Another sample of interventions (n = 295) found 71% of interventions detected drug orders for HCV genotype 1 infection that failed to match the AASLD guidelines for the optimal treatment duration.

**CONCLUSIONS:** By intervening to correct errors such as these, this novel intervention program improved guideline adherence while saving substantial drug costs. In one four-month period (March-June 2014), the interventions identified and corrected by IRIS INSIGHTS resulted in a total cost savings of $9.723 million for HCV medications. This savings did not interfere with patient outcomes; in fact, the changes related to these savings brought patients’ treatment in line with treatment guidelines.

**SPONSORSHIP:** BioPlus Specialty Pharmacy.

**B26 Comparative Effectiveness of Single Versus Multiple Tablet Antiretroviral Therapy Regimens in Clinical HIV Practice**

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**BACKGROUND:** As generic products are emerging in HIV therapeutics, a key question is the relative effectiveness of single (STR) versus multiple tablet (MTR) regimens of antiretroviral therapy (ART).

**OBJECTIVE:** We explored virologic outcomes among patients initiating one ART regimen as STR or MTR in the CNICS cohort.

**METHODS:** CNICS is a network of 8 HIV clinics at academic centers in the U.S. We identified all patients initiating a tenofovir/emtricitabine (FTC)/elvirezen (TDF) regimen from July 2003-December 2012. Patients were divided into those initiating TDF as STR or MTR. Factors associated with time to virologic failure (VF) were explored using Cox proportional hazards regression with two different definitions of VF: VF1: VL > 400 c/ml on 2 consecutive time points (the first point ≥ 180 days after ART initiation; and VF2: VL > 400 c/ml on 2 consecutive time points (the first point ≥ 180 days after ART). Patients not experiencing VF were censored at time of changing regimen (including switch from MTR to STR) or their last VL. Patients lost to follow-up (> 210 days gap in care) were censored at the last visit before the gap. All models were stratified by clinic site.

**RESULTS:** 2,258 patients initiated a TDF regimen: 404 MTR and 1,854 STR. The majority (89%) of MTR patients were on 2 pills and 11% were on 2 pills. Median age was 38 years; 33% Black, 52% White, 19% other; 17% Hispanic; 36% female; 12% HIVDU, 6% MSM, median CD4 272 cells/μl, and median CD4-log10VL 4.6 c/ml. The strong formulation of TDF became available in 2006, all STR patients initiated treatment in the latter part of the study period, whereas the majority of MTR patients initiated ART prior to 2006. For VF1, proportion of patients with events was 7.4% for STR and 6.7% for MTR, univariate HR = 1.33 (95% CI: 0.87, 2.03), adjusted HR = 1.17 (95% CI:
For VF2, proportion of events was 2.3% for STR and 3.0% for MTR, univariate HR = 1.93 (95% CI: 1.00, 3.72), adjusted HR = 1.54 (95% CI: 0.78, 3.04).

CONCLUSIONS: No significant difference was observed in development of VF between those who received MTR vs. STR; a trend toward more VF with MTR was noted, however overall number of failures was small, impacting significance of results. Demonstrating effectiveness of STR vs. MTR TTE may be confounded by temporal trends and unmeasured confounders. Future work will focus on emergence of viral resistance.

SPONSORSHIP: This study was funded by Bristol-Myers Squibb.

B28 Patterns of H. pylori Treatment and Testing for Patients in a Commercially Insured Population

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BACKGROUND: According to the CDC, up to 50% of all antibiotics prescribed are potentially not needed or not optimally prescribed. The overuse of antibiotics may lead to serious health consequences such as C. difficile or other potentially high cost utilization of services. H. pylori is a common chronic bacterial infection that can lead to serious long-term consequences if not tested and properly treated with antibiotics.

OBJECTIVE: The purpose of this database analysis was to examine the real-life patterns of H. pylori treatment and eradication testing

METHODS: The utilization of H. pylori tests (i.e., endoscopy, urea breath tests, serum antigen tests, and fecal antigen test) as well as antibiotic treatments between January 1, 2008, and December 31, 2012 were evaluated using the MarketScan Research Databases (first observed antibiotic prescription for H. pylori treatment was termed the index date). Patients aged > 18 years with continuous health plan enrollment for 6 months pre- and up to 6 months post-index date were analyzed. H. pylori-related treatment was defined as > 2 specific antibiotics for H. pylori eradication (i.e., amoxicillin, clarithromycin, metronidazole, tetracycline, tinidazole, levofloxacin including fixed dose combinations) with or without an antacid within 7 days.

RESULTS: During this 5-year period, 169,853 patients received at least one course of H. pylori-related treatment, but only 41.3% had an H. pylori test preceding treatment, suggesting treatment without proper testing. Furthermore, only 1 in 8 patients (12.7%) receiving H. pylori treatment were retested to confirm eradication in the 6 months after their index date. High-cost endoscopy accounted for 53.3% of the confirmatory tests despite the availability of non-invasive, less expensive, but highly accurate test options. Approximately 22% of patients received 2nd line treatment, and 30% of these patients received the same 2nd line treatment as they received in 1st line despite prior treatment failure.

CONCLUSIONS: There appears to be no improvement in the use of testing prior to treatment for H. pylori infection since the publication of American College of Gastroenterology clinical guideline in 2007. The treatment of patients with antibiotics without proper testing for infection and confirming eradication in the era of increased antibiotic resistance can lead to negative health outcomes and potentially unnecessary treatments. Additionally, the overuse of expensive testing options places additional burden on an already strained healthcare systems.

SPONSORSHIP: This research was funded by Otsuka America Pharmaceutical, Princeton, NJ.

C00-D48 Neoplasms (i.e., Breast Cancer, Lung Cancer, GIST, Melanoma, CML, CLL, Multiple Myeloma)

C1 Examining the Budget Impact of Adopting Netupitant/ Palonosetron for the Prevention of Chemotherapy-Induced Nausea and Vomiting in a U.S. Health Plan

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BACKGROUND: Chemotherapy-induced nausea and vomiting (CINV) is a major adverse effect of cancer treatment and can have a significant impact on patients and caretakers. Current NCCN guidelines recommend a combination of a serotonin-3 receptor antagonist (5-HT3-RA), a substance P/neurokinin 1 (NK1) receptor antagonist, and dexamethasone for patients undergoing highly emetogenic chemotherapy (HEC) for the prevention of CINV. This same combination is also recommended in appropriate patients using moderately emetogenic chemotherapy (MEC) who are at higher risk of CINV.

OBJECTIVE: The purpose of this study was to estimate the budget impact of adopting netupitant/palonosetron (NEPA), a recently approved oral fixed-dose combination of a 5-HT3-RA and an NK1, for the prevention of CINV in HEC and MEC, from a U.S. health plan perspective.

METHODS: A decision analytic model compared antiemetic prophylaxis costs before and after adoption of NEPA in a hypothetical one million-member health plan over a 3-year time horizon. Estimates of plan cancer rates and utilization of HEC and MEC therapies were derived from U.S. epidemiological and market data. Treatment costs were computed using standard prescribing dosages, U.S. drug cost listings and simple reimbursement and dispensing assumptions. Uptake of NEPA was calculated at 5% a year for 3 years. The market shares of the competing antiemetic therapies were reduced proportionately based on their initial market segment and for each year across the time horizon. The resulting cost estimates were calculated as total costs, PMPM costs, and cost per utilizing member for each 5-HT3-RA + NK1 combination.

RESULTS: A total of 5,400 patients with cancer were identified in the model scenario. Of these, 988 (18.3%) would receive HEC and 395 (7.3%) would receive MEC requiring combination therapy, for a total of 1,383 patients eligible for NEPA. Treatment for the prevention of CINV prior to the adoption of NEPA was estimated as costing nearly $4.0 million. Following the adoption of NEPA, cumulative costs were reduced by $512K by the end of year 3. Calculations using PMPM estimates showed cumulative savings of $0.002 in year 1, $0.003 in year 2, and $0.004 in year 3.

CONCLUSIONS: Results of the model indicate that adoption of NEPA for the prevention of CINV will have a relatively neutral impact on a U.S. health plan budget. Additionally, these estimates do not include savings from a potential reduction in the overall rate of CINV.

SPONSORSHIP: Eisai Pharmaceuticals.

C2 Economic Analysis of Panitumumab Versus Cetuximab in Chemorefractory Patients with Wild-Type KRAS Metastatic Colorectal Cancer

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BACKGROUND: The ASPECT trial was a phase 3 head-to-head randomized noninferiority study comparing the efficacy and safety of epidermal growth factor receptor inhibitors (anti-EGFRs), panitumumab and cetuximab, in patients with previously treated, chemotherapy resistant or intolerant, wild-type (WT) KRAS exon 2 metastatic colorectal cancer (mCRC). Trial results indicated similar median overall survival (OS; HR = 0.97, 95% CI: 0.84-1.11), and similar median progression-free survival (PFS; HR = 1.00, 95% CI: 0.88-1.14). Given this similar efficacy, economic modeling may assist decision makers in determining the relative monetary value of one treatment versus another in a context of healthcare budgetary challenges and constraints.

OBJECTIVE: To compare the costs of treatment with panitumumab versus cetuximab among chemorefractory patients with WT KRAS mCRC.

METHODS: A cost-minimization model was developed based on similar treatment efficacy. The model estimated the costs associated with drug acquisition, treatment administration frequency (every 2 weeks for panitumumab, weekly for cetuximab), and incidence of infusion reactions. Average anti-EGFR doses were calculated from ASPECT. Using the medical component of the consumer price index, adverse event costs were inflated to 2014 U.S. dollars, and all other costs were reported in 2014 U.S. dollars. The time horizon for the model was based on mean PFS, estimated from parametric survival analyses of ASPECT data.

RESULTS: Relative to cetuximab in the treatment of chemotherapy resistant or intolerant patients with WT KRAS mCRC, the cost-minimization model estimated lower projected drug acquisition, administration, and adverse event costs for patients who received panitumumab. The overall cost per patient was $47,679 for panitumumab versus $59,630 for cetuximab, resulting in a per-patient savings of $11,952 (20%). Drug acquisition costs alone were 17% less with panitumumab ($46,179 vs. $55,963).

CONCLUSIONS: From a value perspective, the cost-minimization model supports panitumumab versus cetuximab as a preferred treatment option for chemorefractory WT KRAS mCRC patients.

SPONSORSHIP: Amgen.

C3 Economic Burden of Bone and Liver Metastases in Patients with ALK+ Non-Small Cell Lung Cancer

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BACKGROUND: Brain, bone, and liver metastases are among the most frequent metastatic sites in patients with anaplastic lymphoma kinase positive (ALK+) non-small cell lung cancer (NSCLC). Prior studies have documented the economic burden of brain metastases in this population, but information on bone and liver metastases is scarce.

OBJECTIVE: The objective of this study is to estimate the economic burden of bone and liver metastases from a U.S. private payer's perspective.

METHODS: This retrospective study pooled data from two large administrative claims databases IMS LifeLink Health Plan Claims database (January 2001-March 2014) and Truven Health Analytics MarketScan database (January 2002-September 2012). A prescription fill for crizotinib was used to identify patients with ALK+NSCLC among patients with a diagnosis for lung cancer. Adult patients with a diagnosis of bone metastases (BM) and liver metastases (LM) were selected for further analysis if they had sufficient follow-up around the date of the first observed BM or LM diagnosis (≥ 60 days before and ≥ 30 days after).

RESULTS: Among the 213 ALK+NSCLC patients meeting the selection criteria, 175 patients had BM, and 97 patients had LM. The median age was 54.9 years and 53.6 years and males accounted for 39.4% and 44.3% of the sample in the BM and LM groups, respectively. In both groups, healthcare costs substantially increased after the diagnosis of metastatic disease. For the BM sample, average costs were $4,753 PPPM pre BM and $20,205 post BM. The main cost drivers were pharmacology costs (e.g., chemotherapy, targeted therapy), medical imaging costs (e.g., MRI, PET scan, CT scan), and costs related to symptom management, accounting for 48.9%, 18.4%, and 11.1% of the total healthcare costs, respectively. For the LM sample, average costs were $9,400 PPPM pre LM and $25,195 post LM. The main costs drivers were also pharmacy costs, medical imaging costs, and adverse event costs, accounting for 36.2%, 20.8%, and 14.8% of the total healthcare costs, respectively.

CONCLUSIONS: Bone and liver metastases are associated with a substantial economic burden for private payers in the U.S.

SPONSORSHIP: Novartis Pharmaceuticals.

C4 Treatments and Health Care Costs Among U.S. Patients with Advanced Melanoma Initiating Subsequent Systemic Therapy Following Use of Ipilimumab (IPI)

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BACKGROUND: As the treatment landscape for advanced melanoma continues to rapidly evolve, it has become even more critical to focus on unmet needs and understand the associated cost of treatment. While IPI, an immunotherapy indicated for unresectable advanced melanoma has been a mainstay of first-line treatment, there is currently no standard of care following progression.

OBJECTIVE: To describe subsequent therapy post-IPI and the healthcare costs associated with advanced melanoma patients in the U.S.

METHODS: Adult patients diagnosed with stage III or IV melanoma treated with IPI were selected between April 1, 2011 and September 30, 2013 from a large U.S. commercial and Medicare claims database. Patients were evaluated for subsequent chemotherapy, targeted therapy, or immunotherapy. An index date was set as the first medical or pharmacy claim for systemic therapy post-IPI. Per-patient per-month (PPPM) healthcare costs while on active treatment were evaluated from the index date until a 60-day gap in treatment, inpatient death, end of insurance enrollment, or September 30, 2013 (follow-up period). Statistics were descriptive.

RESULTS: Of 361 eligible patients treated with IPI, 111 (30.7%) initiated subsequent systemic therapy (mean age 57 years, 64.9% male). During median post-index follow-up of 130 days, mean (standard deviation, SD) PPPM all-cause total healthcare costs were $20,383 ($18,988), of which $4,800 (23.6%) was related to melanoma drug costs, $5,899 (28.9%) was related to medical claims with a diagnosis of melanoma, and $9,684 (47.5%) was related to other (non-specified) utilization. The most common therapies, single agent or in combination, included: vemurafenib (32.4%), paclitaxel (28.8%), temozolomide (20.7%), and carboplatin (17.1%). Among these, mean (SD) PPPM all-cause total healthcare costs ranged from $19,379 ($10,706) for patients treated with temozolomide to $26,977 ($29,432) for patients treated with carboplatin; the proportion of total costs related to non-specified utilization ranged from 36% ($7,142 of $19,882) for patients treated with vemurafenib to 74% ($19,938 of $26,977) for patients treated with carboplatin.
CONCLUSIONS: When considering the totality of care, including management beyond systemic therapy alone, the costs of U.S. patients with advanced melanoma post-IPI were substantial across all commonly-used agents. Analyses of data with longer follow-up/larger samples, when available, are warranted.

SPONSORSHIP: Bristol-Myers Squibb.

C5 Treatment Patterns and Predictors of Everolimus Use Among Postmenopausal Women with HR+/HER2- Metastatic Breast Cancer in the United States: A Retrospective Chart Review Study

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BACKGROUND: Everolimus (EVE) has recently been approved for treating hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) metastatic breast cancer (mBC) in combination with exemestane (EXE) among patients who fail a non-steroidal aromatase inhibitor (NSAI). To date, limited evidence exists regarding the real-world use of EVE.

OBJECTIVE: The objective of this study was to describe the real-world treatment patterns and predictors of everolimus use.

METHODS: A retrospective chart review was conducted in community-based oncology practices for postmenopausal HR+/HER2- mBC women who had failed NSAI in the adjuvant or metastatic setting and then received EVE, endocrine therapy (ET), or chemotherapy (CT) for mBC between July 1, 2012 and April 15, 2013. Baseline characteristics, treatment sequences and regimens, and dosing patterns were summarized. Patient characteristics associated with use of EVE versus ET or CT were identified using logistic regressions.

RESULTS: A total of 237, 315, and 147 patients received EVE, ET, or CT, respectively, in a quota-based sample. Median age was 65 years and 59% were white. Among patients treated with EVE in any line, EXE was the most commonly used concomitant therapy (58-87%), and 59% were white. Among patients treated with EVE in any line, EXE was the most commonly used concomitant therapy (58-87%), and 59% were white.

C6 Overall Survival with First-Line Endocrine Therapy or Chemotherapy Among Postmenopausal Women with HR+/HER2- Metastatic Breast Cancer: A Retrospective Chart Review Study in the United States

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BACKGROUND: Endocrine therapy (ET) and chemotherapy (CT) are two commonly used treatments of hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) metastatic breast cancer (mBC). Clinical guidelines recommend ET over CT as first line treatment, except in cases of endocrine resistance or symptomatic visceral disease.

OBJECTIVE: The objective of this study was to examine overall survival (OS) of postmenopausal HR+/HER2- mBC patients who received ET or CT as first line treatment in a real-world setting.

METHODS: This study was a retrospective chart review of postmenopausal HR+/HER2- mBC patients who were treated in community-based oncology practices. Included patients had failed adjuvant non-steroidal aromatase inhibitor(s) and received ET or CT as first line treatment for mBC between July 1, 2012 and April 15, 2013. OS was defined as time from the initiation of first line treatment to death and was compared between the two treatment groups using Kaplan-Meier curves and log-rank tests. Multivariable Cox proportional hazards models were used to estimate the hazard ratio (HR) and 95% confidence interval (CI) for OS between first line ET and CT, adjusting for age, race, insurance type, months from the initiation of last adjuvant ET to mBC diagnosis, Charlson comorbidity index (CCI), metastatic sites, and ECOG performance status.

RESULTS: A total of 218 and 69 patients received first line treatment with ET and CT, respectively. ET and CT patients were comparable in age (median: 64.5 and 64.0 years) and race (white: 63.8% and 56.5%). ET patients were significantly less likely to have liver, lung, or any visceral metastases, and had significantly fewer metastatic sites and lower tumor volume compared to CT patients. At 18 and 24 months, 86% and 85% of ET and 74% and 67% of CT patients were alive. ET patients had significantly longer OS than CT patients (HR = 0.44, 95% CI: 0.23 to 0.82; P = 0.01).

CONCLUSIONS: In this retrospective chart review study, postmenopausal HR+/HER2- mBC patients who received ET as first line treatment had significantly longer OS than those who received CT as first line treatment.

SPONSORSHIP: Novartis Pharmaceuticals.

C7 Overall Survival Following Initiation of First-Line Treatment with a Non-Steroidal Aromatase Inhibitor or Fulvestrant Among Postmenopausal Women with Recurrent HR+/HER2- Metastatic Breast Cancer

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BACKGROUND: Endocrine therapy is the recommended first-line therapy for hormone receptor positive (HR+)/human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer (mBC) without endocrine resistance or symptomatic visceral disease. Non-steroidal aromatase inhibitors (NSAIs) and fulvestrant are frequently...
used for recurrent mBC after adjuvant therapy, but little research has directly compared the clinical outcomes between these regimens as first-line treatment of mBC.

**OBJECTIVE:** This study compared the overall survival (OS) of postmenopausal patients receiving first-line NSAI or fulvestrant for recurrent HR+/HER2- mBC in real-world settings.

**METHODS:** This study is a retrospective chart review of postmenopausal recurrent HR+/HER2- mBC patients in community-based oncology practices receiving first-line NSAI or fulvestrant in 2004-2012. OS from the initiation of first-line therapy was described for each therapy using Kaplan-Meier curves and compared using logrank tests. Cox regression models adjusted for baseline characteristics including age, insurance plan type, Charlson Comorbidity Index, metastatic sites at the initiation of first-line therapy, and time from the initial diagnosis of breast cancer to recurrence.

**RESULTS:** This study included 20 patients who initiated first-line NSAI monotherapy and 17 who initiated first-line fulvestrant monotherapy. Baseline characteristics did not differ significantly between the two groups. Among the fulvestrant group, 100% had received adjuvant endocrine therapy, whereas 70% of the NSAI group received adjuvant endocrine therapy. A higher proportion of the fulvestrant group had recurred within 12 months of ending adjuvant therapy (93%) than the NSAI group (60%). The median OS was 41 months for patients who initiated NSAI monotherapy and 19 for those who initiated fulvestrant monotherapy (P = 0.048). The multivariable-adjusted hazard ratio (HR) comparing the OS between the two groups was not statistically significant (HR = 0.69; P = 0.55).

**CONCLUSIONS:** Postmenopausal patients receiving first-line NSAI monotherapy for recurrent HR+/HER2- mBC had significantly longer overall survival than those receiving first-line fulvestrant monotherapy. After adjusting for baseline characteristics, however, there was no evidence of a survival difference between the two groups. One limitation of this study is small sample size. Future studies with larger sample sizes are warranted to further investigate real-world outcomes with first-line endocrine therapies.

**SPONSORSHIP:** This research was funded by Novartis Pharmaceuticals.

**C10** A Qualitative Study Examining the Medical and Psychosocial Impact of Treatment for Metastatic Castration-Resistant Prostate Cancer from the Patients’, Caregivers’, and Physicians’ Perspectives

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Background: Prostate cancer is the second leading cause of cancer death in men in the United States. Newer oral medications for treating metastatic castration-resistant prostate cancer (mCRPC) include abiraterone and enzalutamide. Insight into medical and psychosocial impacts of treatments for mCRPC among patients (PT), caregivers (CG), and physicians (PHY) may inform decision making.

**OBJECTIVE:** To explore the perspectives of patients, caregivers, and clinicians on the use of oral medications to treat mCRPC, qualitative interviews were utilized to understand the experience of mCRPC patients; to investigate individual, social and environmental factors influencing treatment decisions; and to explore perceived clinical benefits and risks of therapies.

**METHODS:** Qualitative semi-structured interviews with mCRPC PT, CG, and PHY (oncologists and urologists) were performed. PT and PH were identified from a large pharmacy claims database and CG were nominated by PT. Interview transcripts were coded using QSR NVIVO 10 software and analyzed to extract prominent and emerging themes using grounded theory.

**RESULTS:** 31 PT, 26 CG, and 30 PHY were interviewed. A majority of PT were age ≥ 70 years. CG were mostly spouses (n = 23, 88%). Over 80% of PT had favorable views of the relationship with their cancer care PHY, from whom most information on mCRPC was obtained. Over 68% of CG cited the internet as a primary source of information, 45% expressed skepticism with doctor information, and 30% wanted more support in their role. PT were impacted by loss of social functioning and viewed chemotherapy negatively. PHY were likely to identify pain as a concern. PT and CG viewed the efficacy of oral medications in terms of lowering prostate-specific antigen levels. Most PT felt they were experiencing minimal side effects, but were unsure if those were symptoms of disease, effects of aging, or medication-related. All groups identified financial barriers to accessing medication. PHY offices were viewed as central to facilitating patient assist-
tance programs. PHY identified challenges navigating the healthcare system to access medications.

**CONCLUSIONS:** This qualitative study identified multiple individual, social, and environmental factors that influence decision-making on treatments for mCRPC. Gaps in disease information, financial concerns, and limited caregiver support impact the PT and CG. PHY preferred oral medications, but cited barriers to patient access. Confirmation of these findings using survey instruments among a larger sample of patients, caregivers, and physicians is needed.

**SPONSORSHIP:** This research was funded by Astellas Scientific and Medical Affairs and by Medivation.

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C12 Axitinib as Subsequent Therapy in Renal Cell Carcinoma: Real-World Treatment Patterns in the United States

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**BACKGROUND:** Axitinib (Inlyta) was FDA approved in 2012 for treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy and has NCCN Category 1 designation as subsequent therapy for predominantly clear cell Stage IV RCC.

**OBJECTIVE:** To further understanding of patient experience in clinical practice and beyond the controlled clinical trial setting, this research was conducted to understand real-world axitinib use as subsequent therapy in RCC.

**METHODS:** Axitinib patients from 22 specialty pharmacies were matched to longitudinal claims from medical office/clinic and prescription databases. All data were de-identified. Included patients were diagnosed with RCC, had prior systemic therapy, and had received ≥ 1 dose of axitinib between May 2012-April 2013. Prior treatment, dosing, duration of therapy and patient and prescriber demographics were assessed.

**RESULTS:** Of 1,175 patients identified, 47% were age ≥ 65, 74% were male and 72% used Commercial insurance. Charlson comorbidity index score, excluding metastatic carcinoma diagnoses, was 2-3 in 80% of patients. 56% of axitinib patients initiated therapy in the 2nd line (2L) and mean duration of therapy in 2L was 172 days. Of axitinib 2nd line patients, the most common 1st line therapy was sunitinib (55%) and second most common was pazopanib (16%). 68% of prescribing physicians had academic affiliation. Of 1021 patients starting at 5 mg BID, 70% remained at this dose throughout therapy, 16% had a dose increase and 14% a dose decrease. Increasing age was associated with decrease in dose (OR = 1.018, 95% CI: 1.0-1.036). Mean and median co-pays were $294 and $33, respectively.

**CONCLUSIONS:** This retrospective cohort study employing multiple claims databases provides insight into routine clinical use of axitinib as subsequent therapy for RCC. Differences in real-world dosing and drug costs have not been studied.

**SPONSORSHIP:** This study was funded by Novartis Pharmaceuticals.
as well as raise health care costs. Few studies have examined the burden of this disease from the patient perspective. We present data on NETs burden in U.S. patients.

**OBJECTIVE:** To describe the health care burden of NETs through analyses of results from a patient survey.

**METHODS:** An anonymous survey of 1,928 NET patients from >12 countries (Americas, Asia, Europe, Oceania), including the United States (n = 758), was conducted by INCA (February-May 2014) in collaboration with Novartis on the NET patient experience. U.S. analyses were performed separately relative to disease burden, medical resource use, and access to care.

**RESULTS:** Patients reported seeing numerous health care providers (HCPs), both prior to diagnosis (≥3 HCPs reported by 36% of patients; range, 1-20 + HCPs) and for management of their disease (≥3 HCPs, 62% of patients). 53% of patients reported a ≥2-year delay from symptom onset to diagnosis; only 23% were diagnosed with NET after initial symptoms. For those diagnosed within the last 5 years, 58% reported their NET had metastasized at time of diagnosis. The most common initial diagnoses were: irritable bowel syndrome (49%), gastritis/other digestive disorders (46%), and anxiety/psychosomatic conditions (26%). Following diagnosis, NET patients continued to experience a wide range of symptoms (often on a daily basis), including general fatigue (61%), diarrhea (35%), skin reactions (47%), and abdominal pain (47%). 33% of patients reported poor/fair health and 73% reported a moderate to large impact of NET on overall quality of life. Many aspects of patients’ lives were negatively affected by NETs, including energy levels (71%), finances (59%), and ability to perform daily chores/care for family (47%/39%). 29% of patients had ≥6 tests/year, often traveling >31 miles (46%) to see their NET medical team. Of those still working (n = 316), 62% reported having to take time off and of those retired (n = 192), 79% stopped working due to NET. Key improvements to help patients live with NETs included expanded access to NET treatments/medical teams (51%/45%) and better understanding of how to manage disease/treatment-related symptoms (44%/40%).

**CONCLUSIONS:** This large survey showed the substantial burden of NETs with respect to medical resource use, symptoms, and delayed diagnosis. Improvements in diagnosis and management of NETs are needed to enhance patient care.

**SPONSORSHIP:** This study was funded by Novartis Pharmaceuticals.

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**D2 Efficiency of Ferric Carboxymaltose in Treating Iron Deficiency Anemia: The Payer Perspective**

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**BACKGROUND:** Intravenous (IV) iron is an effective therapy for iron deficiency anemia (IDA); however, established drugs pose cost and productivity burdens to patients, providers, and payers. The recent introduction of ferric carboxymaltose (FCM) may provide a cost-efficient alternative by reducing the number of IV iron administrations, infusion times, and treatment cycle costs.

**OBJECTIVE:** This analysis compared payer costs, administration times, and treatment patterns between FCM and established IV iron therapies in patients with IDA.

**METHODS:** The study was a non-randomized, non-interventional, prospective, observational study. Decisions on drug choice (FCM, iron sucrose, iron dextran, or ferumoxytol), frequency of infusion, and strategies to help patients live with NETs included expanded access to NET treatments/medical teams (51%/45%) and better understanding of how to manage disease/treatment-related symptoms (44%/40%).

**RESULTS:** A total of 551 patients were included in the analysis (FCM = 166, iron sucrose = 132, iron dextran = 89, and ferumoxytol = 164). Patients were recruited from 5 hospital outpatient departments, 10 large freestanding infusion centers (FICs), and 9 small FICs. FCM delivered the highest mean dose of iron per infusion (751 vs. 200 vs. 626 vs. 511 mg) and per study period (1,416 vs. 891 vs. 1,097 vs. 990 mg) compared to iron sucrose, iron dextran, and ferumoxytol, respectively. FCM had fewer or similar numbers of infusion visits (1.9) compared to iron sucrose (3.3), iron dextran (1.8), and ferumoxytol (1.9). Infusion duration (adjusted per 1,500 mg IV iron) significantly decreased for FCM compared to iron sucrose and iron dextran (413 vs. 342 vs. 277 min; P < 0.001), but increased relative to ferumoxytol (16.2 min; P = 0.098). For payers, this resulted in lower drug administration and lab test costs for FCM (per 1,500 mg IV iron; using wholesale acquisition cost [WAC] relative to the comparator drugs. Medication costs (WAC) for payers were similar between FCM ($1,860), iron sucrose ($1,748, P = 0.100), and ferumoxytol ($1,919, P = 0.330), but increased compared to iron dextran ($876, P < 0.001). Further, the increase in IV iron delivered for FCM did not appear to...
impact the frequency of reported adverse events relative to the comparator drugs.

**CONCLUSIONS:** Ferric carboxymaltose provides greater efficiency in delivering a high dose of IV iron through lower infusion administration costs and similar medication costs for payers, and similar rates of adverse events, despite delivery of a higher iron dose, compared to established IV iron therapies.

**SPONSORSHIP:** This study was sponsored by Luitpold Pharmaceuticals.

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**D3 Hemophilia Impacts Employment, Relationships, and Quality of Life of Young Adults in the United States in the Hemophilia Experiences, Results and Opportunities (HERO) Study**

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**BACKGROUND:** Congenital hemophilia can cause frequent joint bleeds leading to arthritis, pain, and impaired quality of life for young adult people with hemophilia (YA-PWH), families/spouses are indirectly impacted.

**OBJECTIVE:** The global HERO study comprehensively evaluated the impact of hemophilia.

**METHODS:** Analysis of HERO responses from United States (U.S.) YA-PWH.

**RESULTS:** Of 189 U.S. respondents, 66 were age 18-30. Half of YA-PWH used routine prophylaxis to prevent bleeding. Of these, only 27% used treatment medication exactly as prescribed, with 27% using a little less than prescribed. 26% reported difficulties accessing clotting factor in the prior 5 years due to availability or affordability; 82% citing financial issues. They self-reported arthritis (41%) and chronic pain (38%), and on EQ-5D-3L moderate/extreme pain/discomfort (73%) and some/moderate/extreme anxiety/depression (41%). YA-PWH commonly reported pain interference with daily activities in the past 4 weeks (89%). Most (78%) were employed; and reported office work (57%). Although employment rate is similar to U.S. Census data (74–82%), 74% reported hemophilia had a negative impact on employment; 39% reported moderate/very large impact. Rates of disability were double that in U.S. census data (~10–11%); 20% of YA-PWH were disabled and 14% received disability benefits. Difficulty with visiting the hemophilia treatment center was reported by 21% with key issues identified of accessibility (79%), distance (57%), travel time (29%), and inability to get off work (50%) identified as key issues.

While U.S. marriage rates increase to 35% by age 30, only 32% of YA-PWH were married or in long-term relationships, 9% had children, 77% wanted to have children, 32% reported hemophilia had a negative impact on relationships, 62% predicted a future negative impact, and 52% worried about supporting a family. Of YA-PWH reporting most/all of their friends knew about their hemophilia (59%), many received negative reactions (41%). YA-PWH were very/somewhat knowledgeable about hemophilia (91%), and were generally optimistic when looking to the future (pessimistic = 1 to optimistic = 7), with median (IQR) 5 (5–7).

**CONCLUSIONS:** YA-PWH suffer from pain and arthritis during the transition to independence, similar to older adults despite having access to routine prophylaxis during childhood. Consequently, they report hemophilia significantly impacts employment and relationships. During this transition period to the workforce and responsibility for insurance coverage, many face challenges accessing treatment and treatment centers.

**SPONSORSHIP:** Novo Nordisk.

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**D4 The Changing Costs of Caring for Hemophilia Patients in the United States**


Biogen Idec

**BACKGROUND:** Hemophilia is an inherited condition, requiring lifelong, expensive treatment. Initiating prophylaxis treatment with factors VIII (hemophilia A) or IX (hemophilia B) at an early age has been shown to be effective in improving health outcomes. Consequently, in 2007 the National Hemophilia Foundation (NHF) recommended prophylaxis treatment as the optimal therapy for these patients.

**OBJECTIVE:** (1) To explore differences in the economic burden of treating hemophilia A/B over the patient’s lifespan; (2) To quantify changes in factor utilization and related costs over the past decade.

**METHODS:** A retrospective analysis of U.S. health insurance claim database (2004-2012) was conducted. Males with ≥2 pharmacy claims for a hemophilia drug within 3 months, and continuous enrollment for ≥180 days were included. Patients utilizing inhibitor treatments were excluded. Annual payer cost and patient out-of-pocket (OOP) expenses were calculated by service category (inpatient, outpatient, medications), and were further stratified by patient’s age and calendar year of service. All costs were adjusted to 2013 USD values. The Medication Possession Ratio (MPR) was used as a proxy for continuity of treatment. First vs. last year MPRs were compared using a t-test.

**RESULTS:** A total of 727 hemophilia A patients and 161 hemophilia B patients met the inclusion criteria. Increase in payers’ costs was observed during the first 4 decades of life, with peak annual cost at age 34 for hemophilia A patients ($300,763) and at age 29 for hemophilia B patients ($296,990). Annual OOP expenses showed some variation by age, with the mean per patient OOP of $2,672/year for hemophilia A, and $1,838/year for hemophilia B. Between 2007 and 2012, MPR per patient increased for both factor VIII (ADVATE: 0.70 vs. 0.75, P = 0.2021) and factor IX products (BENEFIX: 0.64 vs. 0.69, P = 0.444). An increasing trend of payer cost for drugs dispensed to both hemophilia A patients (2004: $102,704 to 2012: $197,648) and hemophilia B patients (2004: $62,869 to 2012: $169,297) was observed.

**CONCLUSIONS:** The increase in MPR over the past decade, suggests that prophylaxis treatment may have increased in line with the 2007 NHF MASAC recommendations, but further research to assess causality is warranted. Increases in both patients’ and payers’ costs may be associated with these increases as well as with costs of treating other comorbidities.

**SPONSORSHIP:** Biogen Idec.

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**D6 Estimating Cost Per Month of Progression Free Survival (PFS) from a Payer Perspective: Comparing Commonly Used Treatment Regimens for Previously Treated Relapsed and/or Refractory Multiple Myeloma (RRMM)**

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**METHODS:** This study used data from the Consortium of Hematology Oncology (COH) and Preparative Conditioning and Disease-Free Intensive Therapy (PCDFIT) registries. Treatment and adverse event data were integrated using Individualized Disease Adjusted Mortality and Morbidity (iDAMM) scores. Costs were estimated from a payer perspective and included therapy, hospitalization, physician visits, and tests. A Cox regression model was used to calculate the impact of adverse events, relative to the comparator, on progression free survival (PFS) costs.

**RESULTS:** The estimated mean cost per month of progression free survival (PFS) from a payer perspective was $17,843. The comparator was Velcade (Intravenous) with or without Mustang. The monthly cost per PFS from a payer perspective was $17,843 vs. $7,638 for the comparator, which included the costs of adverse events in the model. A higher monthly cost of $3,124 was associated with adverse events compared to the comparator. Costs of adverse events showed a trend of increasing linearly with the increase in the level of adverse events.

**CONCLUSIONS:** The estimated mean cost per month of progression free survival (PFS) from a payer perspective was $17,843. The higher monthly cost of $3,124 was associated with adverse events compared to the comparator. Costs of adverse events showed a trend of increasing linearly with the increase in the level of adverse events.

**SPONSORSHIP:** This study was sponsored by Novartis Pharmaceuticals.
BACKGROUND: Although immunomodulatory drugs and proteasome inhibitors have significantly increased PFS in RRMM patients, there is no established standard of care for patients with RRMM despite the availability of guidelines from various review panels (e.g., NCCN). Patients cycle between active disease and remission, and those who fail to respond to both drug classes are left with minimal treatment options. With several novel (but costlier) therapies in development, a better understanding of cost-to-benefit ratio of existing therapies would provide benchmarks for assessing newer therapies.

OBJECTIVE: To estimate and compare total direct treatment costs per month of PFS for currently available treatment regimens from the perspective of both a commercial managed care plan and Medicare.

METHODS: An economic model was constructed in MS Excel 2010. Model inputs were derived from a targeted review of literature comprising U.S. Census & Medicare data, the Surveillance, Epidemiology, and End Results database, published clinical trials, and other studies. The cost of each regimen was calculated by summing treatment-related costs of drug, administration, monitoring, adverse event (AE) prophylaxis, and costs of managing treatment-emergent grade 3/4 AEs. The cost per month without progression was calculated as the total cost of each regimen (assuming patients remained on therapy for the median duration of therapy) divided by median PFS values based on published clinical studies or product labeling. Costs per progression-free month were estimated for the following treatment regimens: Bortezomib (BTZ) + dexamethasone (Dex), lenalidomide (Len)+Dex, carfilzomib (CFZ)+Len+Dex, and Len+BTZ+Dex.

RESULTS: Total direct medical costs (including costs incurred for treating AEs) for a progression free month were: BTZ + Dex = $8,300 (Commercial) and $6,780 (Medicare), Len + Dex = $9,708 (Commercial) and $9,693 (Medicare); CFZ + Len + Dex = $18,396 (Commercial) and $14,297 (Medicare); Len + BTZ18 + Dex = $15,826 (Commercial) and $118,161 (Medicare). As such, patients with RRMM ranges from $6,780-$18,396. As such, patients with RRMM ranges from $6,780-$18,396. As such, patients with RRMM ranges from $6,780-$18,396. The cost per month without progression was calculated as the total treatment cost of each regimen (assuming patients remained on therapy for the median duration of therapy) divided by median PFS values based on published clinical studies or product labeling. Costs per progression-free month were estimated for the following treatment regimens: Bortezomib (BTZ) + dexamethasone (Dex), lenalidomide (Len)+Dex, carfilzomib (CFZ)+Len+Dex, and Len+BTZ+Dex.

CONCLUSIONS: Based on these results, the cost of a progression-free month in patients with RRMM ranges from $6,780-$18,396. As such, cost-comparable novel therapies that enhance PFS while minimizing the duration of treatment have greater value to payers due to lower overall disease budget impact.

SPONSORSHIP: Submission of this abstract was sponsored by Novartis Pharmaceuticals.

Hereditary Angioedema Drug Utilization and Spend: A Medical and Pharmacy Integrated Analysis

D8

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BACKGROUND: Hereditary angioedema (HAE) is a rare genetic disorder characterized by potentially life-threatening episodic edema attacks. Treatment options include C1 esterase inhibitors: Berinert and Cinryze, the bradykinin receptor antagonist Firazyr (icatibant), and the kallikrein inhibitor Kalbitor (eclaintide). Little is known about HAE prevalence, HAE medication utilization across medical and pharmacy (Rx) benefits, and associated costs.

OBJECTIVE: To assess the prevalence of and costs associated with HAE and to identify drug management opportunities.

METHODS: Integrated Rx and medical claims data from an average of 12.4 million commercially insured members per month were queried between January 1, 2012 and March 31, 2014. Members were not required to be continuously enrolled but were required to have an HAE diagnosis defined as: (1) two or more medical claims at least 30 days apart with an HAE ICD-9 diagnosis code; and (2) one HAE pharmacy or medical drug claim (i.e., Berinert, Cinryze, icatibant, and ecallantide). Descriptive statistics were used to describe overall and pharmacy versus medical benefit utilization patterns, total paid amounts (plan plus member paid), and mean and median HAE drug cost per member.

RESULTS: The prevalence of HAE was 1 per 100,000 (141 members) over the 27-month study period. Identified members were 68% female and averaged 36 years old (range 6-67 years). Total medical and Rx costs for the 141 members were $67.9 million, of which $62.5% (92%) was for HAE drugs. 42% (30%) members had only Rx benefit HAE drug claims, 53% (39%) had both medical and Rx HAE drug claims. Total paid for HAE drugs was $72% ($44.8 million) medical benefit and 28% ($17.7 million) Rx benefit. Median per member HAE drug costs were $443,441 with a mean (plan plus member paid), and mean and median HAE drug cost per member.

CONCLUSIONS: Although HAE requiring drug therapy is rare at 1 per 100,000 members, it is essential to assess HAE drug cost across both the Rx and medical benefits. With 2 per million members hav-
ing >$1 million in HAE drug costs, high touch case management is an important HAE management tool. Other strategies include driving utilization toward a preferred product and alignment across both the medical and pharmacy benefits.

**SPONSORSHIP:** Prime Therapeutics.

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

**E1 Patient and Provider Care Quality Factors Associated with the Incidence of Diabetes-Related Vascular Events in a Large Cohort of Health Plan Members**

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**BACKGROUND:** The Diabetes Recognition Program (DRP) provides specific threshold criteria to assess the performance of several diabetes-related quality measures including: (1) HbA1c > 9.0% achieved by ≤ 15% of provider’s patients; (2) LDL-C < 100 mg/dL achieved by ≥ 50% of provider’s patients; (3) Eye exam conducted on ≥ 60% of provider’s patients; and (4) Foot exam conducted on ≥ 80% of provider’s patients.

**OBJECTIVE:** This retrospective claims-based analysis examined the association of patient characteristics and provider quality threshold attainment (according to the DRP criteria) with the incidence of macro or micro vascular outcomes, or death, using a multivariate regression model.

**METHODS:** Macrovascular events included myocardial infarction, stroke, and major adverse cardiac events, while microvascular events included newly-diagnosed kidney failure, pan-retinal photocoagulation, blindness, and limb amputation. Healthcare claims of 117,099 private health plan members aged 19-75, diagnosed with type 2 diabetes mellitus (T2DM), continuously enrolled in Medicare Advantage or commercial plans from January 2010 to December 2013, and who had ≥ 1 encounter with a provider in 2010 were assessed.

**RESULTS:** For providers achieving the specific HbA1c, LDL-C, and eye exam threshold levels for their patients according to the DRP criteria, the risk of diabetes-related vascular events or death for these patients was lowered by 19% (OR: 0.811; CI: 0.766-0.859), 11% (OR: 0.889; CI: 0.838-0.943) and 6% (OR: 0.942; CI: 0.903-0.982), respectively.

Other key variables, specifically baseline characteristics such as older age (OR: 1.017; CI: 1.013-1.021), higher BMI (OR: 1.046; CI: 1.033-1.060), use of insulin (OR: 1.392; CI: 1.235-1.569) or sulfonylureas (OR: 1.126; CI: 1.141-1.296), and incidence of myocardial infarction (OR: 7.551; CI: 6.897-8.29), renal failure (OR: 2.786; CI: 2.353-3.298), cardiovascular disease (OR: 2.268; CI: 1.727-2.368), retinopathy (OR: 1.312; CI: 1.235-1.393), or hypertension (OR: 1.231; CI: 1.15-1.318) increased the risk (P < 0.001) of diabetes-related vascular outcomes or death. Conversely, higher adherence to oral antidiabetic medications (OR: 0.681; CI: 0.612-0.757) and female gender (OR: 0.808; CI: 0.776-0.841) were associated with a lower risk (P < 0.001) of diabetes-related vascular outcomes or death.

**CONCLUSIONS:** These results suggest a vascular protective effect of provider adherence to diabetes-related quality measures and hint that a more targeted approach to interventions aimed at identifying key patient characteristics and improving diabetes-related quality measure scores is warranted.

**SPONSORSHIP:** Eli Lilly and Company.

### E3 Suboptimal Glycemic Control, Obesity, and Hypoglycemia in Insulin-Treated Diabetes Mellitus Patients: Estimates from Physicians’ Electronic Health Records in the United States, 2010-2012

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**BACKGROUND:** Inadequate glycemic control, weight gain, and hypoglycemia are undesired clinical outcomes experienced by patients with diabetes receiving insulin. Nationally representative data on the extent of these problems in real-world clinical practice are limited and dated.

**OBJECTIVE:** To generate data and update understanding of insulin treated diabetes patients in the real world.

**METHODS:** We analyzed insulin treated diabetes patients (type 1 [T1] = 2,205; type 2 [T2] = 95,476) aged 18 years or older in the physicians’ electronic health records (Humedica) from year 2010 to 2012. Age, gender, last available HbA1c and body mass index (BMI), BMI change, hypoglycemia, and insulin types were summarized. General linear regression (GLM) model was used to test the association between HbA1c and the factors of BMI and hypoglycemia at alpha level 0.05.

**RESULTS:** For T1 patients, median age was 44 years and 53.5% were male; for T2 patients, median age was 62 years and 49.3% were male. Overall, 98.7% of T1 and 97.5% of T2 patients used 2 or more types of insulin. Patients with HbA1c ≥ 7%, ≥ 8% and > 9% were 76.4%, 43.8%, and 17.3% for T1, and 69.4%, 41.7%, and 21.0% for T2, respectively. Patients with BMI ≥ 30 kg/m² and ≥ 35 kg/m² were 30.8% and 10.2% for T1, and 69.4% and 42.0% for T2, respectively. BMI increase of ≥ 2 kg/m² occurred in 10.7% of T1 and 16.9% of T2 patients. Only 9.3% of T1 patients and 5.1% of T2 patients had physician diagnoses of hypoglycemia over the 3 year period. These percentages suggested that hypoglycemia may be underreported in the EHR. Multivariable GLM, adjusting for demographic and clinical characteristics, showed that HbA1c significantly increased with BMI in T2 patients (P < 0.001), while BMI was not statistically significant among T1 patients. The regression also showed that HbA1c was significantly lower among T1 and T2 patients with diagnosis of hypoglycemia (P < 0.001).

**CONCLUSIONS:** This recent U.S. data analysis shows that suboptimal glycemic control, obesity, and hypoglycemia are common in insulin-treated patients; these conditions must be treated in concert to obtain optimal glycemic control.

**SPONSORSHIP:** Eli Lilly and Company.

### E4 Adding Insulin to T2DM Treatment Versus Other Antidiabetic Medications: Implications on Cost and HbA1c

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**BACKGROUND:** Adding insulin therapy to a patient’s medication regimen often comes later than recommendations set forth by the American Diabetes Association (ADA) guidelines when treating type 2 diabetes mellitus (T2DM).

**OBJECTIVE:** The objective of this study was to identify differences in effectiveness and cost between insulin and non-insulin therapies.

**METHODS:** A retrospective analysis using Truven Health MarketScan Research Databases was conducted to identify adult patients (≥18 years) with T2DM diagnosis from 2006-2012. Patients were placed into four cohorts based on their initial T2DM therapy: cohort 1 (n = 597,664), newly diagnosed patients not on pharmacotherapy,
cohort 2 (n = 342,511), non-insulin antidiabetic drug initiators; cohort 3 (n = 99,578), basal insulin initiators; and cohort 4 (n = 62,876), prandial/mixed insulin initiators. Patients transitioned out of a cohort after 4 years or once they met the criteria for the next cohort. Diabetes related total medical expenditures were evaluated to assess costs.

**RESULTS:** Mean age of patients were 59, 56.2, 57.8, and 59.1 in cohorts 1-4, respectively. In comparison to patients starting on non-insulin antidiabetic drugs with a baseline HbA1c of 8.0%, patients starting insulin had HbA1c values well above the ADA goal of ≤7% (9.2% basal insulin; 8.9% prandial insulin). Although patients starting insulin were more poorly controlled, they had a greater decrease in HbA1c (1.1% decrease basal insulin; 0.9% decrease prandial insulin) versus those patients on oral therapy (0.8% decrease; from 8.0% to 7.2%) at the end of the follow up period. From pre-index through year 4, costs of patients on non-insulin therapy increased ($663 to $1,091) while costs for those on basal or prandial insulin decreased ($2,155 to $1,969 and $2,930 to $2,227). Percent of total diabetes related costs increased, but the percent increase of patients on insulin therapy increased at 3.4% versus 4.8% in the cohort using non-insulin therapies. Finally, when evaluating second-line options, such as pioglitazone, sitagliptin, and lar-glutide, study findings show annual costs are higher than that of either insulin glargine or insulin lispro (2012 data: $1,849, $1,730, $2,346 and $1,519, $1,446 respectively).

**CONCLUSIONS:** Prescribers and patients are waiting until diabetes-related comorbidities manifest or HbA1c elevates to well above 8% before initiating insulin therapy. In evaluating insulin therapies, along with the effectiveness and costs compared to non-insulin therapies, prescribers, patients, and payers may benefit from early insulinization.

**SPONSORSHIP:** BD.

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**E7 A Pharmacist-Implemented Initiative to Improve ACEI/ARB Prescribing Among Patients with Comorbid Hypertension and Diabetes Enrolled in a Medicare Advantage Plan**

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**BACKGROUND:** Patients with comorbid diabetes (DM) and hypertension (HTN) are at an increased risk of developing macro- and microvascular complications. Evidence based guidelines recommend angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) as first line therapy as they have been shown to decrease these complications. Despite their proven benefit, ACEIs/ARBs remain underprescribed. The Centers for Medicare and Medicaid Services (CMS) have incorporated a DM Treatment metric within the Part D Star quality ratings to identify if beneficiaries with comorbid DM and HTN are prescribed either an ACEI or ARB.

**OBJECTIVE:** To evaluate the influence of pharmacist initiatives geared to increase prescribing of ACEIs or ARBs to patients with DM/HTN within a Medicare Advantage Plan (MAP).

**METHODS:** This was a retrospective cohort study of DM/HTN patients enrolled within several Texas MAPs with Part D coverage from January 2014 to November 2014. Patients were considered to have DM and HTN if an Rx claim was observed for both a DM and HTN medication. Patients without an Rx claim for an ACEI/ARB by May 2014 in one of the contract plans (Plans A, B and C) were included in the intervention group; a large contract (Plan D) was utilized as the control group. The pharmacy team communicated with the prescriber via fax, health plan representative, or targeted phone call. The percentage of patients initiated on an ACEI/ARB post-intervention was examined and compared to the control group. The intervention type was further analyzed using chi square tests to assess if a specific type of intervention was more effective.

**RESULTS:** A total of 515 patients aged 70 ± 10 years (52.8% male; 47.2% female) were assessed. In the intervention group, 73 patients (31%) were placed on an ACEI/ARB post-intervention; in the control group, 77 patients (27%) were placed on an ACEI/ARB by November 2014. The intervention increased the DM Treatment measure outcome, pre- to post-intervention, from 80% to 91% (2 Star to 5 Star), 83% to 88% (3 Star to 4 Star) and 84% to 89% (3 Star to 4 Star) in Plans A, B, and C, respectively. Plan D increased from 86% to 88%, sustaining them at a 4 star rating. There were no statistically significant differences observed between the types of interventions performed.

**CONCLUSIONS:** An increase in the prescribing of ACEIs/ARBs was seen in the DM/HTN population when a pharmacy outreach was made. This validates that pharmacist interventions may help increase
the Part D Star ratings and the quality of care provided to this high risk population.

**SPONSORSHIP:** This study was conducted without funding.

**E8** Evaluating V-Go in Patients with Poorly Controlled Diabetes: A Health and Economic Analysis from a Diabetes Specialty System

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**BACKGROUND:** Patients with A1c measures >9% are at the highest risk for diabetes related complications. Patients with long standing hyperglycemia despite receiving insulin therapy, typically have increased complications and overall healthcare cost. Addressing this patient population is an essential component of diabetes quality performance measures and can lead to the greatest health and economic impact.

**OBJECTIVE:** A retrospective analysis evaluated patients with poorly controlled diabetes being switched to the V-Go Disposable Insulin Delivery Device (V-Go) to simplify insulin delivery.

**METHODS:** An electronic medical records database from a large diabetes system was used. The efficacy variable was the percentage of decrease in patients at high risk. Changes in background concomitant antidiabetic medications (CAM) were controlled for in this analysis. An established economic model was used to assess the value impact.

**RESULTS:** Seventy-four patients with an A1c >9% (mean A1c 10.5%, weight 99 kg, duration of diabetes 14.9 years, insulin total daily dose [TDD] 75 U/day or 0.75 U/Kg) were switched to V-Go therapy from existing insulin therapies. After a mean duration of 101 days on V-Go, 55 patients achieved an A1c reduction of ≥1% and 70% of patients achieved an A1c ≤9%. Switching to V-Go resulted in a mean (95% CI) A1c change of -2.0 (-2.4 - -1.6), a 19% reduction in TDD and a significant reduction in the percentage of patients with an A1c > 9.0 independent of CAM changes. Despite the large improvement in A1c, overall incidence of reported hypoglycemia was similar to baseline and there was only a mean ± 2.5 kg change in weight. Using adjusted cost savings for ≥1% improvement in A1c at $1,169 (± 10% range: $1,052-$1,286) in this cohort, among patients with poor diabetes control (A1c >9%), the total annual associated cost savings would be $64,295 ($1,286) in this cohort, among patients with poor diabetes control switched to V-Go.

**CONCLUSIONS:** Patients with poor diabetes control switched to V-Go achieved significant A1c improvements with a reduction in TDD and an improved health economic and cost impact. This real-world assessment could be applied more broadly at the health system and plan level.

**SPONSORSHIP:** This study was sponsored by Intarcia Therapeutics.

**E9** Patterns of Medication Adherence and Glycemic Control in Uncontrolled Patients with Type 2 Diabetes

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**BACKGROUND:** Despite the availability of effective antidiabetic therapies, half of U.S. patients with type 2 diabetes (T2DM) are uncontrolled (A1c > 7%). While this population represents the key target for new therapeutic innovation, there are limited data available on patterns of medication adherence and its relationship to glycemic control among these patients.

**OBJECTIVE:** To assess the patterns of medication adherence, glycemic control, and healthcare resource utilization in uncontrolled patients with T2DM using a large, geographically diverse integrated database.

**METHODS:** The Optum-Humedica database, one of the largest U.S. integrated pharmacy/medical claims and electronic medical records databases (>580,000 diabetes patients between January 2007 and March 2014) was utilized for this study. Patterns of glycemic control, medication adherence, and hospitalizations were assessed for adult T2DM patients who were continuously enrolled for at least 15 months, had at least two A1c tests more than 6 months apart with the second A1c reading >7%, and at least one diabetes drug prescription fill during the most recent enrollment year with valid A1c test result(s). Adherence to diabetes medications was measured over 12 months based on proportion of days covered (PDC) ≥80%. Statistical differences between adherent vs. non-adherent patients were determined by two-sample comparisons.

**RESULTS:** A total of 8,733 patients representing a broad range of geographies, types of insurance plans, races and ethnicities, met the selection criteria for this study. Poor glycemic control was persistent with over 73% of these uncontrolled patients remaining uncontrolled after 6 months. An inverse relationship was observed between A1c and levels of adherence to treatment with the most poorly controlled patients being the least adherent to therapy. Sixty-nine percent (69%) of patients with A1c >10% (N = 1,155) met criteria for non-adherence, a 45% higher incidence than that observed for patients with A1c between 7% and 8% (P < 0.001). Increases in A1c over time were 24% more likely to be observed in non-adherent patients compared to adherent patients (P = 0.0013). Non-adherence was associated with higher health care resource utilization. Non-adherent patients had 109% higher mean hospital days per year vs. adherent patients (2.7 days vs. 1.3 days, P<0.001).

**CONCLUSIONS:** The present study suggests that non-adherence to antidiabetes therapy is a significant contributor to poor glycemic control and increased healthcare resource utilization in U.S. patients with uncontrolled T2DM.

**SPONSORSHIP:** This study was sponsored by Intarcia Therapeutics.

**E10** Impact of Comparative Efficacy Data on Prescribing

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**BACKGROUND:** Comparative efficacy (CE) data generated using non-inferiority trials (NITs) have drawbacks like real-world effectiveness and choice of comparators. Although not the best evidence, CE data are the first set of evidence physicians and payers are exposed to. No research exists which establishes the impact of such CE data on prescribing and how, if at all, it is translated into clinical practice.

**OBJECTIVE:** To analyze the impact of CE data, generated as NITs at the time of approval of a new molecular entity (NME), on prescribing.

**METHODS:** From 2000-2010, diabetes mellitus (DM) had the highest proportion (89%) of NMEs with CE data published as NITs and available in the approval package. NMEs along with the comparators used in those trials were identified. Liraglutide (approved in 2010) was the only NME in its category which used the next most recent comparator or clinically relevant alternative (i.e., exenatide) to generate the CE data. They were identified as Market 1 for this study. Of the rest, saxagliptin (approved in 2009) and sitagliptin were identified as Market 2 since they were approved for the same indications as NMEs of Market 1. For each of these markets, a pre-approval and post-approval comparison was designed to measure the changes in prescribing. Prescribing was measured using two variables in the MEPS database. One variable was the total number of unique patients with a
prescription in each identified market (NUP). The other was the quantity of the prescribed NMEs, adjusted to equalize the dose sizes within each market (QP). Descriptive statistics for the variables were calculated and weighted using STATA.

**RESULTS:** In Market 1, with liraglutide’s approval in 2010, NUP and QP for exenatide dropped by 60% and 66%, respectively from 2009 to 2011. Liraglutide had twice the NUP and four times the QP than exenatide in 2011. On the other hand, in market 2, NUP and QP for sitagliptin increased by 17% and 13%, respectively, from 2008 to 2010. Although saxagliptin’s popularity grew after its approval, it did not impact the prescribing of its comparator.

**CONCLUSIONS:** CE data published as NITs do have an impact on prescribing. The degree of impact depends on the choice of comparators. For Market 1, head-to-head comparisons favoring liraglutide could have led to the changes in its prescribing. For Market 2, without head-to-head comparisons, it is hard to interpret the impact of CE data on prescribing. If the FDA devises policies to mandate the generation of CE data for NMEs along with regulations on the choice of comparators, physicians and payers would be able to incorporate this evidence in their decision making at an early stage.

**SPONSORSHIP:** No external funding/sponsorship was required.

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**E13** Evaluating the Effect of a Randomized Controlled Educational Intervention Targeting Improved Glycemic Control: “Act on Threes” Paradigm for Treatment Escalation of Type 2 Diabetes Mellitus (T2DM) in Managed Care

**Objective:** To evaluate the impact of an educational intervention (Act on Threes) on T2DM patients who had not received A1c testing or had a suboptimal control of their A1c (≥ 8.0%) according to the 2012 American Diabetes Association (ADA) position statement on T2DM management.

**Methods:** This was a randomized interventional study of T2DM adult patients with no A1c testing or A1c ≥ 8.0% during a 12 month baseline period, as identified using the Humana Inc. administrative claims database between May 1, 2011 and February 28, 2013. Patients were randomized 3:1 to receive the Act on Threes educational intervention (Intervention group) or usual care (Control group). Being mailed simultaneously to patients and treating physicians, the intervention comprised both general and targeted T2DM educational materials aiming to communicate ADA clinical guideline recommendations and the Act on Threes campaign: A1c testing every 3 months for patients not at A1c goal; intensify treatment every 3 months if not at A1c goal; and consider insulin if using ≥ 3 non-insulin glucose-lowering drugs if A1c not at goal. The intervention and control groups were compared at 1 year follow-up and change from baseline for the following evaluated: A1c level, insulin initiation, Act on Threes campaign-related measures, oral antidiabetes drug patterns, and therapy escalation.

**Results:** 7,472 patients (Intervention group n = 5,463) were included (female: 44.4%, mean age 70.2 years, mean A1c 8.72% [n = 2,008]). At 1 year follow-up, no statistically significant differences were found for the primary outcomes between Intervention and Control groups. The proportions of patients with ≥ 2 A1c tests post-intervention were similar (Intervention 47.6% vs. Control 46.8%), as was the change in proportion from baseline (P = 0.995). Insulin was initiated by 6.3% in the Intervention and 7.6% of the Control group (P = 0.059). A1c levels (mean ± SD) were similar between the Intervention (7.98% ± 1.57) and Control groups (7.94% ± 1.52), as was the change in A1c from baseline (P = 0.24).

**Conclusions:** Diabetes-related education of physician and patients can improve outcomes, but further research is required to identify the optimal intervention targeting alignment to treatment guidelines.

**Sponsorship:** Study funding and editorial support provided by Sanofi U.S.
**E14 Impact of Continuous Glucose Monitoring (CGM) on Diabetes Control and High Cost Events for Type 1 Diabetic Patients**

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**BACKGROUND:** CGM use improves diabetes control; few studies have investigated the impact of CGM in reducing high cost events associated with hypo- and hyperglycemic episodes. CGM provides immediate information including the direction, the rate of glucose change, and high and low glucose alerts. Because of the enhanced decision support, CGM has the potential to benefit both insulin pump users and insulin injectors.

**OBJECTIVE:** To measure the effect of CGM use on (1) diabetes control, and concurrent use of insulin pump; (2) reduction in inpatient admissions and ER visits.

**METHODS:** Using a pre-post and matched case/control design, health insurance claims and lab results from 9 million commercial health plan members was used for this study. Intervention group consisted of type 1 diabetes (T1DM) patients who started Dexcom G4 CGM for a 9-month period. The control group is T1DM who used self-monitoring of blood glucose (SMBG) during the same time period. A propensity score model was developed to select a matching pair from the control pool to ensure equivalency in the CGM and control groups.

**RESULTS:** Of the 5,337 patients in the control group, the average HbA1c dropped by 0.21 from pre- to post-period, compared with a 0.53 reduction of the 120 patients in the CGM group (P = 0.011). More detailed analysis stratified by baseline HbA1c showed CGM group consistently had greater HbA1c reduction at every level of baseline (> 7, between 7 and 9, > 9). Among the CGM users, half (99 out of 201) of the patients also used insulin pump. The CGM alone group (insulin injectors) lowered HbA1c by 0.58 (P = 0.048), compared with 0.45 (P = 0.142) for the CGM + pump users. This result suggests that CGM alone (no-pump) users have similar or better glycemic benefits as the CGM pump users. CGM group was 43% lower in inpatient admission rate (P = 0.185) and 38% lower in ER visit rate (P = 0.145) than control group for the one-year postperiod.

**CONCLUSIONS:** CGM users demonstrated better improvements in diabetes control than SMBG alone and had a 40% reduction in ER visits and inpatient admissions. CGM users without insulin pump saw greater improvement in HbA1c compared with pump users. Considering the cost and complications associated with insulin pump and small sample size in this study, this topic warrants further investigation.

**SPONSORSHIP:** This project was funded by Dexcom, San Diego, CA.

**E15 Achievement of Glycemic Control and Antidiabetic Therapy Changes in Type 2 Diabetes Patients Initiating Glucagon-Like Peptide-1 Receptor Agonist Therapy**

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**BACKGROUND:** Clinical trial data supports use of glucagon-like peptide-1 receptor agonists (GLP-1RA) in patients with type 2 diabetes (T2DM). However, real-world GLP-1RA data on outcomes assessed in diabetes-related quality measure, namely glycated hemoglobin (HbA1c) < 9.0%, is limited as is data on the use of non-GLP-1RA anti-diabetes drugs (ADs) after GLP-1RA initiation.

**OBJECTIVE:** Evaluate categorical and continuous HbA1c outcomes, and changes in the number of prescribed ADs in T2DM patients initiating GLP-1RA treatment in a national electronic medical record database.

**METHODS:** Adult GLP-1RA naïve T2DM patients initiating exenatide once weekly or liraglutide once daily (index date) between February 1, 2012 and March 31, 2013 were included. Outcomes were HbA1c change at 6 and 12 months vs. baseline and the proportion of patients with HbA1c < 9% at 12 months overall, and in patients with baseline HbA1c ≥ 9%. The number of AD classes prescribed at 12 months post-index vs. baseline was also assessed overall. Paired t-tests were used to evaluate changes in HbA1c.

**RESULTS:** The study included 5,141 patients. Mean (SD) age was 57 (11) years; 54% were female; 35% were insulin naive; 30% had baseline HbA1c ≥ 9%. Mean baseline HbA1c was 8.4% (1.6) overall and 10.3% (1.2) in the subset with baseline HbA1c ≥ 9%. Only 10% were AD naïve; 23% used 1 AD class, 34% used 2 classes, and 33% used ≥ 3 classes pre-index date. Mean change in HbA1c at 6 months was -0.6% (1.4) and -1.6% (1.8) overall and for those with baseline HbA1c ≥ 9%; at 12 months, mean HbA1c change was -0.5% (1.3), and -1.4% (1.9) (all P < 0.001). The proportion of patients with baseline HbA1c ≥ 9% whose HbA1c was < 9% at 12 months was 49%. A majority (68%) of patients were prescribed at least 1 less non-GLP-1RA AD class post-index than pre-index date; 23% were prescribed an equal number of non-GLP-1RA classes post index; 9% were prescribed additional non-GLP-1RA classes post index date.

**CONCLUSIONS:** GLP-1RA therapy was associated with significant reductions in HbA1c at 6 and 12 months, and a significant proportion of patients with baseline HbA1c ≥ 9% had follow-up HbA1c below the quality measure target of <9.0%. After initiating GLP-1RA therapy, there also appeared to be a reduction in the number of non-GLP-1RA AD classes prescribed. GLP-1RA therapy may be considered as a T2DM treatment option when aiming to improve glucose control, may simplify therapy, reduce polypharmacy, and may allow patients to avoid the need for AD intensification in the first 12 months of treatment.

**SPONSORSHIP:** AstraZeneca.

**E18 Retrospective Review of Exceptions for Angiotensin-Converting Enzyme Inhibitors (ACEIs) or Angiotensin II Receptor Blockers (ARBs) in Recommendations for a Diabetic Medicare Population**

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**BACKGROUND:** The American Diabetes Association recommends the addition of an ACEI or ARB for diabetics with hypertension or elevated urinary albumin excretion. ACEI therapy is also recommended for diabetics with known cardiovascular disease. While an ACEI/ARB may be beneficial for many patients, there are some for whom the therapies may be clinically inappropriate (e.g., therapy intolerance). The extent to which clinically inappropriate exceptions impact health plans is currently unknown.

**OBJECTIVE:** To: (1) determine the number of patients for whom ACEI/ARB therapy was not recommended; (2) identify reasons why ACEI/ARB therapy was not recommended, and (3) compare ACEI/ARB therapy exception percentages between health plans.

**METHODS:** This was a retrospective, cross-sectional analysis of diabetic Medicare Part D beneficiaries in 1 of 96 health plans enrolled in University of Arizona Medication Management Center’s (UAMMC) Medication Therapy Management (MTM) program from January 1, 2013 to December 31, 2013. The UAMMC evaluates patients’ eligibility for adding ACEI/ARB using two methods: (1) a clinically derived software
system assesses patients’ demographic and medication history; and (2) pharmacists determine eligibility during telephone-administered medication reviews with patients. Patients for whom ACEI/ARB therapy was deemed unacceptable by either assessment method were classified as ‘exceptions.’ UAMMC’s patient database was used to calculate number of diabetic patients and percentage of ACEI/ARB therapy exceptions.

RESULTS: Among the 96 health plans, the average percentage of diabetic patients who qualified for MTM was 55% (range: 19% to 88%). A total of 218,643 diabetic patients were included in the analysis and of these 82,763 had at least one reason why ACEI/ARB therapy was not appropriate. The average exception percentage across health plans was 26%, however the exception rate for all health plans ranged from 0% to 83%. Exception reasons included: inappropriate age (≥90 years); inappropriate medication (e.g., drug-drug interaction); pregnancy; or a pharmacist deemed ACEI/ARB therapy inappropriate during the patient’s medication review.

CONCLUSIONS: There is a substantial difference across health plans of instances where ACEI/ARB therapy is clinically inappropriate to recommend to diabetic patients. Variations in therapy recommendation exceptions should be researched and examined closer to understand the impact of programs and incentives that encourage ACEI/ARB use across broad populations.

SPONSORSHIP: The University of Arizona College of Pharmacy Medication Management Center funded this study.

E19 Impact of a Clinical Outreach Program on CMS Star Rating for Diabetes Treatment

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BACKGROUND: As the U.S. healthcare system is rapidly transitioning away from the fee-for-service business models of the past, the majority of health insurers are placing an increased emphasis on quality of care. To assist payers in improving the quality of care delivered to their beneficiaries, Magellan Rx Management has developed and implemented clinical programs designed to specifically address the quality standards incorporated into the CMS Star Rating measures. One of these measures, D10-Diabetes Treatment (DT), is the appropriate utilization of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, or direct renin inhibitor (ACE/ARBs) in patients with diabetes (DM) and hypertension (HTN).

OBJECTIVE: To measure the impact of a clinical program on the proportion of patients with DM and HTN on ACE/ARB therapy within a regional Medicare health plan.

METHODS: The DT population consists of all members who have filled a DM and HTN medication between January and December 2014. Members are considered compliant when their HTN agent is an ACE/ARB. The treatment rate is calculated by taking the numerator (compliant members) divided by the denominator (compliant + non-compliant members). A clinical program was implemented to increase the DM treatment rate, which was to be accomplished through telephonic outreach by clinical staff to providers, pharmacies, and patients. The focus of this outreach was recommending use of an ACE/ARB, when appropriate.

RESULTS: Between January and October 2014, a total of 4,053 members were identified as part of the DT measure—with a total of 872 non-compliant cases. As a result of outreach, 559 non-compliant cases were able to be resolved; 326 resulted in a claim for either an ACE/ARB; 251 resulted in clinical and non-clinical rationale for non-compliance. As of October 2014, the 326 additional members with a claim for an ACE/ARB resulted in a total of 3,518 compliant members and a treatment rate of 86.8% (4 stars). Full results for 2014 will be available in January 2015.

CONCLUSIONS: As of October 2014, the clinical program has resulted in a 1-star improvement for the DT measure from 2013, at which time the treatment rate was 83.6%. Without cases that transitioned from non-compliant to compliant post-outreach, the treatment rate in October 2014 would have been 79.2% (2 stars). 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 positive results support the efficacy and viability of a clinical program that incorporates advanced analytics and customized clinical outreach.

SPONSORSHIP: This research was conducted by Magellan Rx Management, Newport, RI, without external funding.

E20 Hypoglycemia Rates and Health Care Costs in Patients with Type 2 Diabetes Mellitus (T2DM) Treated with Second-Line Linagliptin or Sulfonylurea After Metformin

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BACKGROUND: Minimizing risk of hypoglycemia is an important component when managing patients with T2DM.

OBJECTIVE: This study describes hypoglycemia rates and associated costs in patients who initiated second-line treatment with antidiabetic agents: linagliptin or sulfonylureas (SU) after metformin.

METHODS: A large, U.S. administrative claims database was used to identify patients with T2DM (during July 1, 2011 to October 31, 2013) who initiated linagliptin or SU after metformin use. Linagliptin users were matched to SU users based on demographic and clinical characteristics identified within a 12-month pre-index period using propensity scores (1:3 ratio, caliper: ±0.001). Hypoglycemia rates and hypoglycemia-related costs (2013 USD) were quantified during a variable follow up period (i.e., the end of study, the end of 12 months follow up, treatment regimen change, or disenrollment, whichever came first). Hypoglycemia rates per 100 person-years were compared using univariate Poisson regression, and hazard of hypoglycemia was obtained from multivariate Cox proportional hazards regression. Mean monthly hypoglycemia-related costs were computed for patients with hypoglycemia, and analyzed using t-tests.

RESULTS: Propensity score matching resulted in a sample of 11,536 patients (linagliptin = 2,884; SU = 8,652) with mean age 56 years and 59% male. The rate of hypoglycemia (per 100 person-years) was lower in the linagliptin than the SU user groups (2.51 vs. 3.63; P = 0.049). Linagliptin users had 33% lower risk of hypoglycemia compared with SU users (hazard ratio = 0.67; 95% CI: 0.47, 0.97; P = 0.031). Among patients who had hypoglycemia, linagliptin users had lower mean monthly hypoglycemia-related costs than SU users ($300 vs. $890; P = 0.092).

CONCLUSIONS: Hypoglycemia rates were lower among patients using linagliptin versus SUs and, when patients experienced hypoglycemia, the associated costs were lower. Careful consideration of newer treatment alternatives may be prudent for optimal T2DM management especially with respect to hypoglycemia.

SPONSORSHIP: Boehringer Ingelheim.
E21 The Distribution of Pharmacy, Medical, and Total Costs for Medicare Beneficiaries with Type 2 Diabetes

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SPONSORSHIP: represent the bulk of total expenditures, and are the main driver of disparities among patients with T2DM have a highly skewed distribution, respectively, but only 16% of pharmacy costs accounted for 76% and 64% of aggregate medical and total costs, while pharmacy costs rose 14-fold ($50 to $682). Medical costs (from $125 to $13,376), medical costs rose 169-fold ($75 to $12,694), and the incident cohort were qualitatively the same as the main cohort.

RESULTS: Patients were followed for a mean of 3.2 years. The upper cost deciles had considerably greater average annual total and medical expenditures, but less substantial pharmacy cost increases. From the 1st to 10th decile, annual total costs increased from $794 to $78,641, and pharmacy costs increased from $377 to $7,439; these increases amounted to 90-, 170-, and 20-fold increases, respectively. In the highest (tenth) decile, medical costs constituted 90.5% of total costs, whereas in the first decile medical costs represented 52.5% of total costs.

Cost distribution was heavily skewed toward medical expenditures. The 10th decile of annual total expenditures accounted for 36.75% ($10,891,987.22) of the total pharmacy and medical costs. Medical and pharmacy PMPM for outlier ($13,987.97 and $1,035.98) accounted for 36.75% of the total pharmacy and medical costs. The outliers' medical and pharmacy PMPM were considerably higher as the 10th decile of annual total costs increased from $794 to $78,641, medical costs from $417 to $71,203, and pharmacy costs from $377 to $7,439; these increases amounted to 90-, 170-, and 20-fold increases, respectively. In the highest (tenth) decile, medical costs constituted 90.5% of total costs, whereas in the first decile medical costs represented 52.5% of total costs.

The results of the sensitivity analysis for monthly expenditures and the incident cohort were qualitatively the same as the main analysis. From the 1st to 10th decile, monthly costs increased from $125 to $13,376, medical costs rose 169-fold ($75 to $12,694), while pharmacy costs rose 14-fold ($50 to $682). Medical costs accounted for 94.9% of total expenditures within decile 10, and decile 10 accounted for 76% and 64% of aggregate medical and total costs, respectively, but only 16% of pharmacy costs.

CONCLUSIONS: These findings demonstrate that medical expenditures among patients with T2DM have a highly skewed distribution, represent the bulk of total expenditures, and are the main driver of this skew for both annual and monthly costs.

SPONSORSHIP: AstraZeneca.

E22 Analysis of the Medicare Diabetic Population to Identify Cost Outliers and Determine Gaps in Care

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BACKGROUND: The prevalence of diabetes in the U.S. Medicare population continues to grow. In 2010, the CDC reported that people aged >65 with diabetes was 10.9 million. By 2050, the number is expected to increase by 165%. The cost attributed to diabetes has paralleled trends. The CDC stated that the 2007 direct and indirect expenditures attributed to diabetes were $116 billion and $58 billion, respectively. According to the CMS, only about 18% of Medicare beneficiaries have diabetes yet they reflect a disproportionate share of the health care expenditure by accounting for 32% of Medicare spending. The American Diabetes Association (ADA) projects that by 2034, Medicare spending alone will represent over 50% of direct spending on diabetes.

OBJECTIVE: To characterize the Medicare diabetic cost outlier population to identify gaps in care to better manage the overall healthcare expenditure.

METHODS: A retrospective analysis based on a 6-month look back of paid pharmacy and medical claims for Horizon Blue Cross Blue Shield of NJ MAPD members of at least 1 consecutive year with a confirmed diagnosis of diabetes was conducted. Patients were stratified based on total paid cost of pharmacy and medical claims. Cost outlier was based on total paid cost by utilizing a calculated standard deviation. Furthermore, pharmacy and medical PMPM were calculated. Based on pharmacy claims, treatment regimen was evaluated. Risk factor for each member was calculated by using internal predictive modeling software, and comorbidities were also accounted for based on medical claims.

RESULTS: Diabetes pharmacy cost for the whole population was 3% ($2,145,979.47) of the total pharmacy cost. Based on a SD>2 (1 SD=+21,894.14), 3.74% (114/3,048) were considered cost outliers, accounting for 36.75% ($10,891,987.22) of the total pharmacy and medical cost. Medical and pharmacy PMPM for outlier ($13,987.97 and $1,035.98) was calculated. Only 14% (161/1,144) were on specialty. 30.7% (391/1,298) whole population were on metformin, while 35.96% (41/114) vs. 20.96% (23/114) outliers were on specialty. 30.7% (35/114) outliers vs. 48.6% (1,481/3,048) whole population were on metformin, while 35.96% (41/114) vs. 20.96% (23/114) outliers were on insulin without metformin. It was calculated that 30.7% (391/1,298) were not on insulin.

CONCLUSIONS: Diabetic cost outliers were 3.74% of the population, yet accounted for 36.75% of the total pharmacy and medical costs. The outliers' medical and pharmacy PMPM were considerably higher as well. Further analysis will be conducted to see how the risk factor and comorbidities contribute to the cost of diabetes care, and to identify gaps in care and to determine how to address those barriers.

SPONSORSHIP: None.

E23 Prescribing Patterns of Antidiabetic and Antihypertensive Agents by KDIGO 2012 Chronic Kidney Disease Stages in U.S. Adults with Type 2 Diabetes Mellitus: NHANES 2007-2010

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BACKGROUND: A relatively small group of patients can incur the bulk of treatment costs for diseases such as type 2 diabetes mellitus (T2DM); therefore, effective interventions for this group would result in substantial cost savings. An understanding of the proportion of treatment costs incurred by the most expensive patients and the drivers of those treatment costs can inform the targeting and design of potential cost-saving interventions.

OBJECTIVE: This study examined the distribution of pharmacy, medical, and total treatment costs for Medicare beneficiaries with T2DM.

METHODS: The study used Medicare claims data from 2006-2009. The prevalent cohort (N = 12,305 patient-year observations) consisted of patients ≥65 years of age with T2DM (≥ 1 claim with T2DM [ICD-9 codes 250.x0 and 250.x2] and ≥ 1 anti-diabetic medication claim). Costs were defined in deciles. Sensitivity analyses included analysis of cumulative and monthly expenditures by category, and the incident cohort.

RESULTS: Patients were followed for a mean of 3.2 years. The upper cost deciles had considerably greater average annual total and medical expenditures, but less substantial pharmacy cost increases. From the 1st to 10th decile, annual total costs increased from $794 to $78,641, medical costs from $417 to $71,203, and pharmacy costs from $377 to $7,439; these increases amounted to 90-, 170-, and 20-fold increases, respectively. In the highest (tenth) decile, medical costs constituted 90.5% of total costs, whereas in the first decile medical costs represented 52.5% of total costs.

Cost distribution was heavily skewed toward medical expenditures. The 10th decile of annual total expenditures accounted for 36.75% ($10,891,987.22) of the total pharmacy and medical costs. Medical and pharmacy PMPM for outlier ($13,987.97 and $1,035.98) accounted for 36.75% of the total pharmacy and medical costs. The outliers' medical and pharmacy PMPM were considerably higher as well. Further analysis will be conducted to see how the risk factor and comorbidities contribute to the cost of diabetes care, and to identify gaps in care and to determine how to address those barriers.

SPONSORSHIP: None.

E24 Chronic Kidney disease (CKD) is common among type 2 diabetes mellitus (T2DM) patients. As kidney function declines, treatment adjustments are recommended for antidiabetic medications (ADM) and antihypertensive medications (AHM) to prevent CKD progression or treatment complications/ineffectiveness.

OBJECTIVE: To estimate the use of ADM and AHM by CKD stages in T2DM.

METHODS: Respondents ≥18 years of age with T2DM were identified from the U.S. National Health and Nutrition Examination Survey (NHANES) 2007-2010 with the most recent prescription questionnaire data available. T2DM was determined based on self-reported diabetes or ADM use. Those with type 1 diabetes, pregnancy, and with missing serum creatinine lab value, age, gender, or race were excluded. CKD was staged based on KDIGO 2012 guideline as: 1 = estimated glomerular filtration rate (eGFR in ml/min/1.73m² estimated by CKD-Epi equation) ≥ 90 with albuminuria; 2 = 60-89 with albuminuria; 3a = 45-59; 3b = 30-44; 4 = 15-29; 5 ≤ 15. Results are reported as projected national estimates using appropriate NHANES weights to account for non-response bias and oversampling.

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The overall bias was -0.3% demonstrating strong agreement between the pre-determined 15% which met the 95% performance criteria. 98.6% of the ≥ 100 mg/dL samples (n = 278/282) fell within (20/20) were within ± 15 mg/dL thus meeting the 95% accuracy performance criteria published in the ISO 15197:2013.

MN. Reference values were obtained using the YSI Model 2300 points). The samples were collected from the fingertip of confirmed were evaluated for performance and bias comparison (n = 302 data received funding from AstraZeneca.

According to the ISO 15197:2013, system accuracy performance criterions results in the ability to regulate an individual’s blood glucose levels. It is known as the ISO 15197:2013. The level of accuracy of the BGMS in measuring the accuracy of BGMS in the testing of diabetes mellitus is considered the gold standard glucose assay for BGMS studies. The correlation coefficient (r) = 0.98 demonstrates a strong linear relationship between the YSI reference method and the meter results.

The objective of this study is to demonstrate whether the GLUCOCARD Vital and YSI reference analyzer results, which is considered the gold standard glucose assay for BGMS studies. The correlation coefficient (r) = 0.98 demonstrates a strong linear relationship between the YSI reference method and the meter results.

CONCLUSIONS: The data acquired on the GLUCOCARD Vital met the ISO 15197:2013 system accuracy performance criteria, the most stringent BGMS requirement in the monitoring of diabetes mellitus.

SPONSORSHIP: This study was internally funded by ARKRAY USA.

RESULTS: Of the 1,380 T2DM patients, 44.1% had CKD, primarily Stage 1 to 3a (76.9%). ADMs and AHMs were used in 85.9% and 85.8% of patients with CKD, respectively. As kidney function declined, insulin use increased from 16.2% in Stage 1 to 62.8% in Stage 5; Biguanides use dropped from 68.1% in Stage 1 to 3.0% in Stage 5; sulfonylurea use was stable before Stage 5, where it dropped from 55.6% in Stage 4 to 14.9% in Stage 5; and the use of thiazolidinediones and DPP-4 inhibitors remained flat in Stages 1 to 3b (41.1%-19.7% and 4.4%-11.5%, respectively). AHM use increased from 63.4% in Stage 1 to over 96.0% in Stage 3b to 5. ACE inhibitors were the most commonly used AHM in Stage 1 (52.9%) and 2 (50.9%), while diuretics (DIU, 49.8%-76.1%) and beta blockers (BB, 40.7%-75.9%) were the most used AHMs in Stages 3a to 4. In later CKD stages, the dominance of thiazide DIU was replaced with loop DIU which was used in 53.5% and 33.9% in Stage 4 and 5, respectively. Angiotensin II receptor blockers (ARB) use increased to 35.4% in Stage 4 from 11.1% in Stage 1.

CONCLUSIONS: In this nationally representative population with T2DM and CKD, we demonstrated that, DIU, BB, and ARB use increased with worsening kidney function and ADM use was consistent with the national treatment recommendations based on CKD stage. Limited options for ADM in later CKD stages stresses the need for aggressive ADM/AHM treatment earlier on when more options are available to slow progression.

SPONSORSHIP: This study was conducted by HealthCore, which received funding from AstraZeneca.

E25 Accuracy of a Blood Glucose Meter System (BGMS) As It Relates to the ISO 15197: 2013 Requirements in the Monitoring of Diabetes Mellitus

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BACKGROUND: Blood glucose monitoring systems (BGMS) are a critical tool used in the management of diabetes. The gold standard in measuring the accuracy of BGMS in the testing of diabetes mellitus is known as the ISO 15197:2013. The level of accuracy of the BGMS results in the ability to regulate an individual’s blood glucose levels. According to the ISO 15197:2013, system accuracy performance criteria is defined as 95% of the BGMS results falling within ± 15 mg/dL of the reference analyzer results with glucose concentrations less than 100 mg/dL. For samples with glucose concentrations ≥ 100 mg/dL, 95% of the BGMS results need to be within 15% of the reference analyzer results. Furthermore 99% of all results are required to be in the A and B zones of the Consensus Error Grid.

OBJECTIVE: The objective of this study is to demonstrate whether the GLUCOCARD Vital aligns with the ISO 15197:2013 BGMS accuracy performance requirements.

METHODS: Two lots of GLUCOCARD Vital blood glucose test strips were evaluated for performance and bias comparison (n = 302 data points). The samples were collected from the fingertip of confirmed diabetics by trained personnel at the ARKRAY Factory in Minneapolis, MN. Reference values were obtained using the YSI Model 2300 Analyzer. The data was analyzed using the minimum system accuracy performance criteria published in the ISO 15197:2013.

RESULTS: The results showed that 100% of the <100 mg/dL samples (20/20) were within ± 15 mg/dL thus meeting the 95% accuracy criteria. 98.6% of the ≥ 100 mg/dL samples (n = 278/282) fell within the pre-determined 15% which met the 95% performance criteria. All data were within the A and B zones of the Consensus Error Grid. The overall bias was -0.3% demonstrating strong agreement between the GLUCOCARD Vital and YSI reference analyzer results, which is considered the gold standard glucose assay for BGMS studies.

CONCLUSIONS: The data acquired on the GLUCOCARD Vital met the ISO 15197:2013 system accuracy performance criteria, the most stringent BGMS requirement in the monitoring of diabetes mellitus.

SPONSORSHIP: This study was conducted by HealthCore, which received funding from AstraZeneca.

E28 Impact of a Combined Value-Based Design and Medication Therapy Management Program on Adherence in Diabetic Patients

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BACKGROUND: Value-based design (VBD) waives prescription copayments to reduce member cost barriers to refilling medications and medication therapy management (MTM) reinforces member’s knowledge regarding medications, addressing two known barriers to medication adherence. Both have been shown to increase adherence in patients, particularly when used in combination. However, studies of such programs have often been completed within integrated health systems and rarely include control populations.

OBJECTIVE: To determine the impact of a program combining VBD copayment waivers with an external, unaffiliated retail pharmacist-mediated MTM program on key medication adherence metrics among diabetic members of a large commercial employer group in the Midwest.

METHODS: A retrospective pre/post longitudinal analysis of pharmacy claims data was performed for 77 members who enrolled in the program between June 1, 2013 and December 1, 2013, as well as for 77 invited members who elected not to participate in the program, matched by baseline proportion of days covered (PDC), number of oral diabetic medications, age, and gaps in therapy (GIT). Oral diabetic medication adherence and cost-related outcomes for all pharmacy claims were evaluated, both within-subject, comparing the initial six months of intervention to a six month period immediately preceding enrollment, as well as between-subject, comparing the intervention and control groups.

RESULTS: The PDC increased 2.7% (0.929 to 0.954) by intervention, indicating a non-significant trend towards improvement (95% CI: -0.029, 0.081), while the PDC decreased 1.2% (0.928 to 0.917) in the control arm (95% CI: -0.066, 0.045). GIT also improved by intervention, decreasing 29% (9.69 to 6.86, 95% CI: -11.03, 5.37), while the GIT increased 29% (9.78 to 12.60) in the control group (95% CI: -5.39, 11.02). As expected, pharmacy claims costs paid by the plan per member per six month period significantly increased by 55% ($1,991.23 to $3,092.74, 95% CI: $22.28, $2,180.73), compared to a non-significant 17% increase ($1,402.21 to $1,643.68) in the control arm (95% CI: $835.76, $1,322.69).

CONCLUSIONS: While statistically significant improvements to adherence were not observed among this population of members who were highly adherent at baseline, improvement trends demonstrated that combined VBD/MTM programs may have the potential to influence member behavior in commercial employer groups. Additional benefit may be realized by targeting members with lower adherence metrics at baseline, examining potential cost savings associated with medical outcomes, and optimizing the external MTM program.

SPONSORSHIP: This research was conducted by Navitus Health Solutions, Madison, WI, without external funding.
**E29 Lower A1c Values in Patients Compliant with Pharmacist-Led Clinical Program Appointments Compared to Patients Who Were Noncompliant with Appointments**

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**BACKGROUND:** Diabetes currently affects approximately 18.8 million Americans and is projected to increase to over 30 million Americans by year 2025. Healthcare costs associated with complications and potential hospitalizations are a rising concern as the disease continues to grow in prevalence. Poor medication adherence is an area of opportunity for diabetes management. A pharmacist-led clinical outreach program provided by a PBM with access to claims data and medication filling history is hypothesized to have an impact on hemoglobin A1c outcomes.

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

**METHODS:** This was a retrospective cross-sectional study using lab records collected at the county employee plan's outpatient clinic. Participants in the county employee plan's diabetes program who were seen by the pharmacist between December 2013 and October 2014 were assigned into two groups based on completion of scheduled appointments. A total of 289 patients were divided into two groups: 176 formed the appointment-compliant group and 113 formed the appointment non-compliant group. The most recent hemoglobin A1c (A1c) values available were recorded for each patient. Differences between parametric continuous data were analyzed with mean and student's two-tailed t-test using Microsoft Excel software. Additional analysis compared differences amongst age groups.

**RESULTS:** The average A1c for the appointment-compliant group was 7.28 g/dL and 8.67 g/dL for the appointment non-compliant group. This results in a significant difference of 1.19 g/dL in A1c value between the groups (P < 0.001). When comparing differences between groups based on age, all groups showed an overall reduction in A1c values in the appointment-compliant group compared to the appointment non-compliant group. The largest difference observed was seen in the 14-29 age group (2.975 g/dL).

**CONCLUSIONS:** Patients who were more compliant with diabetes outreach clinical program appointments demonstrated lower overall A1c values compared to appointment non-compliant patients. Pharmacist-led clinical diabetes outreach provided by a PBM demonstrates overall better patient outcomes.

**SPONSORSHIP:** None.

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**E30 Evaluation of Blood Glucose Test Strip Overutilization in a Medicaid Population: A Pharmacy Claims Analysis**

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**BACKGROUND:** Diabetes mellitus (DM) in the United States (U.S.) is becoming more prevalent and in 2010, it was estimated that 26 million individuals in the U.S. had DM. The increased prevalence of DM has resulted in increasing healthcare expenditures. A large contributor of DM related health care expenditure stems from use of self-monitoring of blood glucose (SMBG) supplies—most notably blood glucose test strips. Test strips have a wide range in price per strip as well as a wide preference range for frequency of member testing.

**OBJECTIVE:** To identify actionable areas of potentially wasteful spend on self-monitoring of blood glucose supplies in a Medicaid population.

**METHODS:** This retrospective pharmacy claims analysis from January 1, 2014, to September 30, 2014, included 51,757 Medicaid members with SMBG testing supplies utilization. Members were categorized based on their concomitant pharmacy claims during this timeframe: (1) at least one paid claim for insulin; (2) paid claim for an anti-diabetic medications excluding insulin; (3) no paid claim for anti-diabetic medications (including insulin). Members daily test strip utilization was estimated based on quantity of strips received and frequency of test strip claims. Each group had different maximum thresholds of what was deemed, “appropriate utilization,” based on available literature and guidelines. Members with at least one paid insulin claim had a threshold of 5 test strips per day; members with anti-diabetic medication claims excluding insulin had a threshold of 2 test strips per day, and members without any insulin or anti-diabetic medication claims’ threshold was 1 claim for test strips, regardless of number of strips. Any use beyond these thresholds was calculated using database management software and deemed “potential waste.”

**RESULTS:** During the trial period there was $10.6 million dollars paid for glucose test strips in the analyzed Medicaid markets. Of this total spend an estimated $1.4 million (13.37%) was deemed “potential waste”. Stratifying by concomitant insulin use, concomitant anti-diabetic medication excluding insulin use and no diabetic medication, there was $5,845,461; $4,002,975 and $847,084 of test strip spend, respectively, with waste associated with these groups calculated to be $339,520 (6%), $623,693 (15.9%) and $466,325 (55.05%).

**CONCLUSIONS:** Further analytics must be performed to determine whether “potential waste” was actually wasteful spending or if it was warranted. Strategies need to be discussed regarding test strip policies and implementation for these benefits to optimize efficiency and curb fraud, waste, and abuse.

**SPONSORSHIP:** This research was conducted by Anthem Pharmacy Solutions, Norfolk, VA.

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**E31 Development of a Pharmacoeconomic Model to Demonstrate Clinical Pharmacist Impact in Chronic Disease Management**

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Department of Veterans Affairs

**BACKGROUND:** VA clinical pharmacists play an important role in assuring medication safety and improving clinical outcomes. Although the use of clinical pharmacists in the VA is widespread, systematic documentation of their workload, interventions and resultant outcomes has been lacking. The Pharmacists Achieve Results with Medications Documentation (PhARMD) Project is an operational project which nationally deployed a data collection tool to document specific interventions and patient outcomes, made by clinical pharmacists in their role as non-physician providers. Archimedes software is a validated pharmacoeconomic tool which can accurately project long-term clinical and economic consequences of changes in a given population demographic.

**OBJECTIVE:** Clinical pharmacist intervention and outcome data derived from the PhARMD tool was used to populate the well validated Archimedes modeling program to predict the long-term impact of pharmacist provided pharmacotherapy management on patient outcomes and costs for diabetic patients.

**METHODS:** Baseline patient demographics and biomarkers were extracted for diabetic patients having more than 1 encounter with a pharmacist provider using the PhARMD tool. Treatment biomarker values were extracted 12 months following the anchor visit. The number of visits with the pharmacist and visit time were quantified by
CPT codes. Simulation modeling was used to estimate long-term cost and consequences using the validated Archimedes Model. A sensitivity analysis was conducted to assess the extent to which our results were dependent on assumptions related to program effectiveness and costs.

RESULTS: Over 10,000 patients met inclusion and exclusion criteria and were included in the Archimedes modeling. Analysis of cost and events for a 5, 10 and 20-year time horizon demonstrated that patients would have fewer major cardiovascular events (MACE), myocardial infarctions, episodes of acute heart failure, foot ulcers and foot amputations in comparison with a control group receiving usual medical care. An incremental cost-effectiveness ratio for cost per QALY during the 5-, 10-, and 20-year time horizons was cost saving.

CONCLUSIONS: Clinical pharmacists, in the role of non-physician providers performing chronic disease management for veterans with diabetes, improve patient outcomes and result in lower overall costs when compared to controls.

SPONSORSHIP: Department of Veterans Affairs, Pharmacy Benefits Management.

E35 Development of the Prescription Medication Adherence Prediction Tool (RxAPT) to Predict Nonadherence to Oral Antidiabetic Drugs

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PROBLEM DESCRIPTION: Adherence to oral antidiabetic drugs (OADs) is an important factor that can greatly influence CMS star ratings for managed care organizations (MCOs). However, adherence to OADs in the Medicare population is low. Adherence intervention programs that target the entire patient population require more resources and are not cost effective. Proactive identification of patients at risk for future non-adherence can provide MCOs with a selective cost-effective approach to implement adherence intervention programs.

GOAL: To develop a risk assessment tool (Prescription Medication Adherence Prediction Tool [RxAPT]) to predict non-adherence to OADs using Medicare claims data.

PROGRAM DESCRIPTION: The study used 2012-2013 claims data from a MCO; data from 2012 (baseline period) was used to develop the tool to predict adherence in 2013. Members 65 years and older with diabetes diagnosis, at least 1 prescription for any of the 4 classes of OADs (biguanides, sulfonylureas, thiazolidinediones, and DPP-IV inhibitors), no insulin prescription, and continuously enrolled for both the years were included in the study. Adherence to OADs was the study outcome, defined as the proportion of days covered (PDC) by the OADs in 2013 (dichotomized at ≥ 80%). Predictor variables were calculated from baseline period and included patient demographics, disease and medication characteristics. A logistic regression model was used to identify the significant predictors for adherence and develop the tool using 70% of the data, and the remaining 30% was used for validation. The tool was tested for discrimination ability, goodness-of-fit, sensitivity, and prediction ability.

OBSERVATIONS: Total sample included 7,028 patients. Days of supply of last refill, coverage of last refill, total number of refills in the baseline year, different classes of OADs prescribed in the baseline year, pill burden, prior adherence to OADs, and average monthly cost of prescription medications were the significant predictors of PDC ≥ 80% and were part of the tool's algorithm. In the validation sample, RxAPT performance statistics were as follows: C-statistics = 0.74, Hosmer-Lemeshow goodness-of-fit P < 0.05, sensitivity = 0.71, specificity = 0.66, positive prediction value = 0.79, and negative prediction value = 0.62. RxAPT predicted future non-adherence 1.84 times more accurately (P < 0.0001) compared to the model that used current PDC as the predictor for next year’s adherence.

FINDINGS/RECOMMENDATIONS: RxAPT is an effective tool to identify patients who are likely to become non-adherent to OADs in the next year. The tool requires only pharmacy claims data and can be automated for routine use.

SPONSORSHIP: No sponsorship/funding was received for this study.

E37 Budget Impact of Signifor LAR (Pasireotide) for the Treatment of Acromegaly—a Rare Endocrine Disorder

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BACKGROUND: Acromegaly is a rare disorder characterized by the overproduction of growth hormone (GH). Patients often experience a range of chronic comorbidities including hypertension, cardiac dysfunction, diabetes, osteoarthropathy, and obstructive sleep apnea. Untreated or inadequately controlled patients incur substantial healthcare costs, while normalization of GH levels may reduce morbidity and mortality to levels similar to the general population.

OBJECTIVE: The objective of this study was to assess the 3-year budget impact of pasireotide LAR on a U.S. managed care health plan following pasireotide LAR availability.

METHODS: Two separate economic models were developed to calculate expected costs associated with introduction of pasireotide LAR for treatment of patients with acromegaly: one from perspective of an entire health plan (total budget impact) and another from perspective of pharmacy budget (pharmacy budget impact). Both models compare expected costs with and without pasireotide LAR availability for all patients receiving drug therapy (1L+) and patients receiving subsequent drug therapy (2L+). The total budget impact model includes costs of drug therapies, monitoring, adverse events and comorbidities. Drug therapies include labeled use of pasireotide LAR, octreotide LAR, lanreotide, pegvisomant, bromocriptine, cabergoline, and unlabeled use of these therapies in combination based on real-world data and market research. The pharmacy cost calculator only considers drug costs, from the perspective of a health plan pharmacy.

RESULTS: The total estimated budget impact for 1L+ therapy associated with the introduction of pasireotide LAR is $0.031 per member per month (PMPM) in the first year, 0.78 cents ($0.0078) in the second year, and 1.42 cents ($0.0142) in the third year following FDA approval. The budget impact for 2L+ treatment was lower by approximately 20% due to a smaller number of patients receiving second and later lines of therapy. Costs were similar or lower from a pharmacy budget impact perspective. For each patient achieving disease control, cost savings from reduced comorbidities amount to $10,240 per year. Costs for acromegaly-related comorbidities may be underestimated because comorbidity costs for the general population had to be used for some comorbidities, in absence of data on acromegaly-related costs, while costs in acromegaly may be higher.

CONCLUSIONS: The budget impact of pasireotide LAR is expected to be modest, with an expected increase of 1.42 cents PMPM on the total health plan budget in the third year after FDA approval.

SPONSORSHIP: Novartis Pharmaceuticals and Analysis Group.
E39 Use of ICD-9 Codes for Obesity: Trends in the United States

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BACKGROUND: Previous research shows that the prevalence of ICD-9 coding for obesity is low and differs by Body Mass Index (BMI). However, little is known about other factors that may be related to obesity coding.

OBJECTIVE: To understand the prevalence of obesity coding, characteristics of individuals coded for obesity, and whether such practices have changed over time in the U.S.

METHODS: A cross-sectional two-part analysis of primary care electronic medical records from a nationally representative U.S. database (GE Centricity) was conducted. In the first part of the analysis, individuals were required to have an index BMI of any value between January 1, 2010 and December 31, 2012. All pre-index and 1-year post-index medical records were then searched for an ICD-9 code of 278.0x to determine if that individual received a code for obesity. Characteristics of individuals with obesity (BMI > 30 kg/m²) with and without codes were compared. In the second part of the analysis, records of individuals with any BMI value during a given calendar year (2005-2012) were searched to determine if obesity was coded during that year. Annual prevalence of coding was also examined by BMI category (30-35, 35-<40, 40+). Descriptive results for both analyses are presented.

RESULTS: The sample for the first analysis included 4,767,221 individuals who had a BMI of any value, of which 578,414 (12.1%) had received an obesity diagnostic code either prior to or one year after the index date. Among individuals with BMI > 30 kg/m², the percent of individuals coded for obesity was lower for those in lower BMI categories (e.g., BMI 30-34.9 kg/m² = 15.3% vs. BMI 50+ kg/m² = 65.3%). Additionally, individuals with BMI > 30 kg/m² with an ICD-9 code for obesity, as compared to those without an ICD-9 code for obesity, more often were also coded for type 2 diabetes (30% vs. 20%), cardiovascular disease (66% vs. 55%), hypertension (58% vs. 47%), dyslipidemia (54% vs. 44%), sleep apnea (10% vs. 4%), and depression (22% vs. 14%). While the use of the ICD-9 codes for obesity increased between 2005 and 2012, frequency still remained low. For instance, among individuals with a recorded BMI ≥ 30 kg/m², 18.4% were coded for obesity in 2005 as compared to 23.4% in 2012.

CONCLUSIONS: Individuals with obesity in the U.S. do not frequently receive an ICD-9 code for obesity. Further, clinical characteristics, namely the presence of comorbidities, may influence the likelihood of receiving a code for obesity. Therefore, use of ICD-9 codes alone to identify individuals with obesity is severely limited.

SPONSORSHIP: This study was funded by Novo Nordisk.

E40 Health Care Costs and Resource Utilization Related to Cardiovascular Events Among Commercially Insured Patients with Hyperlipidemia

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BACKGROUND: Reducing LDL-C levels reduces risk of cardiovascular events (CVEs). Previous studies have examined the economic burden of primary CVEs and short-term costs but not long term costs, costs associated with 2nd and 3rd CVEs, and costs comparing CVEs to a hyperlipidemia population without CVEs.

OBJECTIVE: To estimate acute, short-term and long-term health care costs among hyperlipidemia patients following a CVE.

METHODS: This retrospective cohort study examined hyperlipidemia patients using longitudinal administrative claims data from a large commercial U.S. insurer. Those with a CVE and those without a CVE were propensity score matched to adjust for differences in demographics, comorbidities, and coronary heart disease risk. Qualifying CVEs were MI, ischemic stroke, PCI, CABG, unstable angina, TIA or heart failure. Patients were followed from index (date of first CVE or a randomly selected date for those w/o a new CVE) until the earlier of disenrollment, August 31, 2012, or 36 months after the index. Analyses reported here are limited to commercially enrolled CVE patients and their matched no CVE pair. The payer perspective was taken for all analyses with cost representing the total health plan-patient paid amounts converted to per-patient per-month (PPPM). Mean ± SD costs are presented for the following periods: acute (days 0-30), short-term (days 31-365), 2nd year (days 366-730) and 3rd year (days 731-1,095).

RESULTS: The study included 156,679 pairs and patients were mostly male (63% for CVE cohort and 57% in cohort no CVE) and age 61 ± 12 years (CVE) and 67 ± 11 (no CVE). Acute PPPM costs were $25,049 ± 52,433 and largely driven by inpatient costs $19,550 ± 49,320. Acute costs among those no CVE were less at $806 ± 4,063 comparatively (P < 0.001). Costs in the short-term were $2,324 ± 7,269 ($752 ± 2,355 for those no CVE, P < 0.001), 2nd year costs were $1,674 ± 5,186 ($473 ± 1,570 for those no CVE, P < 0.001) and 3rd year costs were $1,549 ± 5,108 ($289 ± 1,052 for those no CVE, P < 0.001). Compared to baseline, costs in CVE patients increased $5,873 ± 36,081 PPPM during the 36 month follow-up period (those w/o remained unchanged). Compared with first events, 2nd (n = 68,505) and 3rd CVEs (n = 43,258) had lower acute costs ($13,354 for 2nd CVE and $9,956 for 3rd), but higher over the following years (2nd CVE: $2,797 for short-term, $1,937 for 2 year, and $1,720 for 3 year; 3rd CVE: $3,089, $2,036, and $1,684 respectively).

CONCLUSIONS: The main driver of costs following a CVE was inpatient hospitalizations. Higher costs, compared to those without a CVE, persist for several years.

SPONSORSHIP: Research funding for this study was provided to Optum by Amgen.

E41 Cardiovascular Risk of Patients with Lysosomal Acid Lipase Deficiency

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BACKGROUND: LAL, an essential enzyme in normal lipid metabolism, is responsible for the lysosomal hydrolysis of cholesteryl esters and triglycerides. LAL deficiency is a rare, progressive multisystemic disease that is under-recognized as a cause of cirrhosis, severe dyslipidemia, and early-onset atherosclerosis. Currently, there are no effective therapies available. Sebelipase alfa (SA) is the first enzyme replacement therapy being developed for LAL deficiency.

OBJECTIVE: To determine 10 year Framingham Risk Score (FRS) and atherosclerotic cardiovascular disease (ASCVD) risk in patients with LAL deficiency before and after treatment with SA.

METHODS: This study used data from a randomized Phase 3 clinical trial (n = 66, median age = 13 years) designed to evaluate the efficacy and safety of SA in children and adults. Sixty-six patients, 36 in SA and 30 in placebo (PBO) arm were randomized. FRS can only be computed for patient’s age 30 to 74 and ASCVD for 40 to 79 years. Six subjects met criteria for FRS and 4 for ASCVD. Delta FRS is a measure of incremental risk created by LAL Deficiency. It was defined as difference between risk of a LAL Deficient patient and risk for a normal patient adjusted for age and risk factors at normal levels as defined by Framingham Heart equation. Descriptive statistics were generated.
due to low sample size. Risk is underestimated as the trial excluded patients with diabetes and no smokers were enrolled.

RESULTS: Overall, mean age (n = 6) LAL deficiency patients at baseline was 45, 50% males, with average FRS 7.1% and delta 2.5% suggesting a mean increase in risk of 54% over the normal population. At baseline, 10-year FRS and delta scores for PBO arm (n = 3) were 6.7% and 3.5% and 0%, at 20 weeks was 6% and 3%, suggesting a 14.3% reduction in incremental CV risk in 20 weeks. For SA arm (n = 3), FRS and delta scores at baseline were 7.5% and 1.5%, at 20 weeks were 4.7% and -1.6%, suggesting a 20.7% reduction in incremental CV risk over 20 weeks. The 10-year ASCVD risk analysis showed similar results, indicative of normalization of CV risk in LAL deficient patients in the SA arm.

CONCLUSIONS: In addition to complications due to liver cirrhosis, LAL deficiency patients appear to have higher CV risk than the general population with mitigation of this risk by SA treatment based on an analysis of patients over 30 years of age in this trial. Future studies with a larger sample size are needed to validate the effects of SA on reducing CV risk and whether FRS and ASCVD are appropriate estimators, given the younger age of these patients.

SPONSORSHIP: This research was funded by Synageva Biopharma.

E42 Cystic Fibrosis Prevalence and Total Cost of Care in a Commercially Insured Population
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BACKGROUND: Ivacaftor (Kalydeco) was approved in 2012 for cystic fibrosis (CF) patients 6 years and older with the genotype found in about 50% of CF patients. Approval was expanded in 2014 to additional rare mutations. In November 2014, an FDA application was submitted for combination ivacaftor and lumacaftor for ages 12 and older who have the genotype found in about 50% of CF patients.

OBJECTIVE: To estimate the prevalence of members with CF by age and total claims expense for these members in order to estimate ivacaftor and lumacaftor costs and potential offsetting claims savings.

METHODS: All commercially insured members in 11 health plans who were continuously enrolled between April 1, 2013 and September 30, 2014 were identified and classified as having CF if they had 2 or more claims with a CF diagnosis code 30 or more days apart. All medical and pharmacy claims for these members in the 12 month interval October 1, 2013 to September 30, 2014 were categorized. Members were stratified by age on September 30, 2014 into those: (1) receiving ivacaftor, (2) who had lung transplantation during the 12 months, (3) with previous lung transplantation, and (4) all others.

RESULTS: 1,067 members were classified as having CF; 101 of 303,973 age 1.5-< 6 years, 152 of 659,230 age 6-< 12, and 814 of 7,399,196 age 12 and older, for a respective prevalence of 25.6, 23.1, and -1.6%, suggesting a 206.7% reduction in incremental CV risk over 20 weeks. The 10-year ASCVD risk analysis showed similar results, indicative of normalization of CV risk in LAL deficient patients in the SA arm.

CONCLUSIONS: The finding that 3.7% of CF members 6 years and older are receiving ivacaftor suggests that most are being treated who are eligible. If a similarly large fraction of CF members meeting genotype and age criteria are treated with the new therapy, commercial plans will experience at least a 10-fold increase in CF pharmacy expense. It is plausible that there may be offsetting claims cost savings, but these would be small relative to the new drug therapy cost.

SPONSORSHIP: Prime Therapeutics.

E43 Reference Pricing: An Alternative Approach to Manage Preferred Drug Programs
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BACKGROUND: Due to dramatically rising pharmaceutical costs, creative cost-control strategies are being used to administer prescription benefits. Reference pricing is a unique cost share strategy to contain overall costs in a specific drug class based upon review of clinical studies, clinical practice guidelines, development of preferred drug lists and creation of a maximum per unit reference price value for the non-preferred drugs. For these non-preferred drugs the patient is responsible for any cost above the reference price, unless a prior authorization is done to establish the medical necessity of the non-preferred medication.

OBJECTIVE: To examine the cost-savings potential of implementing reference pricing on the therapeutic class of HMG-CoA reductase inhibitor (statin) medications.

METHODS: Pharmacy claims data from Southern Scripts members in 2014 were queried. A total of 1,276 patients on statin medications across 6 benefit plans were analyzed. A therapeutic evaluation was conducted on the statin class, and a list of preferred drugs was created: atorvastatin, lovastatin, pravastatin and simvastatin. CRESTOR 40 mg was excluded from this analysis due to lack of clinical evidence of a therapeutically equivalent alternative. Predictive modeling was done to assess the potential impact of reference pricing on the statin class. This study was approved by the Investigational Review Board of The University of Louisiana-Monroe.

RESULTS: The average plan paid amount among the four preferred statin medications was $0.33, which served as the reference price for all non-preferred statins in this modeling. For each rosuvastatin patient impacted, the savings from a reference pricing intervention was predicted to be $164 per member per month (PMPM) or $1,968 per member per year (PMPY). For each pitavastatin patient impacted, the savings was predicted to be $115 PMPM or $1,380 PMPY. Overall, statin spending was predicted to decrease by 50.6% for the patient impacted, the savings from a reference pricing intervention was predicted to be $164 per member per month (PMPM) or $1,968 per member per year (PMPY). For each rosuvastatin patient impacted, the savings from a reference pricing intervention was predicted to be $164 per member per month (PMPM) or $1,968 per member per year (PMPY). For each pitavastatin patient impacted, the savings was predicted to be $115 PMPM or $1,380 PMPY. Overall, statin spending was predicted to decrease by 50.6% for the patient population analyzed based upon a 75% rate of patients switching to a preferred medication.

CONCLUSIONS: The predicted success of reference pricing is dependent on the actions of the patient and prescriber to evaluate and address the appropriateness of the medication being prescribed compared the preferred alternatives. This strategy to address preferred drugs within certain therapeutic drug classes has tremendous savings potential for both the plan sponsor and the patient. Prospective studies are warranted to examine the impact of reference pricing on prescription benefit plans and patients compared to conventional cost-control strategies across multiple drug classes.

SPONSORSHIP: This research was conducted by Southern Scripts, Natchitoches, LA, without external funding.
Predictive Analysis of Disease Burden and Cost of Lysosomal Acid Lipase Deficiency in a U.S. Commercial Health Plan

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BACKGROUND: Lysosomal acid lipase (LAL) deficiency is an ultra-rare genetic disease that is characterized by a marked reduction or absence of LAL enzyme activity, leading to lysosomal accumulation of cholesterol esters and triglycerides in the liver, intestine and other organs. Children and adults can rapidly progress through stages of liver disease (i.e., fibrosis and cirrhosis), which may lead to complications including liver failure, hepatocellular carcinoma, liver transplant, and death. The disease also causes severe dyslipidemia with its attendant cardiovascular risks.

OBJECTIVE: To evaluate and document the impact of disease progression of LAL deficiency on morbidity and direct medical costs in infants, children, and adults.

METHODS: A six-state, lifetime Markov model was developed to simulate liver disease progression of LAL deficiency patients. Given a very low prevalence of disease and the paucity of directly observed or published data on LAL deficiency, key model parameters (e.g., transition probabilities) were adapted from Markov models of nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, and hepatitis C patient populations with clinical guidance provided by a panel of clinical experts. The direct medical costs to a health plan were estimated from published literature and include costs associated with cardiovascular and gastrointestinal complications from LAL deficiency, in addition to liver disease costs. Cost estimates were adjusted to 2014 USD using a 3.5% annual inflation factor.

RESULTS: Annual costs for each disease state were estimated at $625 for fibrosis, $2,389 for compensated cirrhosis, $61,059 for decompensated cirrhosis, and $108,659 for liver transplant. Average annual costs for cardiovascular and gastrointestinal complications were estimated at $582 and $1,265, respectively. In the absence of an effective treatment, progression to cirrhosis is more rapid in LAL deficiency than in other progressive liver diseases, which contributes to significant morbidity and high costs. Baseline state for a cohort of LAL deficiency patients was drawn from the ARISE clinical trial for sebelipase alfa. The model predicts that within 20 years, up to 90% of patients will have transitioned to liver transplant or death in the current care paradigm. Enzyme replacement therapy in development shows promise in preventing disease progression, potentially causing disease regression and improving survival.

CONCLUSIONS: LAL deficiency is a progressive and costly multisystemic disease with significant unmet clinical and economic need.

SPONSORSHIP: Synageva BioPharma.

Analysis of the Cost Burden Due to Relapse in Opioid Prescription Drug Dependent Patients Treated with Buprenorphine/Naloxone and Patients Without Pharmacological Treatment

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ZRx Outcomes Research; Creativ-Ceutical USA; Indivior PLC

BACKGROUND: Retrospective analysis of the Truven Health MarketScan Medicaid (Medicaid insurance claims) database identified a considerable number of opioid prescription drug dependent (OPD) patients that were diagnosed, but receiving no treatment.

OBJECTIVE: To compare resource use and healthcare costs between the following groups of patients: (1) patients treated with BUP/NAL (buprenorphine/naloxone) and relapsing, (2) patients treated with BUP/NAL and not relapsing, (3) patients without pharmacological treatment.

METHODS: Statistical analyses were conducted on Medicaid insurance claims database from January 1, 2007 through December 31, 2013. The index date was the date of first BUP/NAL prescription for the treated population and the date of first diagnosis for the population without pharmacological treatment. OPD patient was defined

Mental and Behavioral Disorders (i.e., Depression, Antipsychotics, Schizophrenia, Bipolar Disorder)
as patient with at least 28 days of cumulative treatment with opioid medication during the 6 months before index date. Further selection was made to examine OPD patients treated with BUP/NAL who had at least one pharmacy claim for BUP/NAL and minimum 182 days of continuous enrolment preceding the prescription date. OPD patient without pharmacological treatment had minimum two diagnoses of opioid dependence on two different dates within six months period and was continuously enrolled for the minimum of 182 days preceding the first diagnosis. Relapse was defined by presence of ER visit or hospitalization or in/out patient visit or by treatment reinitiation after discontinuation. There was 477, 1293 and 8254 OPD patients treated with BUP/NAL and relapsing, treated with BUP/NAL and not relapsing and OPD patients without pharmacological treatment respectively.

RESULTS: Comparing OPD patients on BUP/NAL that do and do not relapse, in the 12 months post-index period, resource use was comparable in all categories except BUP/NAL pharmacy was 14% higher for non-relapsers (P<0.001) and 52% lower in terms of psychiatric hospitalization (P=0.00002). Healthcare costs were comparable between two groups and reported similar results (for non-relapsers higher BUP/NAL pharmacy cost and lower costs in terms of psychiatric hospitalization). Comparing OPD patients on BUP/NAL that do not relapse to OPD patients receiving no pharmacological treatment resulted in significantly higher costs in all categories (P<0.0001), except BUP/NAL pharmacy cost.

CONCLUSIONS: Medicaid system OPD patients that receive BUP/NAL treatment, whether relapsing or not relapsing use less healthcare resources and cost the public healthcare system less than OPD patients receiving no pharmacological treatment.

SPONSORSHIP: This study was sponsored by Indivior PLC.

F4 Impact of Opioid Classifications and Use on Overall Health Care Expenditures Among Medicaid Enrollees in Oklahoma

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BACKGROUND: The effectiveness of abuse-deterrent opioid formulations to reduce diversion is debatable. Little is known about the impact of newer opioids on overall healthcare costs.

OBJECTIVE: In this study we examine the relationship between overall healthcare costs and use of brand abuse-deterrent or tamper-resistant extended-release opioids (ADTR) vs. similar generic alternatives (GA), and examine whether this relationship was modified by enrollee characteristics such as age, gender, race, urban classifications, Charlson comorbidity scores (CCS), opioid dependence (OD), and comorbidities of addiction (CA) among Oklahoma Medicaid enrollees.

METHODS: A cross-sectional study design was used. Study participants were Oklahoma Medicaid enrollees ≥21 years) with at least one paid pharmacy claim for long-acting opioids between September 2013 and August 2014. Enrollees who were adherent to long-acting opioids were classified as chronic pain patients and placed in the ADTR or GA opioid groups if they had a proportion of days covered (PDC) ≥0.6 for products within that group. The relationship between expenditures (prescription, medical, and overall healthcare costs) and opioid groups was examined using multiple linear regression models. The impact of enrollee characteristics (age, gender, race, urban classifications, CCS, OD, and CA) on this relationship were examined.

RESULTS: Prescription costs ($9,265,554) accounted for 35% of overall healthcare costs ($26,304,693) among 938 enrollees during the 12 month reference period. Results showed that a significant proportion (23%) of variation in overall healthcare costs (R²=0.23; P<0.01) were explained by opioid groups, CCS, OD, age, and gender. Median costs among ADTR vs. GA users differed across CCS and CA; differences between median costs were larger among enrollees with higher CA and CCS than those with lower CCS holding all other factors constant. A significant proportion (36%) of variation in prescription costs was explained by opioid groups, CCS, OD, age, and gender (R²=0.36; P<0.01). Median costs among ADTR versus GA differed by gender and CCS. Total prescription costs were higher among ADTR than GA users and rose with increasing CCS (P<0.01). Older age was associated with higher overall prescription costs (P<0.01).

CONCLUSIONS: The use of ADTR is associated with higher prescription expenditures due to the cost of brand products. More research is needed to determine the efficacy of ADTR on incidence of opioid dependence and drug abuse to better inform policies regarding the use of ADTR versus generic alternatives.

SPONSORSHIP: No funding was received for this work.

F5 A Literature Review of Community-Based Interventions to Improve Oral Medication Regimen Adherence Among Individuals with Substance Use Disorders

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BACKGROUND: Poor medication adherence has been shown to cause complications, death, and increased healthcare costs and may be of particular importance in patients with substance use disorders (SUD). Concerns of poor adherence in this population may influence the decision by healthcare providers and payers to prescribe or manage a medication regimen requiring high adherence to optimize healthcare outcomes. Guidance defining the best practices in promoting medication adherence among individuals with SUD is lacking.

OBJECTIVE: To conduct a literature review of studies examining the effectiveness of community-based interventions to promote adherence to oral medication regimens for the treatment of chronic diseases in patients with SUD.

METHODS: A review of English articles published between October 1, 1994 and October 1, 2014 was conducted. Search terms included medication adherence, intervention studies, treatment outcome, program evaluation, pilot project, follow up studies, cohort studies, comparative studies, trials, substance-related disorders and SUD. Randomized trials, case series, and quasi-experimental study designs were included. Articles were excluded if the intervention was in context of inpatient treatment, injectable medication regimens, and/or acute conditions.

RESULTS: A total of 745 articles were retrieved out of which 26 met the inclusion and exclusion criteria. The length of interventions ranged from six days to six months in various community settings. Adherence was measured with various methods including self-report, direct observation, electronic medication bottle caps and urine monitoring. Improvement in adherence was observed in 20 out of the 26 studies (77%). Effective interventions included case management, motivational interviewing, cognitive behavior therapy, technological support, voucher reinforcement, medication counseling and medication management programs.

CONCLUSIONS: This review identified efficacious interventions that promote medication adherence in patients with chronic diseases and SUD. Heterogeneity of study designs precluded determination of optimal interventions to promote adherence in this population. Further evaluation of interventions that support adherence may inform the development of best practices in treating chronic disease in this population.

SPONSORSHIP: This research was funded by University of Massachusetts Medical School Commonwealth Medicine Internal Grants Initiative, Shrewsbury, MA.
WITHDRAWN
hospitalizations, outpatient hospital services, emergency room visits, physician office visits, relapse, and 7 and 30 day readmissions were comparable between cohorts (P > 0.05). LAI2 had higher all-cause total cost compared to LAI1 ($34,459 vs. $26,008, P < 0.01), which was attributable to higher cost difference in outpatient services ($2,304, P < 0.01) and prescription cost ($6,614, P < 0.01).

CONCLUSIONS: Prescription and outpatient services costs accounted for the higher all-cause total cost for LAI2. The greater use of ACT may suggest greater disease severity for the LAI2 cohort. While the prescription cost was higher for LAI2, it was not reflective of discounts or rebates. Also, higher persistence in LAI2 may have contributed to the difference in prescription cost.

SPONSORSHIP: Janssen Scientific Affairs.

### F12 Health Care Resource Utilization and Costs Among Young Adult Commercial Health Plan Members Before and After Initial Schizophrenia Diagnosis

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BACKGROUND: Symptoms indicative of schizophrenia (SCZ) often emerge during adolescence and early adulthood, with challenges accompanying timely diagnosis.

OBJECTIVE: To explore patterns of all-cause, MH-related, and SCZ-related healthcare utilization and costs in the 6 months before and after patients’ initial SCZ diagnosis.

METHODS: Retrospective claims data analysis of commercial enrollees from the Optum Research and the Impact National Benchmark Databases. Patients were ≥18 years old, continuously enrolled for 3 years pre- and 1 year post-index, and newly diagnosed with SCZ (primary ICD-9-CM 295.9X) from January 2007-February 2013. Initial SCZ diagnosis (index date) was from either an inpatient stay or the ambulatory setting (followed by ≥1 additional SCZ diagnosis and/or ≥1 antipsychotic prescription within 6 months). Pre- and post-index all-cause and MH-related utilization and costs, and post-index SCZ-related utilization and costs, were measured quarterly: pre-Q2, 4-6 months pre-index; pre-Q1: 1-3 months pre-index; post-Q1: 1-3 months post-index (including index date), etc. Descriptive analysis was performed.

RESULTS: The final sample of 1,278 patients had mean (standard deviation) age of 21.7 (3.1) years and 68.9% were male. All categories of mean all-cause and MH-related utilization and costs (office and outpatient facility, inpatient, emergency department [ED], medication, and total) increased sharply in pre-Q1, peaked in post-Q1 (capturing the date of initial SCZ diagnosis), remained somewhat elevated in post-Q2, and declined thereafter. Mean all-cause medical costs were $2,842 in pre-Q2, $4,957 in pre-Q1 (74.4% increase), $12,079 in post-Q1 (+143.7%), $4,149 in post-Q2 (-65.7%), and $3,384 in post-Q4. Mean MH-related medical costs followed the same pattern and accounted for 72.8% of mean all-cause costs in pre-Q2, 82.3% in pre-Q1, 91.9% in post-Q1, and 76.8% in post-Q2. Mean SCZ-related medical costs were 72.1% of MH-related medical costs in post-Q1, and 32.7% in post-Q2. Over 48% of this population had a MH-related inpatient stay (incurred mean $8,434 in costs) and 40.4% had a MH-related ED visit during the quarter coinciding with the initial SCZ diagnosis.

CONCLUSIONS: Patients newly diagnosed with SCZ had increasing pre-index healthcare utilization and costs in the 3 months leading to the initial diagnosis, peaking sharply during the quarter coinciding with SCZ diagnosis, and remaining relatively elevated in the quarter after SCZ diagnosis before declining. Timely SCZ diagnosis and effective management of multiple mental health conditions may help lower expenditures over time.

SPONSORSHIP: Funding for this analysis was provided by Janssen Scientific Affairs.

### F13 Evaluation of HEDIS Quality Measures for Individuals with Schizophrenia or Bipolar Disorder in a Large U.S. Health Plan

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1Sunovion Pharmaceuticals; 2Comprehensive Health Insights

BACKGROUND: The National Committee for Quality Assurance (NCQA) evaluates performance of health plans using a set of quality measures on several dimensions of care and services—the Healthcare Effectiveness Data and Information Set (HEDIS). Weight gain related
antipsychotic discontinuations and non-adherence among patients with serious mental illness (SMI) result in high rates of relapse, subsequent psychiatric re-hospitalization and higher healthcare costs. In 2013, four new HEDIS measures were added to assess health plans’ quality of care for mental illness.

**OBJECTIVE:** To examine performance on the four new HEDIS measures in treating commercially insured and Medicare patients with SMI.

**METHODS:** Medical and pharmacy claims for plan year 2013 were used to identify commercial (n = 8,536) and Medicare (n = 54,575) members age ≥ 19 diagnosed with schizophrenia or bipolar disorder in a large U.S. payor. Using the Technical Specifications manual, the proportion of patients that were monitored on the following HEDIS measures were calculated as a percentage of the total number of patients who qualified for inclusion: (1) diabetes screening (a glucose or HbA1c test) for those with schizophrenia or bipolar disorder using antipsychotic medications, (2) diabetes monitoring (low-density lipoprotein cholesterol [LDL-C] and HbA1c tests) for those with diabetes and schizophrenia, (3) cardiovascular monitoring (LDL-C test) for those with cardiovascular disease and schizophrenia, and (4) adherence (≥ 80% annual proportion of days covered -PDC) to antipsychotic medications for those with schizophrenia.

**RESULTS:** The overall population results are: (1) 82% with schizophrenia or bipolar disorder on antipsychotic treatment received a diabetes screening [NCQA published rate = 79.3%], (2) 77% with diabetes and schizophrenia were monitored for diabetes [68.5%], (3) 76% with cardiovascular disease and schizophrenia received cardiovascular monitoring [79.1%], (4) 74% were adherent to their antipsychotic medication [60.1%]. Results for the Medicare population followed the same pattern as the overall population, while rates for the commercial population were 10-20% lower.

**CONCLUSIONS:** These findings suggest that providers apply the HEDIS standards of care to their Medicare SMI patients. The largest difference between rates obtained for the Medicare population compared to the published Medicaid rates is in the adherence to antipsychotic medication.

**SPONSORSHIP:** Sunovion Pharmaceuticals.

**F15** Descriptive Analysis of Real-World Treatment Patterns of Antipsychotics Among Patients with Schizophrenia

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**BACKGROUND:** The heterogeneity of response to antipsychotic treatment among patients with schizophrenia is well documented in clinical studies. In the real-world setting, this results in physicians attempting several different antipsychotic treatments with the ultimate goal to find a suitable treatment that is both tolerable and efficacious.

**OBJECTIVE:** The study objective is to analyze real-world treatment patterns among patients receiving antipsychotics for the treatment of schizophrenia.

**METHODS:** Administrative claims data from Truven Medicaid, Medicare, and Commercial insurance health plans from January 2010-June 2013 were used to identify patients with broad-range ICD-9 codes for schizophrenia; a pending analysis will narrow the data to a focused group containing only ICD-9 295.xx for comparison. Two non-exclusive patient cohorts were identified: patients newly initiating treatment with any antipsychotic (Cohort A) and patients initiating treatment with an atypical antipsychotic (Cohort B). Cohort A data were used to investigate the patient journey through different lines of treatment failures, and Cohort B data were used to estimate the proportion of patients either switching or discontinuing treatment from their index atypical antipsychotic treatment. Patients were required to have health plan enrollment 12 months before and 24 months after their first antipsychotic claim.

**RESULTS:** Within 5 months of index antipsychotic treatment, 57% of the 6,583 patients in Cohort A progressed to 2nd line antipsychotic treatment. Of the patients who switched to a 2nd line antipsychotic treatment, 47% progressed to 3rd line treatment within 4.2 months from initiation of 2nd line treatment. Among 6,355 patients in Cohort B, the 3 most commonly used index atypical antipsychotics were risperidone (n = 2,033, 31%), quetiapine (n = 1,387, 21%), and aripiprazole mixed-effects models were used to estimate the incremental impact of lurasidone on individual changes in weight trajectory. Analyses were stratified by whether patients had previously received an SGA associated with a higher-risk (clozapine, olanzapine, quetiapine, or risperidone) or lower-risk (aripipazole, ziprasidone, first-generation antipsychotics, or no prior antipsychotics) for weight gain.

**RESULTS:** Of the 439 patients initiating lurasidone, 70% were women. Mean (median) age was 42.4 (42.0), and 27% received another SGA associated with higher-risk for weight gain prior to lurasidone. Mean number of lurasidone prescriptions was 2.0, and the mean duration of lurasidone was 55 days. In the year before lurasidone initiation, mean weight increased by 1.64 kg (P < 0.01) and decreased by 2.41 kg (P < 0.05) in the year after. In the higher-risk group, mean weight increased by 2.08 kg (P < 0.05) in the year before and decreased by 3.76 kg (P < 0.05) in the year after lurasidone. In the lower-risk group, mean weight increased by 1.50 kg (P < 0.05) in the year before, and decreased by 2.12 kg (P = 0.09) in the year after lurasidone. Among those on lurasidone ≥ 90 days (n = 179), weight increased 2.01 kg (P = 0.01) before, and decreased 4.23 kg (P < 0.001) after lurasidone.

**CONCLUSIONS:** This real-world analysis demonstrated that lurasidone was associated with significant weight reduction in the year after lurasidone initiation in patients with serious mental illness. These observed weight changes were unrelated to prior use of any antipsychotic.

**SPONSORSHIP:** This study was sponsored and funded by Sunovion Pharmaceuticals, Marlborough, MA.
A descriptive analysis of treatment patterns indicated a high percentage of patients with these index treatments either discontinued or switched over the follow-up period: risperidone, 66%; quetiapine, 60%; and aripiprazole, 72%.

CONCLUSIONS: Treatment patterns in the real-world setting indicate that patients quickly progress through multiple lines of antipsychotics. Although several antipsychotics exist, treatment options may be limited after considering an individual patient’s baseline comorbidities and disease severity, previous treatment failures, and risk for adverse events; this combined with treatment response heterogeneity may quickly exhaust the number of available treatment options for physicians.

SPONSORSHIP: This study was sponsored by Otsuka America Pharmaceutical, and H. Lundbeck A/S, Copenhagen, Denmark.

Comparison of Medicaid Spending in Schizoaffective Patients Treated with Once-Monthly Paliperidone Palmitate or Oral Atypical Antipsychotics

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BACKGROUND: Compared to treatment with oral atypical antipsychotics (OAAs), long-acting injectable antipsychotics may improve adherence and reduce risk of relapse in schizoaffective disorder (SAD) patients.

OBJECTIVE: Evaluate the impact of once-monthly paliperidone palmitate (PP) injection vs. OAAs on healthcare resource utilization and Medicaid spending among SAD patients using two propensity score approaches.

METHODS: Medicaid data from FL, IA, KS, MO, MS, and NJ between January 2009 and December 2013 were used to identify adults with ≥2 SAD diagnoses initiating PP or OAA (index date). Baseline characteristics were assessed during the 12 months pre-index, and outcomes were evaluated during the 12 months post-index. Propensity score matching (PSM) and inverse probability of treatment weighting (IPTW) were used to reduce confounding and compare the estimated treatment effect for PP vs. OAA.

RESULTS: Relative to OAA patients (N = 10,778), PP patients (N = 876) were younger (40.8 vs. 43.2 years), less likely female (45% vs. 55%), and more likely to have used other antipsychotics in the baseline period. Both PSM and IPTW resulted in well-balanced treatment groups with respect to baseline demographics and clinical characteristics, however, PSM retained only OAA patients that resembled PP patients (N = 846 in each cohort with 45% PP vs. 47% OAA female) while IPTW weighted patients such that PP patients resembled the overall study population (pseudo-population: 5,589 PP vs. 6,065 OAA with 53% and 54% female, respectively). Both approaches found significantly lower medical costs (mean monthly cost difference [MMCD] PSM method: -$383, P < 0.001; IPTW method: -$403, P = 0.016) driven by lower inpatient costs (MMCD PSM method: -$243, P = 0.004; IPTW method: -$256, P = 0.002) for PP vs. OAA patients. These lower medical costs offset higher pharmacy costs (MMCD PSM method: $270, P < 0.001; IPTW method: $350, P < 0.001) for PP patients resulting in similar total healthcare costs (MMCD PSM method: -$113, P = 0.414; IPTW method: -$53, P = 0.697) for PP vs. OAA, respectively. Reduced risk of hospitalization (PSM: incidence rate ratio [IRR] = 0.85, P = 0.128; IPTW: IRR = 0.96, P = 0.004) and fewer hospitalization days (PSM: IRR = 0.74, P = 0.008, IPTW: IRR = 0.85, P < 0.001) were observed in PP relative to OAA treated patients.

CONCLUSIONS: Both PSM and IPTW methods revealed significantly lower medical costs driven by fewer and shorter inpatient visits for PP vs. OAA treated patients. This offset higher pharmacy costs associated with PP and resulted in similar total healthcare cost for PP and OAA treated patients.

SPONSORSHIP: Janssen Scientific Affairs.

A Markov Chain Analysis for Comparing Cost-Effective Pharmacotherapy in Alzheimer’s Disease

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BACKGROUND: Alzheimer’s disease is the most expensive condition in the U.S. The direct costs of Alzheimer’s are estimated reach $1.2 trillion in 2050. Memantine, an unconventional N-methyl-D-aspartate receptor, has been confirmed by numerous clinical trials to reduce the rate of deterioration in cognitive and functional areas. However, its economic advantage remains to be established.

OBJECTIVE: The purpose of this study was to evaluate the cost-effectiveness of memantine compared with standard donepezil treatment in the moderate-to-severe Alzheimer’s disease.

METHODS: A Markov model was used to present three health state transitions: moderate, severe, and death. Disease severities were determined by Mimi Mental State Evaluation scores over a 5-year time period. The five year time horizon was judged to reflect a realistic timeframe. Transition probabilities of patients taking memantine were obtained from a research article by Jones et al.; data of donepezil treatment was retrieved from a study led by Neumann et al. and an article composed by Stewart et al. Data of cost was derived from an article published in Health Affairs. Only direct cost was taken into consideration and inflated to 2014 currency. Sources of utilities data were a study led by Neumann et al. and a Danish longitudinal study. Further, sensitivity analysis comprised scenarios analysis against a range of various assumptions made in the model.

RESULTS: The study revealed that mean overall costs over a 5-year time period covered by the Markov model were lower with Memantine compared to standard donepezil treatment. The clinical benefits on AD progression with memantine resulted in incremental cost per QALY gained of $4,820.90. The cost-effectiveness acceptability curve showed a 73.8% probability that memantine would be superior to donepezil with $50,000 willingness-to-pay (WTP) benchmark. When WTP exceeds $3,670, the cost preference would be more in favor for memantine than donepezil. Findings from sensitivity analyses were consistent with the base case analysis.

CONCLUSIONS: Our study concluded memantine is the dominant cost-effective pharmacotherapy in the moderate-to-severe Alzheimer’s disease. Given the rising economic burden of Alzheimer’s to the U.S. health care, the developed Markov chain analysis seems a valid model for use in economic evaluation in Alzheimer’s disease.

SPONSORSHIP: Department of Sociobehavioral and Administrative Pharmacy, Nova Southeastern University College of Pharmacy, and Department of Clinical Pharmacy, King Abdulaziz University College of Pharmacy.

Medical Cost Reductions for Paliperidone Palmitate Versus Placebo in Randomized, Double-Blind Trial of Patients with Schizoaffective Disorder

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BACKGROUND: Schizoaffective disorder (SCA) is a complex illness for which optimal treatment is not well established. A 15-month
randomized, double-blind, placebo-controlled, parallel-group study of paliperidone palmitate evaluated time to relapse in patients with schizoaffective disorder.

**OBJECTIVE:** The objective of this study was to estimate the difference in medical costs among patients treated with once-monthly paliperidone palmitate (PP1M) versus placebo based on clinical event rates reported in the 15-month study.

**METHODS:** Rates of relapses and serious and non-serious treatment-emergent adverse events (TEAEs) were obtained from the trial. The incremental annual medical cost for a relapse from a U.S. payer perspective was obtained from published literature and the costs for serious and non-serious TEAEs were based on Common Procedure Terminology codes and obtained from Medical Expenditure Panel Survey data and the Medicare Reimbursement Benefit Guideline, respectively. Differences in total annual medical costs for patients treated with PP1M vs. placebo were then estimated. Additionally, one-way and Monte Carlo sensitivity analyses were conducted.

**RESULTS:** A lower rate of relapse (-18.3%) and serious TEAEs (-3.9%) were associated with use of PP1M vs. placebo. As a result of the reduction in these clinical event rates the total annual medical cost was reduced by $7,140 per patient treated with PP1M vs. placebo. One-way sensitivity analysis showed that variations in relapse rates had the greatest impact on the estimated medical cost offset (range: $9,786, $4,670). Even greater medical cost offset was seen in the patients treated with PP1M monotherapy. The Monte Carlo simulations results demonstrated that the original estimated medical cost differences were relatively robust to random variations.

**CONCLUSIONS:** Use of PP1M for treatment of patients with schizoaffective disorder is associated with a significantly lower rate of relapse and consequently a substantial reduction in medical costs compared to placebo. Further cost evaluation in the real-world setting is warranted.

**SPONSORSHIP:** Janssen Scientific Affairs.

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**F24 Impact Analysis of an Implemented ADD/ADHD Clinical Edit in a Medicaid Population**

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**Health Information Designs**

**BACKGROUND:** Attention deficit disorder (ADD) and attention deficit/hyperactivity disorder (ADHD) have been diagnosed in approximately 11% of children ages 4-17 years in the U.S. as of 2011. The rising trend of medication-based therapy has made appropriate use of these agents a concern for payers and prescribers.

**OBJECTIVE:** To determine the impact on utilization and reimbursement of a recently-implemented ADD/ADHD clinical edit in a Medicaid population.

**METHODS:** A clinical edit for ADD/ADHD was implemented for a Medicaid population in February 2014. The edit was applied to the fee-for-service (FFS) population, while the managed care organizations (MCOs) had the option to implement the edit as written or apply their own variation. The edit was designed to ensure proper utilization by applying daily dosage limits, age restrictions, and diagnosis requirements based on ADD/ADHD medication classes. Data was collected for six months pre- and post-implementation for clients enrolled in FFS and MCOs, and included diagnosis, pharmacy claims, and reimbursement data. A comparison of the pre and post data was performed.

**RESULTS:** Implementation of the edit improved appropriate utilization in three areas: use of extended-release (ER) stimulants in patients with a history of substance abuse, inappropriate use of ER stimulant and non-stimulant (NS) medications in clients less than 6 years of age, and use of IR stimulants in children 3-5 years of age. A decrease in claim volume was seen in clients with a history of substance abuse using ER stimulants (FFS -28.7%, MCO -6.1%). The claims cost for these clients decreased in the FFS population and increased slightly in the MCO population (FFS -28.1%, MCO +0.8%). For clients less than 6 years of age, ER claims volume decreased (FFS -37.3%, MCO -19.3%) as did claims volume for NS medications (FFS -61.1%, MCO -34.6%). The claims cost for these clients decreased in the ER stimulant group (FFS -34.8%, MCO -12.1%), as well as the NS group (FFS -58.6%, MCO -13.9%). For clients 3-5 years of age, a decrease in claims volume was seen in the FFS group (-18.9%), while the MCO group showed an increase (+61.7%). Likewise, the claims cost decreased for the FFS group (+14.9%) and increased for the MCO group (+127.6%).

**CONCLUSIONS:** Implementing an edit that applies restrictions on maximum daily doses, age, and diagnoses for ADD/ADHD medications
can help ensure appropriate utilization of the medications. In addition, cost savings related to the medications may be realized.

**SPONSORSHIP:** This study was supported by internal funding only.

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**G00-G99 Diseases of the Nervous System**

(i.e., Multiple Sclerosis, Migraine, Seizures, Restless Leg, Sleep Apnea)

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**G2 The Economic Burden of Illness of Parkinson’s Disease Psychosis Among U.S. Medicare Patients**

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**BACKGROUND:** Parkinson’s disease psychosis (PDP) is a costly, debilitating condition which develops years after diagnosis of Parkinson’s disease (PD). Cost estimates of PDP are hampered by clinical under-diagnosis and multiple care settings. Scant data is available to quantify the costs associated with the medical care of PDP patients.

**OBJECTIVE:** To examine health care expenditures among patients with PDP compared to PD patients without psychosis and all Medicare-insured patients in the U.S.

**METHODS:** This cross-sectional analysis was conducted using Medicare Current Beneficiary Survey (MCBS) Cost and Use files between 2001 and 2010. The MCBS is a longitudinal survey linked to Medicare claims for all respondents. PDP cohorts were identified using ICD-9 diagnosis for PD (332.0) identified through self-report and validated in Medicare claims, as well as 2+ claims with a ICD-9 diagnosis of psychosis, hallucinations, delusions, dementias or mood disorders. A group of PD patients without psychosis (ICD-9 332.0 and no psychosis), and all Medicare-insured patients in Medicare during the survey timeframe were analysed for cost comparison. Expenditure measures included: all-cause inpatient, prescribed medicines, outpatient, long-term care and skilled nursing facility, home health, hospice and total costs. Utilization measures included: inpatient visits, outpatient visits, days spent in long-term care, home health visits, and days spent in hospice.

**RESULTS:** A sample of 381 PDP patients was identified in the MCBS out of a total 1,502 PD patients. Compared to PD and all Medicare patients, PDP patients were more likely to be female (58%), dually eligible beneficiaries (30%), spent time in nursing home or skilled-nursing facility (28%) and have restrictions in activities of daily living (27% in community; 49% in facility). All costs were higher for patients with PDP compared to both PD and all-Medicare cohorts, with the highest annual cost differentials found in long-term care ($25,196 for PDP patients versus $15,432 for PD patients), and skilled nursing facility ($3,496 for PDP patient versus $15,432 for PD patients). PDP patients spent an average of 143 days in long-term care compared with 88 days for PD patients.

**CONCLUSIONS:** This study utilized multiple years of linked Medicare survey-claims data to determine costs associated with a claims-based diagnosis of PDP. As expected, long-term care utilization and expenditure was significantly higher for PDP patients compared to PD patients without psychosis. Reducing long-term care utilization among patients with PDP may significantly lower the overall economic burden associated with PDP.

**SPONSORSHIP:** This research was funded by Acadia Pharmaceuticals, San Diego, CA.

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**G3 Health Care Utilization and Costs Associated with Falls and Fractures in Patients with Parkinson’s Disease in a U.S. Population**

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UCB Pharma

**BACKGROUND:** Many Parkinson’s disease (PD) patients experience recurrent falls and have a higher risk of fracture. Few long-term studies have evaluated healthcare (HC) utilization and direct costs of falls/fractures in PD patients.

**OBJECTIVE:** Estimate the HC utilization and direct costs associated with accidental falls/fractures in PD patients in a U.S. population.

**METHODS:** This U.S.-based claims database (Truven Health Analytics Inc. MarketScan) retrospective cohort study examined HC utilization and direct costs in PD patients with accidental falls/fractures requiring fracture treatment (events; PD-T), in comparison to PD patients with no falls/fracture events or with fractures not requiring treatment (PD-NT). The study period included a 12-month post-index period (index date: first diagnosis of a fall [ICD-9-CM codes E800.xx–E889.xx and E888.xx] or fracture [ICD-9-CM codes 800.xx–829.xx and E887.x] from January 1, 2008 to December 31, 2010). Fractures were defined by ≥1 inpatient/outpatient claim as a principal or secondary diagnosis and accompanying site-specific fracture repair procedure code during the post-index period. Pathologic fractures (ICD-9-CM code 733.1x) resulting from cancer, infection, osteomalacia, Paget’s disease, or other conditions were excluded. PD-T and PD-NT patients were matched by age, gender, residence region, prior- and post-index medical coverage durations. HC utilization included office, outpatient, and emergency department (ED) visits, and hospitalizations in the post-index period.

**RESULTS:** The overall cohort comprised 1,534 PD patients, with PD-T patients (1 event: n = 605; > 1 event: n = 164) matched to PD-NT patients (N = 767). PD-T patients with 1 event had numerically more visits, and direct costs in PD patients with accidental falls/fractures requiring fracture treatment (events; PD-T), in comparison to PD patients with no falls/fracture events or with fractures not requiring treatment (PD-NT). The study period included a 12-month post-index period (index date: first diagnosis of a fall [ICD-9-CM codes E800.xx–E889.xx and E888.xx] or fracture [ICD-9-CM codes 800.xx–829.xx and E887.x] from January 1, 2008 to December 31, 2010). Fractures were defined by ≥1 inpatient/outpatient claim as a principal or secondary diagnosis and accompanying site-specific fracture repair procedure code during the post-index period. Pathologic fractures (ICD-9-CM code 733.1x) resulting from cancer, infection, osteomalacia, Paget’s disease, or other conditions were excluded. PD-T and PD-NT patients were matched by age, gender, residence region, prior- and post-index medical coverage durations. HC utilization included office, outpatient, and emergency department (ED) visits, and hospitalizations in the post-index period.

**CONCLUSIONS:** This study in a U.S. population suggests that PD-T patients with falls/fractures use more healthcare resources and have more direct costs than PD-NT patients.

**SPONSORSHIP:** UCB Pharma.

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**G4 A Cost-Effectiveness Study Comparing AbobotulinumtoxinA and OnabotulinumtoxinA for the Treatment of Cervical Dystonia**

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**BACKGROUND:** Cervical dystonia (CD), a focal dystonia, characterized by the abnormal posture of the head and neck that can be sustained or spasmodic. Botulinum toxin (BoNT), a neurotoxin produced by the bacterium clostridium botulinum, causes...
impairment of neuromuscular transmission leading to flaccid paralysis. Intramuscular injections of BoNT have been shown to be efficacious and well tolerated when used to treat CD. AbobotulinumtoxinA (ABO) and onabotulinumtoxinA (ONA) have both been granted orphan drug designation by the FDA for the treatment of CD.

**OBJECTIVE:** To estimate the cost-effectiveness of abobotulinumtoxinA compared with onabotulinumtoxinA in treating cervical dystonia over a four-week treatment period.

**METHODS:** For each toxin, the treatment efficacy measure was the change in the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score four weeks post injection time, and the efficacy of each treatment was based on a mixed treatment comparison analysis of multi-armed randomized clinical trials from systematic literature review. The medical costs were calculated from a commercial payers’ perspective, i.e. considering only the direct medical cost including the drug cost and the cost associated with dysphagia as the main adverse event based on FDA-approved product package insert information. The medical costs were estimated based on claims data to reflect real-world treatment patterns and costs. The incremental cost-effectiveness ratio (ICER) of ABO was calculated as the additional cost per TWSTRS total score point reduction compared with ONA. Uncertainty of parameters in the analysis was addressed with one-way sensitivity analysis and probabilistic sensitivity analysis.

**RESULTS:** Over the four-week treatment period, ABO and ONA reduced the TWSTRS total score by 11.1 and 9.1, respectively. Dysphagia rates associated with ABO and ONA were 15% and 19%, respectively. The medical cost was $385.79 for ABO and $461.24 for ONA. The probabilistic sensitivity analysis results showed that if the willingness to pay (WTP) was set to $100 per TWSTRS total score point reduction compared with ONA, ABO treatment was considered cost-effective vs. ONA with a probability of 84.1%.

**CONCLUSIONS:** The analysis in this study suggests that ABO is more cost-effective compared with ONA as the treatment for cervical dystonia from a commercial payer’s perspective.

**SPONSORSHIP:** IPSEN Biopharmaceuticals provided financial support for this study.

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**G7 Multiple Sclerosis (MS) Patient Adherence to Delayed-Release Dimethyl Fumarate and Patient-Reported Side Effects from a Specialty Pharmacy Program**

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**BACKGROUND:** Biogen Idec’s delayed-release dimethyl fumarate (DMF), also known as gastro-resistant DMF; TECFIDERA oral medication to treat MS became available in March 2013 for relapsing forms of MS. Walgreens Connected Care for MS (CCMS) program provides enhanced management and care for patients taking DMF including assessments of patient-reported side-effects and related information. Limited real-world evidence is currently available for MS patients taking DMF.

**OBJECTIVE:** The main objective was to describe 6- and 12-month adherence levels, after controlling for other factors. A secondary objective was to describe the prevalence of patient-reported side effects.

**METHODS:** Adherence was measured using PDC (proportion of days covered) for a 6- or 12-month follow-up period. Patient-reported side effects were collected through the CCMS telephonic assessments. 5,279 patients were at least 18 years of age and initiated therapy from April 2013 to December 2013, and followed through June 2014.

**RESULTS:** The demographic profile of patients was similar to the national MS population. Median PDC for the 3,319 patients with 6 full months of data was 92.9% (range 16-100). For these patients, adherence to other MS medications utilized prior to DMF was 90.1%; (range 7.1-100). For the 1,216 patients with 12 months of data, the median PDC was 82.2% (range 0-100). 214 (4.0%) patients switched from DMF to another DM in 12 months; the proportion was significantly lower among patients reporting no side effects (P<0.02). 4,179 patients were asked at least one side effect question. The most common response was none (1,830 or 43.8%), followed by reports of flushing (1,790 or 42.9%) and abdominal pain (698 or 16.7%). For assessed patient relapse within the last 30 days, 107 reported a relapse (2.6%) after the first 62 days of therapy through end of study.

**CONCLUSIONS:** In the first year postapproval, the 6-month adherence rates for patients utilizing DMF were equivalent to those of other patients treated with a DMT prior to starting DMF. As observed with other chronic medication use, adherence was lower at 12 months. Adherence was influenced by patient characteristics and length of CCMS participation. Rates of patient-reported side effects were comparable to those seen in clinical trials, and the percentage of patients reporting no side effects (43.8%) was higher than that reported in the clinical literature.

**SPONSORSHIP:** This study was funded by Biogen Idec.
Burden of Illness in Relapsing-Remitting and Secondary Progressive Multiple Sclerosis Patients in the United States

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BACKGROUND: Patients with relapsing-remitting multiple sclerosis (RRMS) may progress to secondary progressive multiple sclerosis (SPMS) over time. Although there has been an increase in the number of approved disease-modifying therapies (DMTs) indicated for relapsing forms of multiple sclerosis in the United States (U.S.), the treatment patterns and DMT use for SPMS versus RRMS patients is unknown.

OBJECTIVE: The objective of this study is to describe the burden of illness including the Expanded Disability Status Scale (EDSS) scores, number of relapses and patient-reported use of DMTs in RRMS and SPMS patients in the U.S.

METHODS: Patient-reported data were identified from the Adelphi Multiple Sclerosis Disease Specific Programme, a cross-sectional study of 114 neurologists and 1,697 patients in the U.S. between November 2013 and March 2014. 1,004 patients were diagnosed as RRMS and 266 with SPMS. Fisher's exact or chi-squared (for categorical outcomes) and Wilcoxon rank-sum test (for numerical outcomes) were used to determine differences between RRMS and SPMS patients.

RESULTS: SPMS patients were older with a mean age of 50.5 years vs. 41.9 years of age for RRMS patients (P < 0.0001). Over 80% of SPMS patients were likely to be unemployed versus approximately 40% of RRMS patients (P < 0.0001). The mean EDSS scores for SPMS patients were higher than RRMS patients both at time of questionnaire administration (5.04 vs. 2.32, P < 0.0001) and 12 months prior (4.55 vs. 2.26, P < 0.0001), respectively. SPMS patients also reported an average of 2.14 more relapses in total compared to RRMS patients (5.36 vs. 3.22, P < 0.0001). A higher proportion of SPMS patients vs. RRMS patients reported not using any DMT for their MS (19.2% vs. 9.85%, P < 0.0001).

CONCLUSIONS: In this study, compared with RRMS patients, SPMS patients have a significantly higher burden of illness, which includes a higher EDSS score and increased number of relapses experienced. In addition, SPMS patients are less likely to be treated with a DMT for their disease than RRMS patients, further highlighting the unmet need for therapies indicated for the treatment of SPMS.

SPONSORSHIP: This study was funded by Biogen Idec.

Patient-Reported Symptom Burden among Relapsing-Remitting Multiple Sclerosis (RRMS) Versus Secondary Progressive Multiple Sclerosis Patients (SPMS) in the United States

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BACKGROUND: Multiple sclerosis (MS) is a chronic and progressive neurological disease that is associated with a substantial clinical burden. As a result of the disease, MS patients experience a range of symptoms with varying degrees of severity, both daily and during exacerbations.

OBJECTIVE: The objective of this study is to evaluate the symptoms reported by both RRMS and SPMS patients in the United States (U.S.).

METHODS: Data were identified from the Adelphi MS Disease Specific Programme, a cross-sectional study of 114 neurologists and 1,697 patients in the U.S. Patient-reported data was available for 444 RRMS and 99 SPMS patients. The Wilcoxon rank-sum test was used to determine unadjusted differences between RRMS and SPMS patients. Patients reported symptoms as either “mild,” “moderate,” or “severe” and symptoms that were reported as “moderate” in at least 10% of either RRMS or SPMS patients have been included.

RESULTS: A higher proportion of SPMS patients than RRMS patients reported the following symptoms as “moderate”: stiffness and rigidity in muscles (30.3% vs. 10.8%, P < 0.0001), loss of movement in muscles (19.2% vs. 7.4%, P < 0.0001), weakness in muscles (36.4% vs. 14.2%, P < 0.0001), spams or cramps (19.2% vs. 11.0%, P = 0.0021), walking or mobility problems (32.3% vs. 9.9%, P < 0.0001), pain without apparent cause (11.1% vs. 6.8%, P < 0.0001), loss of coordination (20.2% vs. 14.6%, P = 0.0044), loss of balance (15.2% vs. 9.2%, P = 0.0066), bladder problems (22.2% vs. 4.5%, P < 0.0001), loss of interest in sex (10.1% vs. 4.7%, P < 0.0001), constipation (13.1% vs. 4.3%, P < 0.0001), depression (16.2% vs. 9.2%, P = 0.0212), fatigue (27.3% vs. 22.1%, P = 0.0233), symptoms worsening with heat or cold (11.1% vs. 5.0%, P = 0.0193), blurred vision/eye pain (21.2% vs. 11.9%, P = 0.2635), numbness, tingling or buzzing sensations (25.3% vs. 14.9%, P = 0.0631), loss of sensation or total numbness (11.1% vs. 5.6%, P = 0.0657) as well as difficulty concentrating (16.2% vs. 9.5%, P = 0.2976).

CONCLUSIONS: There is a high clinical burden experienced by MS patients, with the majority of symptoms reported by RRMS and SPMS patients related to physical or mobility problems. As the clinical burden of SPMS is higher than RRMS, there is a need to prevent patients from progressing from RRMS to SPMS.

SPONSORSHIP: This study was funded by Biogen Idec.

Patient-Reported Physical Functioning and Impact on Instrumental Activities of Daily Living (IADLs) in Relapse-Remitting Multiple Sclerosis (RRMS) and Secondary Progressive Multiple Sclerosis (SPMS) Patients in the United States

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BACKGROUND: Multiple sclerosis (MS) is a chronic inflammatory disease that can lead to increased physical impairment and diminished health related quality of life (HRQoL).

OBJECTIVE: The objective of this study is to evaluate patient-reported physical functioning, impact on HRQoL, and the need for assistance with IADLs in RRMS and SPMS patients in the U.S.

METHODS: Data were drawn from the Adelphi MS Disease Specific Programme, a cross-sectional study of 1,004 RRMS and 266 SPMS patients in the U.S. Patient reported data was available for 444 RRMS and 99 SPMS patients. Physical aspects of HRQoL were assessed using the Hamburg Quality of Life Questionnaire in MS (HAQUAMS) physical subscales, in which higher scores indicate more disability. Fisher’s exact or chi-squared (for categorical outcomes) and Wilcoxon rank-sum test (for numerical outcomes) were used to determine differences between RRMS and SPMS patients.

RESULTS: A higher proportion of SPMS than RRMS patients reported physical symptoms of motor (86.87% vs. 65.77%; P < 0.0001) and coordination symptoms (58.59% vs. 46.62%; P = 0.0348). Mean scores for the HAQUAMS lower limb subscale and upper limb subscale were higher for SPMS than RRMS patients (3.21 vs. 1.95; P < 0.0001, and 2.50 vs. 1.54; P < 0.0001, respectively). Furthermore, physicians report that a higher proportion of SPMS patients than RRMS patients require someone to be responsible for their daily needs (60.5% vs. 14.7%; P < 0.0001), which includes physical activities such as help getting into and out of bed (33.84% vs. 4.44%; P < 0.0001), preparing meals (47.15% vs. 9.50%; P < 0.0001), eating (6.84% vs. 0.21%; P < 0.0001), walking (54.75% vs. 4.55% vs. 2.26; P < 0.0001), walking or mobility problems (32.3% vs. 9.9%; P < 0.0001), pain without apparent cause (11.1% vs. 6.8%; P < 0.0001), loss of coordination (20.2% vs. 14.6%; P = 0.0044), loss of balance (15.2% vs. 9.2%; P = 0.0066), bladder problems (22.2% vs. 4.5%; P < 0.0001), loss of interest in sex (10.1% vs. 4.7%; P < 0.0001), constipation (13.1% vs. 4.3%; P < 0.0001), depression (16.2% vs. 9.2%; P = 0.0212), fatigue (27.3% vs. 22.1%; P = 0.0233), symptoms worsening with heat or cold (11.1% vs. 5.0%; P = 0.0193), blurred vision/eye pain (21.2% vs. 11.9%; P = 0.2635), numbness, tingling or buzzing sensations (25.3% vs. 14.9%; P = 0.0631), loss of sensation or total numbness (11.1% vs. 5.6%; P = 0.0657) as well as difficulty concentrating (16.2% vs. 9.5%; P = 0.2976).
CONCLUSIONS: There is a significant burden experienced by MS patients, with SPMS patients reporting a greater burden on physical functioning as well as higher levels of disability in upper and lower limb physical subscales than RRMS patients. Moreover, SPMS patients are more limited in their ability to perform instrumental daily activities and require assistance with their daily needs. As the impact on physical functioning is higher in SPMS than RRMS patients, there is a need to prevent patients from progressing to SPMS.

SPONSORSHIP: This study was sponsored by Biogen Idec.

G11 Predictors of Adherence Using Panel Survey Data from Multiple Sclerosis Patients Currently Treated with High-Dose, High-Frequency Interferons

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BACKGROUND: Treatment adherence is important for optimizing patient care in multiple sclerosis (MS).

OBJECTIVE: To evaluate the relationship between treatment with high-dose, high-frequency interferons and adherence among MS patients.

METHODS: A random sample of relapsing-remitting MS patients (age ≥ 18 years, clinical trial-naïve) from the U.S. National Health and Wellness Survey or Lightspeed Research Panel completed an Internet survey in November/December 2012. Adherence was evaluated among those indicating current treatment (≥ 4 months) with subcutaneous interferon beta-1a (scIFNB1a) three times weekly (tiw) or subcutaneous interferon beta-1b (scIFNB1b) every other day (cod). Adherence was measured using the 4-item Morisky Medication Adherence Scale (forget to take medication, careless at times about taking, stop if better, stop if worse; higher adherence = all negative responses). Baseline characteristics were compared using chi-square and t-tests. Logistic regression evaluated the relationship between scIFNB1a or scIFNB1b treatment and the odds of having high adherence. Covariates included age, sex, exercise, and therapy-related variables (months on therapy, satisfaction, perception of effectiveness, cost).

RESULTS: Of 969 surveyed, 80 scIFNB1a and 63 scIFNB1b patients met inclusion criteria (mean [standard deviation] age: 49.0 [10.4] years, 88.8% female vs. 51.3 [8.7] years, 87.3% female, respectively; P < 0.05). A greater percentage of scIFNB1a patients reported high adherence compared with scIFNB1b patients (38.8% vs. 33.3%; P = 0.0025). After adjusting for covariates, scIFNB1a patients had a greater odds of high adherence (odds ratio [OR] 2.92; P = 0.0101). Male sex (OR 4.37; P = 0.0297), time since last relapse (years; OR 1.04; P = 0.0483), frequent exercise (OR 1.06; P = 0.0094), and Patient-Determined Disease Steps score (OR 1.34; P = 0.0110) were predictive of high adherence.

CONCLUSIONS: In this exploratory analysis, treatment with scIFNB1a tiw was strongly associated with high adherence relative to scIFNB1b cod.

SPONSORSHIP: EMD Serono, Rockland, MA (a subsidiary of Merck KGaA, Darmstadt, Germany), and Pfizer, New York, NY.

G12 An Assessment of Adherence Among Multiple Sclerosis Patients Newly Initiating Treatment with a Self-Injectable Versus Oral Disease-Modifying Drug

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BACKGROUND: As the multiple sclerosis (MS) disease-modifying drug (DMD) class expands with oral entrants, it is important to understand how oral therapy may affect adherence.

OBJECTIVE: To evaluate adherence among MS patients newly initiating a self-injectable versus oral DMD.

METHODS: MS patients (age 18-63; ≥ 1 medical claim with MS diagnosis: ICD-9-CM:340.xx) with ≥ 1 DMD claim (first claim = index date), with continuous eligibility 12 months pre- and post-index, and with no DMD use during the pre-index period, were identified from a random sample of 5 million lives in the IMS LifeLink Plus database from July 1, 2010-June 30, 2013. Patients were stratified by index DMD type: self-injectable versus oral. Fisher and Wilcoxon tests were used in unadjusted statistical comparisons. Logistic regression was used to evaluate the likelihood of nonadherence (12-month post-index categorical medication possession ratio < 0.8 vs. ≥ 0.8) to index DMD group. Covariates included age, sex, and baseline comorbidities.

RESULTS: The analysis included 5,238 self-injectable and 444 oral DMD patients (mean age: 43.0 vs. 44.0, respectively; P = 0.0418). In unadjusted analyses, the percentage of patients who were nonadherent in the self-injectable (45.2%) and oral (41.8%) DMD groups did not differ statistically (P = 0.1791). After controlling for covariates, index DMD type was not a significant predictor of nonadherence (P = 0.1858). Male sex and older age groups (vs. 18-34) were associated with significantly lower likelihood of nonadherence (odds ratio [OR]: 0.811 and ORs: 0.697-0.813, respectively; P < 0.05). Depression was associated with higher likelihood of nonadherence (OR: 1.732, P < 0.0001).

CONCLUSIONS: In this analysis, there was no difference in nonadherence attributable to self-injectable versus oral DMDs. Male sex and older age were associated with a lower risk of nonadherence and depression was associated with a higher risk of nonadherence.

SPONSORSHIP: EMD Serono, Rockland, MA (a subsidiary of Merck KGaA, Darmstadt, Germany), and Pfizer, New York, NY.

G14 Budget Impact of Adding Peginterferon Beta-1a to the Formulary for the Treatment of Relapsing Forms of Multiple Sclerosis

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BACKGROUND: Peginterferon beta-1a is a new interferon that is dosed every 2 weeks via subcutaneous injection and indicated for the treatment of relapsing forms of multiple sclerosis (MS).

OBJECTIVE: To estimate the budget impact of adding peginterferon beta-1a to a managed care formulary in the U.S.

METHODS: A model was developed in Microsoft Excel to evaluate the budget impact over a 5-year time horizon of adding peginterferon beta-1a to the current mix of disease-modifying therapies (DMTs) used for the treatment of relapsing forms of MS. The model compared the drug-related and relapse costs of the current mix of treatments with the costs of an estimated treatment mix with peginterferon beta-1a included on a managed care organization (MCO) formulary for an MCO with 1,000,000 covered lives. The number of people with relapsing forms of MS in the MCO was estimated using published data.
prevalence data. Treatment share of peginterferon beta-1a was assumed to increase from 3% in 2014 to 7% in 2018 with this market share taken proportionately by treatment shares from the other interferons. Drug-related costs included: acquisition costs adjusted by co-payments or co-insurance rates and dispensing fees; administration and monitoring costs for related resource use; and adverse event treatment costs based on resource use for two potential adverse events, influenza-like symptoms and injection site necrosis. Annual relapse treatment costs were estimated using relapse rates from the ADVANCE phase 3 trial placebo group, relative risk reduction of a relapse for each DMT in the treatment mix derived using a mixed-treatment comparison analysis, and the treatment cost for a relapse from a U.S. study. A one-way sensitivity analysis was performed changing key input parameter values.

**RESULTS:** The estimated budget impact of adding peginterferon beta-1a to the formulary was negative for the first 5 years: in 2014, with a treatment share of 3.0%, the estimated budget decrease was 0.07% of the total annual costs for DMT-related and relapse treatment costs and a decrease of $0.005 per member per month (PMPM); in 2018, with a treatment share of 7%, the estimated budget decrease was 0.23% of the total annual costs and a decrease of $0.014 PMPM. Sensitivity analyses showed that the model was most sensitive to the acquisition costs of peginterferon beta-1a.

**CONCLUSIONS:** Under model assumptions for market shares, adding peginterferon beta-1a to the MCO formulary would result in a small decrease in MCO costs for patients with relapsing forms of MS.

**SPONSORSHIP:** Funding for this study was provided by Biogen Idec.

**G16** Research Effort Reveals Opportunities for Managing the Utilization of Dimethyl Fumarate

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**AcariaHealth**

**PROBLEM DESCRIPTION:** In December 2013, a national specialty pharmacy began a 12-month study of patients starting dimethyl fumarate. The observational study was designed to gain a better understanding of patient-reported tolerability and adherence by collecting endpoints that include the incidence of all adverse events and proportion of unresolved adverse events, as well as patient-reported adherence at predefined intervals (weeks 0, 1, 4, 8, 12, 24, 48). The study has since been extended to 96 weeks, and as of November 1, 2014, 165 of 750 enrolled patients had completed endpoint collection at week 24. Analyzing interim results of the study revealed additional opportunities for managing the utilization of dimethyl fumarate in relapsing-remitting MS patients. At the week 1, 4, 8, 12, and 24 assessments, 24%, 27%, 17%, 19%, and 13% of patients reported unresolved adverse events, respectively. Most common adverse events reported include flushing, stomach/GI upset and diarrhea. While most patients remained on therapy without modification, the rate of therapy modification (change in regimen) or discontinuation ranged from 1-7%. Notably, other than the week 4 assessment, the combined therapy modification and discontinuation rate did not exceed 2% of patients. During the week 4 assessment, 7% of patients reported modifying or discontinuing the medication since the week 1 assessment due to unresolved adverse events. The adverse events reported were consistent with product labeling. Regarding adherence, although 31% of patients reported missing at least one dose in the first 4 weeks of therapy, only 7% reported missing more than 2 doses.

**GOAL:** Based on these interim results, there was opportunity to address therapy discontinuation and adherence in the first month of therapy.

**PROGRAM DESCRIPTION:** After taking into account the needs of all stakeholders in the patient's health, the specialty pharmacy decided to augment the patient and prescriber education programs for all dimethyl fumarate patients to highlight the findings, while recommending that payers review their utilization to determine if the similar opportunities exist.

**OBSERVATIONS:** Options explored include a split-fill program, modifying recommended initial authorization period and an additional targeted adherence program. Outcomes of this effort are forthcoming.

**FINDINGS/RECOMMENDATIONS:** Future insights into patient-initiated vs. prescriber-initiated therapy modifications and discontinuations as well as efficacy outcomes (relapse and hospitalization rates) will further refine the approach to patient and utilization-management programs.

**SPONSORSHIP:** Research study sponsored by Biogen Idec. Review and analysis sponsored by AcariaHealth, a Centene Corporation Specialty Company.
Patients were excluded if they (1) were on combination therapy (i.e., diagnosed with epilepsy. The index date was the first date of AED use. January 2007 to October 2010 were extracted for adults (18-63 years) monotherapy patients were associated with epilepsy-related events.

**RESULTS:** The study assessed if change in treatment patterns for monotherapy patients were associated with epilepsy-related events. The event rate ratio (ERR) was computed for controlling for demographics, chronic disease score, mental comorbidity, and type of epilepsy. The event rate ratio (ERR) occurred. A Cox proportion hazard model evaluated the risk of an epilepsy-related event for the change versus non-change cohorts, while switches, and discontinuations within 9 months of index date (i.e., change-cohort). For the change-cohort, the ‘change’ date was the date at which the treatment change occurred, while for the non-change cohort, the corresponding date was a random date of an AED fill. Patients were followed for another 3 months after the change date or until an epilepsy-related event (i.e., emergency department visit or hospitalization) occurred. A Cox proportion hazard model evaluated the risk of an epilepsy-related event for the change versus non-change cohorts, while controlling for demographics, chronic disease score, mental comorbidities, and type of epilepsy. The event rate ratio (ERR) was computed for the cohorts. SAS 9.3 was used for statistical analyses.

**RESULTS:** Patients with epilepsy initiated on monotherapy (n = 3,647) had a mean age of 37.9 ± 13.4 years, were primarily female (58.5%), White (42.1%), on phenytoin (33.8%), with a mean CDS of 1.2 ± 3.1. About 3.5% added at least one AED, 12.0% switched to a different AED, and 46.4% discontinued the index AED. Commonly, phenytoin (22.8%) was used as add-on AED, while levetiracetam (23.7%) was used in the switch-to AED. The overall number of events were 91 (2.5% of patients). Based on the Cox proportional hazard model, there were no significant differences in risk of an epilepsy-related event between the addition (hazard ratio [HR] = 0.99, P = 0.8963), switch (HR = 0.97, P = 0.5794), discontinuation (HR = 0.99, P = 0.7190), and the non-change cohorts. Also, the overall change versus non-change cohorts did not demonstrate significant differences in the ERRs for epilepsy-related events (ERR: 1.19, 95% CI: 0.73-1.93).

**CONCLUSIONS:** For this sample, no differences were found in the 3-month risk of an epilepsy-related event between patients who added, switched, and discontinued the index AED and those with no change in treatment pattern. Other patient populations should be studied.

**SPONSORSHIP:** None.

**G24 Events Associated with Change in Treatment Patterns for Patients with Epilepsy Initiated on Antiepileptic Monotherapy**

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**BACKGROUND:** Monotherapy with antiepileptic drugs (AEDs) is the preferred initial management approach in patients with epilepsy.

**OBJECTIVE:** To conduct a meta-analysis of the literature, comparing treatment of chronic migraine with/without onabotulinumtoxinA.

**METHODS:** We conducted a systematic review using PubMed, Cochrane and MEDLINE databases to identify RCTs of onabotulinumtoxinA in migraine conducted between January 2008 and December 2014 and published in English. Eligible studies included those with at least 15 headache days/month as a baseline measure and treatment with onabotulinumtoxinA in comparison with a control group. The outcome was operationalized as the difference in pre-post change in number of headache days between treatment and control. A random effects model was used for analysis.

**RESULTS:** Of the 129 articles reviewed, 16 studies met the inclusion criteria. The overall weighted mean difference (WMD) of 0.202 days (0.047 to 0.357, P = 0.010) favors treatment. The WMDs at 1 month, 2 months, 3 months, 6 months, and >9 months were 0.143 days (-0.066 to 0.353, P = 0.180), 0.202 days (0.047 to 0.357, P = 0.188), -0.057 days (-0.257 to 0.142, P = 0.574), 0.715 days (0.254 to 1.177, P = 0.002), and -0.075 days (-0.416 to 0.266, P = 0.667), respectively. In the sensitivity analysis, the WMD (0.395 days [0.222 to 0.568, P < 0.0001]) after excluding placebo responders (PR) was statistically significant whereas the WMD (0.160 days [-0.049 to 0.365, P = 0.126]) after excluding placebo non-responders (PNR), was not significant. However, the effectiveness for the PR and PNR groups was consistently significant at the 6-month interval.

**CONCLUSIONS:** The overall results suggest that onabotulinumtoxinA has slightly better effectiveness in reducing number of headache days. However, further long-term follow-up studies are needed to draw a definitive conclusion.

**SPONSORSHIP:** This research did not receive any funding.

**G25 Effectiveness of OnabotulinumtoxinA Therapy in the Management of Episodic and Chronic Migraine: A Meta-Analysis**

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**BACKGROUND:** Migraine is a chronic neurological disorder characterized by recurrent episodes of headache and associated symptoms. The FDA recently approved onabotulinumtoxinA (BOTOX®) for management of pain in chronic migraine patients. Previous randomized controlled trials (RCTs) of safety and efficacy of onabotulinumtoxinA have not definitively established its value.

**OBJECTIVE:** To assess quality-of-life measures in patients with chronic migraine with/without onabotulinumtoxinA.

**METHODS:** A randomized, placebo-controlled trial was previously conducted in patients with narcolepsy with cataplexy (N = 228) who were randomized to placebo or SXB 4.5 mg, 6 mg, or 9 mg nightly for 8 weeks; 6- and 9-gm/night doses were titrated in weekly 1.5-gm increments. In addition to previously reported measures of sleepiness and cataplexy, quality of life was assessed at baseline and end of treatment using the SF-36. Changes from baseline, using last-observation-carried-forward, were compared between active treatment groups and placebo using the Mann-Whitney test, and effect sizes were estimated (Cohen’s d; 0.20 = small, 0.50 = medium, and 0.80 = large).

**RESULTS:** Baseline values on all SF-36 domains were substantially lower than normative values for the U.S. general population. After 8 weeks of treatment, mean ± SD improvement from baseline on the Physical Component score was significantly greater than
placebo (1.5 ± 6.2) with SXB 9 gm/night (6.3 ± 9.1; P = 0.005), showed a moderate effect size (0.616), and exceeded the minimal clinically relevant difference of 5. On the Mental Component score, none of the differences between SXB and placebo was significant. SXB 9 gm/night resulted in significantly greater improvement on the domains of Physical Functioning (4.4 ± 9.2 vs. 1.0 ± 8.0; P = 0.016; effect size = 0.394), General Health (3.1 ± 7.0 vs. 0.4 ± 6.8; P = 0.036; effect size = 0.395), and Social Functioning (6.8 ± 16.8 vs. 1.1 ± 9.6; P = 0.033; effect size = 0.417). On the Vitality domain, all SXB doses resulted in statistically significant improvements from baseline relative to placebo (P < 0.05) in a dose-dependent manner, demonstrated moderate effect size, and exceeded the clinically significant difference of 5. No significant differences versus placebo were observed on the domains of Physical Role, Emotional Role, and Mental Health.

CONCLUSIONS: SXB appeared to improve quality-of-life measures in patients with narcolepsy with cataplexy in a dose-dependent manner with positive impact at the 9-gm/night dose on the Physical Component score and individual SF-36 domains of Vitality, General Health, and Physical and Social Functioning.

SPONSORSHIP: This study was funded by Jazz Pharmaceuticals.

G27 The Association Between Number of Antiepileptic Drug Pills Taken Per Day and Health Care Costs Among Patients with Epilepsy in the United States

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BACKGROUND: Epilepsy is a common chronic neurological disorder affecting more than 2.2 million individuals in the United States (U.S.) and has a significant impact on medical expenditure. Lower pill burden has been associated with decreased health care costs in several therapeutic areas, and its impact among patients with epilepsy needs to be assessed.

OBJECTIVE: This study evaluated the impact of the number of antiepileptic drug (AED) pills per day at initiation of monotherapy on health care costs among patients with epilepsy in a large real-world setting.

METHODS: A retrospective analysis of the large U.S. commercial claims IMS PharMetrics Plus database (January 1, 2006-December 31, 2011) was conducted to assess the impact of AED pill burden, defined as the number of AED pills per day, on health care costs in adults with epilepsy. Patients aged 18-65 years with ≥ 2 epilepsy diagnoses and ≥ 2 AED prescription claims were selected for study inclusion. The date of the first AED monotherapy claim was defined as the index date. Continuous health plan enrollment 12 months pre- and post-index date was required. Two cohorts were formed based on treatment type: monotherapy (no additional AED prescription overlapping with index AED prescription) and adjunctive therapy (additional AED claim with a 30-day overlap of the index AED prescription). Follow-up all-cause and epilepsy-related healthcare costs were compared using gamma-distributed log-link linear regression models.

RESULTS: Of the 53,338 study patients, 13.2%, 37.6%, 20.8%, and 28.4% had 1, 2, 3, and > 3 AED pills per day at initiation of an AED monotherapy, respectively. Adjusting for confounders, an AED pill burden of > 3 pills per day was associated with a 6.7% increase in total annual health care costs compared to patients with 1 AED pill per day (P < 0.001). Disease-related annual health care costs among patients with index AED pill burdens of 2, 3, and > 3 AED pills per day were 13.3%, 23.9%, and 38.3% higher, respectively, compared to 1 AED pill per day (P < 0.001). The adjusted total and epilepsy-related mean per-person annual health care costs were estimated at $22,619 and $4,890, respectively. For patients initiating a 1, 2, 3, and > 3 pills per day AED monotherapy, adjusted mean per-person annual health care costs were estimated at $21,974, $23,280, $23,049, and $21,730, and adjusted mean per-person epilepsy-related health care costs were estimated at $3,776, $5,483, $4,106, and $5,195, respectively.

CONCLUSIONS: In this study, patients initiating an AED prescribed as a single pill per day incurred lower health care costs during the year following monotherapy initiation than patients with greater pill burdens.

SPONSORSHIP: This study was sponsored by Sunovion Pharmaceuticals.

G28 Cost Analyses Among U.S. Veterans Diagnosed with Epilepsy and Treated with Antiepileptic Drug Monotherapy or Adjunctive Therapy

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BACKGROUND: Few epilepsy population-based cost analyses have been completed utilizing the U.S. Veterans Health Administration (VHA) population. Previous studies have produced varied results when evaluating the cost of both monotherapy and adjunctive therapy.

OBJECTIVE: To identify risk factors associated with high healthcare costs among patients with antiepileptic drug (AED) monotherapy and adjunctive therapy.

METHODS: Adult patients (≥ 18 years) with ≥ 2 diagnosis claims for epilepsy (ICD-9-CM: 345) or one diagnosis claim for epilepsy and one for other convulsion (ICD-9-CM: 780.39) were selected from the VHA dataset (October 1, 2008-September 30, 2012). Patients were required to have ≥ 1 AED prescription claim post-epilepsy diagnosis, with the first AED prescription designated as the index date. Continuous health plan enrollment 12 months pre- and post-index date was required. Two cohorts were formed based on treatment type: monotherapy (no additional AED prescription overlapping with index AED prescription) and adjunctive therapy (additional AED claim with a 30-day overlap of the index AED prescription). Follow-up all-cause and epilepsy-related healthcare costs were compared using gamma-distributed log-link linear regression models.

RESULTS: Patients in the adjunctive therapy cohort (n = 764) were younger (55 vs. 58 years, P < 0.001), and had lower rates of diabetes (15.3% vs. 19.7%, P = 0.003) and cardiovascular disease (44.9% vs. 57.13%, P < 0.001) compared to those in the monotherapy cohort (n = 8793). In the adjusted analyses, patients treated with adjunctive therapy incurred significantly higher all-cause ($31,021 vs. $23,602, P < 0.001) and epilepsy-related healthcare costs ($15,880 vs. $10,726, P < 0.001) compared to those prescribed monotherapy. Older age, race (African American), Charlson comorbidity index ≥ 3, ER/Inpatient visits, schizoaffective, depression, PTSD and intentional injuries were significantly associated with an increase in all-cause healthcare costs. Presence of obesity and outpatient visits in the 12-month pre-index period were associated with lower all-cause costs. These same factors were predictive of epilepsy-related costs, with the exception of Charlson comorbidity index ≥ 3, depression and PTSD.

CONCLUSIONS: In this study of the VA patient population, patients with baseline psychiatric disorders and those treated with adjunctive therapy incurred higher follow-up healthcare costs. Further examination concerning the cost of various treatment methods and the role of psychiatric and medical disorders among epilepsy patients is needed.

SPONSORSHIP: This study was sponsored by Sunovion Pharmaceuticals.
G29 Breath-Powered Nasal Delivery of Sumatriptan Powder (AVP-825): An Exploratory Analysis of Rapid Response in Migraine Patients Grouped by Prior Triptan History from the Phase 3 TARGET Study

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BACKGROUND: Triptans are a valuable therapy choice for acute treatment of migraine, though observational studies consistently show low persistence with triptan therapy and frequent switching. Switching may occur for various reasons including cost, formulary restrictions, adverse events, and perceived lack of efficacy. Since many patients seek treatment after trying multiple triptans, the clinical impact of migraine drugs should also be evaluated in these patients. AVP-825 is an investigational combination product containing low-dose (22 mg) sumatriptan (the most commonly used triptan) powder delivered using Bi-Directional Breath Powered technology.

OBJECTIVE: To assess the efficacy of AVP-825 vs. placebo based on history of prior triptan use in patients from the TARGET trial (NCT014628112).

METHODS: This phase 3, multicenter, randomized, double-blind, placebo-controlled, single-dose, parallel-group study was conducted in patients with 1-8 migraines/month in the year prior to screening. Patients with a history of sumatriptan resistance or non-response to ≥2 other triptans at an adequate dose and treatment duration were excluded. Each patient treated a single migraine of moderate or severe intensity with 1 dose of AVP-825 or identical device containing placebo. Proportion with headache relief and pain freedom at 10, 15, 30, 45, 60, 90 and 120 minutes post-dose was calculated in patients with a history of using ≥2 <2 triptans, or prior sumatriptan, and analyzed using Fisher’s exact test (AVP-825 vs. placebo) and logistic regression models (subgroup comparisons).

RESULTS: Patients who had previously used ≥2 triptans had significantly greater pain relief rates with AVP-825 (n = 34) vs. placebo (n = 39) from 30 minutes (47.1% vs. 23.1%, P < 0.05) through 120 minutes (61.8% vs. 35.0%, P < 0.05). AVP-825 conferred superior pain freedom rates at 45 minutes (23.5% vs. 5.1%, P < 0.05) through 120 minutes (32.4% vs. 7.5%, P < 0.05). Migraine relief rates with ≥2 triptans were generally consistent with those for ≥2 triptans, though with larger magnitude of effect that was not statistically significant. In patients previously using sumatriptan, pain relief rates with AVP-825 (n = 49) were superior to placebo (n = 42) at 30 minutes (51.0% vs. 22.0%, P < 0.05) through 120 minutes (77.6% vs. 38.1%, P < 0.05), as were pain freedom rates at 45 minutes (22.5% vs. 4.9%, P < 0.05) through 120 minutes (36.7% vs. 4.9%, P < 0.05).

CONCLUSIONS: In patients who have tried multiple triptans, as is common in the migraine population, AVP-825 delivery of low-dose sumatriptan powder produced rapid relief and superior efficacy versus placebo on multiple measures of headache.

SPONSORSHIP: TARGET was co-funded by OptiNose U.S. and Avanir Pharmaceuticals.

G33 Cost of Opioid Overutilization in a Medicare Population Under Alternative Definitions of Overutilization

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BACKGROUND: The CMS Medicare Part D Overutilization Monitoring System and 3 draft measures of opioid overutilization from the Pharmacy Quality Alliance (PQA) incorporate patient-level criteria of ≥4 prescribers and ≥4 pharmacies and morphine equivalent dose (MED) of ≥ 120 mg.

OBJECTIVE: The purpose of this study is to examine the prevalence and costs of opioid overutilization patients under alternative overutilization definitions.

METHODS: This study utilized medical and pharmacy claims from the Humana Research Database (Humana, Louisville, KY) for Humana Medicare members. Members were included if they were continuously enrolled during 2013, ≥18 years of age, had ≥2 opioid Rx’s and ≥1 medical claim during 2013. Cancer patients were excluded. Two base measure definitions were evaluated: (1) Members receiving opioid Rx’s from ≥4 prescribers and ≥4 pharmacies (Shoppers), and (2) Members meeting the Shopper criteria AND receiving >90 consecutive days of 120 mg MED (Shopper+MED). For each definition, mean healthcare (medical + pharmacy) cost per member and total plan healthcare cost for members meeting overutilization criteria were calculated. Thresholds of the prescriber and pharmacy criteria, each ranging from 3 to 6, were assessed for both base measures to evaluate the impact of varying the criteria and to inform opioid quality improvement strategies.

RESULTS: Of the study population (n = 317,908), 4,744 members (1.49%) met Shopper criteria and 631 (0.20%) members met Shopper+MED criteria. Mean healthcare cost per member was $33,032 for Shopper and $35,227 for Shopper+MED. Mean pharmacy costs per member were $4,840 for Shopper and $7,446 for Shopper+MED. Of the total 2013 healthcare cost for the study population ($4.91 billion), Shoppers accounted for 3.39%, while Shopper+MED patients accounted for 0.45%. When prescriber/pharmacy thresholds were set at 3/3, Shoppers (n = 17,590, 5.53%) had mean cost per member of $28,528 and representative 10.23% ($501.8 million) of total healthcare costs while 6/6 threshold Shoppers (n = 526, 0.17%) had corresponding results of $55,713 per member and represented 0.60% ($293.3 million) of total healthcare costs. Results will be presented in the poster for both base measures at prescriber and pharmacy thresholds ranging from 3 to 6.

CONCLUSIONS: Changing thresholds for number of prescribers and number of pharmacies or adding a dosage criterion changes the population size and cost of patients meeting opioid overutilization criteria. This information can help managed care plans assess trade-offs in the design of interventions to improve appropriate use of opioids.

SPONSORSHIP: This study was funded by Janssen Scientific Affairs.
OBJECTIVE: To (1) assess the effect of adding an IVR component to a letter-based refill reminder and 90-day fill adherence intervention, and (2) describe and quantify patients’ self-reported barriers to medication adherence.

METHODS: CMS Patient Safety Reports for the January-October 2013 and January-October 2014 periods were compared to estimate program effects on health plan adherence rates. Market share of 90-day fills were compared to address additional effects of the prescriber program. Summarized self-reported data during June-November 2014 was used to evaluate call activity and patients’ response. Published CMS Star Ratings and Patient Safety Reports were used to track plan quality performance for the last 3 CMS measurement years.

RESULTS: A total of 2,738 refill reminder calls were made between June-November 2014. The percentage of calls authenticated was 48.9% from which 69% of patients indicated plans to refill. Among the remaining patients reporting no intent to refill, 57% provided a reason or barrier. The most common reason was cost prevented refill (46.2%), followed by doctor recommended stopping (21.8%), problems with side effects (14.1%), lack of transportation (10.3%), and not understanding instructions (7.7%). Market share for 90-day use increased an average 5.6% from 2013 to 2014. Adherence rates from January-October 2014 for DM, HTN and CHOL were an average 2.1 points higher than the same 2013 period.

CONCLUSIONS: IVR outreach communication with existing adherence programs continued to demonstrate effectiveness improving medication adherence rates. Results suggest incremental improvements over letter-only based communications. Data acquired through IVR technology may serve to enhance intervention performance and patient outcomes by understanding adherence barriers.

SPONSORSHIP: This research was conducted by MedImpact Health-care Systems, San Diego, CA, without external funding.

13 Health Care Resource Utilization and Costs Among Patients with Atherosclerotic Cardiovascular Disease

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BACKGROUND: Atherosclerotic cardiovascular disease (ASCVD) is a leading cause of morbidity and mortality in the U.S. This study investigated healthcare resource utilization (HCRU) and costs among ASCVD patients, as defined by the 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines, in a real-world environment, in order to understand the burden of disease and unmet need in this population.

OBJECTIVE: To describe baseline and follow-up all-cause and ASCVD-related HCRU and costs among ASCVD patients.

METHODS: This retrospective cohort study utilized claims data from the HealthCore Integrated Research Database (HIRDM) to identify newly diagnosed ASCVD patients between January 1, 2007 and November 30, 2012 (index date = first ASCVD diagnosis date). Patients had both ≥12 month pre- and post-index health plan enrollment and no lipid lowering medication (LLM) use at baseline. Descriptive and inferential statistics were used to examine all-cause and ASCVD-related HCRU and costs at baseline and 12 and 36 months follow-up, among all patients and by subgroups based on LLM use pattern and/or follow-up low-density lipoprotein cholesterol (LDL-C) levels. Costs were adjusted to 2013 dollar values.

RESULTS: 128,017 ASCVD patients were identified with a mean age of 59 years, 43.1% female, and 48.8% with ≥36 months follow-up. Patients on high intensity statins or with follow-up LDL-C <70 or 100 mg/dL had a high proportion of acute coronary heart syndrome as their ASCVD index diagnosis. Baseline mean (SD) all-cause costs were $8,852 ($25,608). At 12 months follow-up, mean (SD) all-cause and ASCVD-related costs were $31,443 ($34,040) and $20,289 ($45,159), respectively. The mean (SD) all-cause and ASCVD-related costs for patients on high-intensity statins in all 4 quarters of follow-up were $36,324 ($52,954) and $50,015 ($50,490), respectively, primarily driven by high inpatient utilization. Patients with LDL-C reduction >50% or follow-up LDL-C <70 or 100 mg/dL had mean (SD) all-cause costs of $42,988 ($53,980), $40,969 ($53,143), and $33,418 ($48,195) and ASCVD-related costs of $34,448 ($50,842), $31,771 ($48,609), and $24,577 ($43,824), respectively. The 36-month analysis provided similar findings.

CONCLUSIONS: ASCVD patients, who met the 2013 ACC/AHA guidelines with intensive statin therapy or the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guidelines on LDL-C goal attainment, had significant residual HCRU and costs. Additional management may be required to address unmet need and reduce the cost burden among ASCVD patients.

SPONSORSHIP: Study funding was provided by Eli Lilly and Company.

14 Comparison of Health Care Costs Between Patients Achieving Low-Density Lipoprotein Particle Targets and Patients Achieving Low-Density Lipoprotein Cholesterol Targets

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BACKGROUND: We previously conducted a real-world analysis of a large commercially insured U.S. population comparing cardiovascular (CV) events between high risk patients achieving an LDL particle (LDL-P) target vs. LDL cholesterol (LDL-C) target. We observed reductions in CV risk in the LDL-P target group of 22-25% which may influence health care costs.

OBJECTIVE: To examine differences in health care costs across patients achieving LDL-P vs. LDL-C targets.

METHODS: Adult patients were selected from the HealthCore Integrated Research Database. Patients who achieved LDL-P <1,000 from 2006-2012 were placed into the LDL-P cohort, patients without LDL-P tests, but who achieved LDL-C <100, were placed into the LDL-C cohort. Index date was the earliest observed LDL-P or LDL-C target. High risk patients were those with CHD or diabetes pre-index. Baseline characteristics were assessed 6 months pre-index and patients were followed for 12-36 months post-index. Propensity score matching was used to balance pre-index demographic and comorbidity differences while leaving treatment patterns intact. CVD-related costs included all health plan paid amounts related to CV events or lipid management based on ICD-9-CM codes. Costs were Winsorized prior to comparison. Generalized linear models with a log link and gamma distribution were used to estimate differences across cohorts.

RESULTS: Matched LDL-P and LDL-C patients (N = 2,094 per cohort with ≥12 months of follow-up) were balanced with respect to demographics and comorbidities. At 12 months follow-up, mean CVD-related medical costs were lower in the LDL-P cohort ($556 vs. $635, P<0.001), while lipid-altering Rx costs were higher ($704 vs. $455, P<0.001), leading to higher total (medical + Rx) costs ($2,326 vs. $3,139, P<0.001). At 24 and 36 months further improvements in medical costs offset the increased Rx costs, leading to lower but...
non-significant differences in total costs across the cohorts ($4,849 vs. $5,131 at 36 months; P = 0.473).

**CONCLUSIONS:** Recent work suggests that real-world patients achieving LDL-P targets received more aggressive lipid-lowering treatment than patients achieving LDL-C targets, and that these treatment differences are associated with a reduction in CV event rates. The current analysis suggests that these treatment differences and reductions in CV risk result in higher pharmacy costs initially but lower medical costs over time among patients achieving LDL-P targets. Greater potential cost savings may be achieved over a longer time horizon particularly with the increased use of higher potency generic statins.

**SPONSORSHIP:** Liposcience.

**18 Heart Failure in the Medicare Population: An Actuarial Cost Analysis**

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**BACKGROUND:** The high prevalence, morbidity, mortality and cost of heart failure (HF) demand attention in the Medicare population. Quantifying the components of this burden for the Medicare fee for service (FFS) population highlights the opportunity for more efficient management of the HF population.

**OBJECTIVE:** The aim of this analysis was to quantify the burden of HF in the FFS Medicare population, focusing on cost, mortality and utilization metrics, using paid claims data.

**METHODS:** This was a descriptive, claim based analysis using the de-identified 2012 Medicare 5% sample. Beneficiaries were required to have eligibility in all of 2011 and at least one month in 2012, not be enrolled in a Medicare Advantage plan and have Part A and B eligibility during the study period. HF beneficiaries were identified using standard HEDIS criteria. Admission, readmission and SNF utilization were identified using a combination of revenue and HCPCS codes. Readmission rates were calculated using a modified version of the Agency for Healthcare Research and Quality methodology. Mortality data was available in the beneficiary eligibility files.

**RESULTS:** There were 160,390 beneficiaries meeting the HF study inclusion criteria from an initial 1,461,935 Medicare FFS beneficiaries for an 11% prevalence rate. The per member per month (PMPM) cost (mean; trended to 2014) for the HF population was $3,482 versus $791 for the non-HF population. Overall, 34% of total Medicare FFS spending was contributed by beneficiaries with HF. The annual inpatient admission rate was 1,307/1,000 HF beneficiaries versus 227/1,000 non-HF beneficiaries. The HF population contributes 55% of total Medicare FFS all-cause readmissions with a 28% all-cause readmission rate among the HF population compared to a 16% rate for the non-HF population. The mortality rate among the HF population was 21.5% versus 4.1% for the non-HF population, amounting to 39% of all Medicare FFS all-cause readmissions with a 28% all-cause readmission rate among the HF population compared to a 16% rate for the non-HF population. The mortality rate among the HF population was 21.5% versus 4.1% for the non-HF population, amounting to 39% of all Medicare FFS beneficiary deaths contributed by HF beneficiaries. The skilled nursing facility (SNF) admission rate per year was 356/1,000 HF patients compared to 45/1,000 non-HF patients, amounting to 49% of all Medicare FFS SNF admissions contributed by the HF population.

**CONCLUSIONS:** Using paid claims data, we calculated key cost and utilization metrics for Medicare FFS beneficiaries with HF. Our analysis has demonstrated that beneficiaries with HF use a disproportionate share of Medicare services, and have substantially higher mortality and admission rates than beneficiaries without HF. Opportunities exist for better HF management for payers and providers.

**SPONSORSHIP:** Novartis Pharmaceuticals.

**19 Utilization of Dabigatran in Patients with Atrial Fibrillation: Impact of the ACCP Guidelines and the SAMe-TT2R2 Score**

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**BACKGROUND:** The American College of Chest Physicians Antithrombotic Guidelines, 9th edition (AT9) recommends dabigatran (D) over warfarin (W) in patients with atrial fibrillation (AF) with certain exceptions. The SAMe-TT2R2 (STR) score identifies patients likely to be well controlled on W (INR 2-3). Due to the cost of D, it is important to anticipate the demand for this drug in order to properly plan for budgetary and formulary considerations.

**OBJECTIVE:** The objective of this study was to determine the proportion of patients eligible to receive D based upon the AT9 guidelines and the STR score in a cohort of patients with AF treated with W.

**METHODS:** Patients with AF receiving W with a CHA2DS2VASc ≥ 2 followed at our university teaching hospital were evaluated for potential D use based on the AT9 guidelines and the STR score. Reasons for exclusion for the use of D were tabulated.

**RESULTS:** A total of 1,624 consecutive patients with AF treated with W with a CHA2DS2VASc ≥ 2 were included. Based on AT9, 1,213 (74.7%) patients had an exclusion to the use of D. These included valvular heart disease in 73 (4.5%), stable coronary artery disease in 600 (36.9%), recent stent placement in 276 (17.0%), acute coronary syndrome without stenting in 49 (3.0%), and CrCl < 30 ml/min in 215 (13.2%). Of the remaining 411 (25.3%) of patients, an STR ≥ 2 indicating poor INR control with W was found in 112 patients. After exclusions based on AT9 and the STR, 18% (299/1,624) of patients would be eligible for D.

**CONCLUSIONS:** Based on the recommendations of the AT9 and the STR, the use of D would be considered appropriate in 18% of patients with AF eligible for anticoagulation. The most common reasons for exclusion of D were coronary artery disease, recent stent placement, poor renal function, and an STR indicating a high probability of adequate INR control on W.

**SPONSORSHIP:** None.

**10 Real-World Assessment of Hospital Readmission Among Hospitalized Patients with Nonvalvular Atrial Fibrillation Treated with New Oral Anticoagulants: An Early Evaluation**

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**BACKGROUND:** Three new oral anticoagulants (NOACs), apixaban (apix), dabigatran (dabi), and rivaroxaban (riva), are currently approved in the U.S. for stroke prevention among patients with nonvalvular atrial fibrillation (NVAF). In clinical trials, NOACs were shown to have different efficacy and bleeding profiles relative to warfarin.

**OBJECTIVE:** To conduct a real-world analysis to provide an early view of hospital readmissions among hospitalized NVAF patients treated with NOACs in the U.S.

**METHODS:** Patients ≥ 18 years of age with a primary or secondary hospital discharge diagnosis of AF who received apix, dabi, or riva any time during the hospitalization were identified from the Premier Hospital database between January 1, 2012 and February 28, 2014. Patients were grouped into 3 cohorts depending on which NOAC was treated. Patients were grouped into 3 cohorts depending on which NOAC was received during hospitalization. Patient demographics and clinical characteristics were evaluated. Multivariable logistic regressions were performed.
used to evaluate the risk of all cause and bleeding-related hospital readmission within 1 month associated with use of the 3 NOACs. Additionally, multivariable generalized linear models were used to evaluate the impact of use of the different NOACs on hospital healthcare utilization.

RESULTS: Among NVAF patients included in the study population, 4,138 received apix, 37,754 received riva, and 32,838 received dab in during hospitalization. Patients who received apix were older (apix: 73.6 years vs. riva: 72.3 years, vs. dab: 71.9 years, P < 0.001) and had higher risks of stroke and bleeding as measured by CHADS2: (apix: 2.2 vs. riva: 2.0 vs. dab: 2.1, P < 0.001) and HAS-BLED scores (apix: 2.6 vs. riva: 2.4 vs. dab: 2.3, P < 0.001). Of the study cohorts, those who received dab had the lowest bleeding risk. After controlling for patient characteristics, including comorbidity and stroke and bleeding risks, in comparison with use of apix, the odds of all cause and bleeding related 1-month hospital readmissions were estimated at 1.2 (P < 0.001) and 1.4 (P < 0.01) respectively for riva and 1.1 (P < 0.18) and 1.2 (P = 0.13) respectively for dab in. In comparison with use of apix, use of riva and dab in were associated with longer hospital lengths of stay of 0.25 days (P < 0.001) and 0.11 days (P = 0.08), respectively, due to the 1-month readmissions.

CONCLUSIONS: In this early real-world evaluation, NVAF patients using different NOACs had different patient characteristics, including their stroke and bleeding risks. Use of riva vs. apix was associated with significantly greater risk of all cause or bleeding-related 1-month readmissions.

SPONSORSHIP: This research was funded by Bristol-Myers Squibb and Pfizer.

112 Health Care Resource Utilization in Heart Failure: Differences Based on Health Plan Type
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BACKGROUND: The resource burden of heart failure (HF) to society and the healthcare system is substantial; understanding variability of this burden across certain subgroups may provide useful insights for their management.

OBJECTIVE: This study examined healthcare resource utilization (HCRU) and costs among patients with HF based on health plan (Medicare Advantage with Part D [MAPD] vs. commercial).

METHODS: A retrospective study of medical and pharmacy claims data from a large U.S. health plan was conducted. Included individuals were ≥ 18 years with ≥ 2 medical or ≥ 1 inpatient claim(s) with ICD-9-CM diagnosis code for HF (402.x1, 404.x1, 404.x3, 428.xx). Date of earliest claim for HF during January 2010-December 2011 was defined as the index date. Individuals ≥ 65 years with commercial coverage were excluded. Cohort assignment (2) was based on health plan at index. All-cause and HF-related HCRU (indicators and per-subject-per-month [PSPM] costs) and PSPM healthcare costs were calculated for up to 24 months following index date. Pearson's chi-square tests and independent samples t-tests were used to examine differences in post-index HCRU indicators and costs, respectively, by cohort. Note that lack of data on supplemental coverage may bias comparisons of cost data by health plan.

RESULTS: A total of 118,385 individuals with claims for HF (median age 74 years, 52% female) were identified, 88,904 with MAPD coverage and 29,381 with commercial coverage. Compared with commercial enrollees, a smaller percentage of MAPD enrollees had a Charlson score of zero (18.0 vs. 32.1%) and a larger percentage had a score ≥5 (15.5 vs. 9.2%). Compared with commercial enrollees, MAPD enrollees experienced fewer PSPM all-cause ambulatory visits (2.0 vs. 2.5 visits, P < 0.001). However, larger percentages of MAPD enrollees were hospitalized (all-cause: 74.3 vs. 65.7%; HF-related: 64.2 vs. 57.3%; P < 0.001) and readmitted in 30 days of a HF-related hospitalization (all-cause: 24.2 vs. 18.3%; HF-related: 17.7 vs. 11.3%; P < 0.001). PSPM all-cause total healthcare costs were $5,147 for MAPD enrollees (medical: $4,838; pharmacy: $309) and $8,491 for commercial enrollees (medical: $8,031; pharmacy: $480). PSPM HF-related medical costs were $3,156 for MAPD enrollees and $5,034 for commercial enrollees.

CONCLUSIONS: Compared to commercial enrollees, MAPD enrollees experienced fewer all-cause ambulatory visits, yet hospitalization and rehospitalization (within 30 days of HF-related hospitalization) occurred in larger percentages of MAPD enrollees. Strategies to mitigate these differences across health plans in patients with HF are required.

SPONSORSHIP: This study was funded by Novartis Pharmaceuticals, East Hanover, NJ.

113 Patients with Cardiorenal Comorbidities on Submaximum Doses or Who Discontinued Eein-Angiotensin-Aldosterone System Inhibitors Manifested Significantly Worse Cardiorenal Outcomes than Patients on Maximum Doses of RAASi
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BACKGROUND: Renin-angiotensin-aldosterone system inhibitors (RAASi) are recommended in patients with chronic kidney disease (CKD) and heart failure (HF), however, because these drugs can provoke hyperkalemia, they are often given at suboptimal doses or discontinued. Few studies have investigated the association between RAASi doses and clinical outcomes.

OBJECTIVE: To investigate the association between RAASi doses and clinical outcomes.

METHODS: Deidentified medical records (2007-2012) from a large population of U.S. patients aged ≥ 5 years with ≥ 2 serum potassium measurements were evaluated (N = 1.7 million). Inclusion required ≥ 1 RAASi prescription prior to the index date of July 1, 2009. Patient age, classified as < 65, ≥ 65 years, and comorbidities, CKD stages 3-4, HF, were characterized during a ≥ 12-month preindex period. Patients with preindex end-stage renal disease (ESRD) were excluded. Frequency of adverse events (AEs) and death was assessed from July 1, 2009 to the end of the data period (mean, 3 years). Adverse events included CKD progression, ESRD, stroke, acute myocardial infarction, coronary artery bypass, and percutaneous coronary intervention. RAASi dose level was classified as maximum (Max), submaximum (Submax) or discontinued. RAASi discontinuation was assumed if no new RAASi prescription was found within 390 days. Outcomes included a composite measure of any AE or death and a single measure of death. For the composite endpoint, RAASi dose was assessed at the last RAASi prescription before first AE or death (if any), or as the majority dose category among postindex RAASi prescriptions for patients with no AEs. For death alone, patient’s last RAASi dose level was assumed to be discontinued. RAASi discontinuation was associated with AEs. Among patients with HF, 44.3% on Max RAASi doses had an AE or died compared with 52.3%
on Submax doses and 59.8% who discontinued RAASi (all comparisons, P < 0.0001). Mortality alone was similarly associated with dose level. Among HF patients, 13.7% on Max RAASi doses died compared with 27.7% on Submax doses and 30.1% who discontinued RAASi (all comparisons, P < 0.0001). Patients with CKD and older patients showed similar dose associations. In patients aged < 65 years with comorbidities, no difference was seen between those on Submax doses and those who discontinued RAASi.

CONCLUSIONS: In this retrospective database analysis, patients on submaximum doses or who discontinued RAASi had significantly worse cardiorenal outcomes than patients on maximum doses of RAASi.

SPONSORSHIP: Funding support was provided by Relypsa.

14 Rate of Hospitalizations and Associated Costs for Heart Failure Patients in a Large U.S. Commercial Claims Database

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BACKGROUND: Heart failure (HF) is a progressive medical condition with high economic burden. In 2010, the direct costs associated with treatment of HF in the United States were $35 billion, of which 60% were due to hospitalizations.

OBJECTIVE: To estimate annual hospitalization rate and associated costs for patients with HF.

METHODS: A retrospective observational study was conducted using the Optum Research Database, a large administrative claims database. Adult patients with first observed inpatient heart failure claim (ICD-9: 428.xx; in primary position) between January 1, 2008, and June 30, 2013, were included. Patients having an inpatient claim for HF in the 2 months prior to the first observed claim were excluded. In order to account for varying lengths of follow-up in the presence of censoring due to disenrollment, a per-patient-year estimation method was used to calculate the cumulative rate of hospitalizations. Cumulative hospitalization rates and associated costs were estimated for all-cause hospitalizations, HF-related hospitalizations, and cardiovascular (CV) hospitalizations. Total costs included the Centers for Medicare and Medicaid Services (CMS) payment, as well as patient out-of-pocket costs.

RESULTS: A total of 63,678 patients had a primary inpatient claim for HF during the study period. Mean age was 82 years, and 61% of patients were women. On average, patients were hospitalized twice (2.19 times per patient-year) a year for all-cause hospitalization. Including the first observed hospitalization, patients were hospitalized on average once (1.02 times) per patient-year for HF- and 1.30 times for CV-related hospitalization. The estimated costs associated with first observed HF-related hospitalization were approximately $14,000 and with a CV-related hospitalization approximately $25,800. On average, all-cause hospitalization after first observed claim cost $14,500.

CONCLUSIONS: The results of the study indicated that patients with HF identified in an inpatient setting, on an average, experienced 2 hospitalizations per year for all causes and 1 hospitalization per year for worsening of HF. Based on the type of hospitalization, the associated costs ranged from $14,000 to $25,000.

SPONSORSHIP: Amgen provided funding for this research.

15 Burden of Hospitalization in Heart Failure Patients: A Look at Medicare Beneficiaries

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BACKGROUND: In the United States, direct costs for heart failure (HF) were estimated to be $35 billion in 2010. HF is the leading cause of readmissions in the Medicare population.

OBJECTIVE: To estimate the annual hospitalization rate and associated costs for Medicare beneficiaries having HF.

METHODS: Individuals with first observed primary inpatient claim for HF (ICD-9: 428.xx) between July 1, 2005, and December 31, 2011, were identified from the 5% national sample of Medicare beneficiaries. Patients having HF diagnoses in the 6 months prior to first observed claim were excluded. In order to account for varying lengths of follow-up in the presence of censoring due to disenrollment, a per-patient-year estimation method was used to calculate the cumulative rate of hospitalizations. Cumulative hospitalization rates and associated costs were estimated for all-cause hospitalizations, HF-related hospitalizations, and cardiovascular (CV) hospitalizations. Total costs included the Centers for Medicare and Medicaid Services (CMS) payment, as well as patient out-of-pocket costs.

RESULTS: A total of 63,678 patients had a primary inpatient claim for HF during the study period. Mean age was 82 years, and 61% of patients were women. On average, patients were hospitalized twice (2.19 times per patient-year) a year for all-cause hospitalization. Including the first observed hospitalization, patients were hospitalized on average once (1.02 times) per patient-year for HF- and 1.30 times for CV-related hospitalization. The estimated costs associated with first observed HF-related hospitalization were approximately $14,000 and with a CV-related hospitalization approximately $25,800. On average, all-cause hospitalization after first observed claim cost $14,500.

CONCLUSIONS: The results of the study indicated that patients with HF identified in an inpatient setting, on an average, experienced 2 hospitalizations per year for all causes and 1 hospitalization per year for worsening of HF. Based on the type of hospitalization, the associated costs ranged from $14,000 to $25,000.

SPONSORSHIP: Amgen provided funding for this research.

16 Comparison of Hospital Charges Between Hospitalized Nonvalvular Atrial Fibrillation Patients Treated with Either Apixaban or Warfarin

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BACKGROUND: Previously presented propensity-score matched analyses based on a large U.S. hospital database showed that among patients who were hospitalized with nonvalvular atrial fibrillation (NVAF), those treated with apixaban had shorter length of stay (LOS), on average by 1 day, than those treated with warfarin.

OBJECTIVE: Because LOS is an important cost driver for U.S. hospitals, the present study’s objective was to compare hospital charges between hospitalized NVAF patients treated with either apixaban or warfarin.

METHODS: This was a retrospective, observational cohort study based on a large U.S. database including diagnosis, procedure, and drug administration information from over 600 acute-care hospitals. Patients selected for study were aged ≥ 18 years and had a hospitalization record with an ICD-9-CM diagnosis code for atrial fibrillation (AF) in any position from January 1, 2013 to February 28, 2014 (index hospitalization). Patients with diagnoses indicative of rheumatic mitral valvular heart disease or a valve replacement procedure during index hospitalization were excluded. Patients were required to have been
Comparison of Hospital Length of Stay and Costs Between Nonvalvular Atrial Fibrillation Patients Treated with Either Apixaban or Warfarin

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BACKGROUND: Patients with nonvalvular atrial fibrillation (NVAF) are at increased risk for stroke. To reduce stroke risk, physician and patients can choose from both standard anticoagulants (e.g., warfarin) as well as novel oral anticoagulants (NOACs; e.g., apixaban, dabigatran, and rivaroxaban) that are associated with relative advantages and disadvantages.

OBJECTIVE: To compare and quantify LOS and hospitalization costs between hospitalized NVAF patients treated with either apixaban or warfarin via a large claims database.

METHODS: Adult patients (age ≥ 18 years) diagnosed with AF (ICD-9-CM code: 427.31) were selected from the Premier Perspective Claims Database (January 1, 2009-March 31, 2014). Patients were required to have 30 days of follow-up post-index hospitalization discharge. Patients with evidence of mitral valvar heart disease, valve replacement procedures, pregnancy or claims for other NOACs during the index hospitalization were excluded. Patients were categorized into two cohorts: apixaban and warfarin. Demographic and clinical characteristics were collected 12 months prior to and during the NVAF index hospitalization. The cohorts were compared using 1:1 propensity score matching (PSM) to control for patient and hospital characteristics. Primary outcomes were hospital LOS (days) and index hospitalization costs. A sensitivity analysis was conducted in which hospital LOS was measured from first administration of apixaban or warfarin to hospital discharge.

RESULTS: Before PSM, patients treated with warfarin were older and sicker compared to those treated with apixaban. After applying PSM, a total of 2,571 patients were included in each cohort, and baseline characteristics were balanced. For both cohorts, the mean CHADS2-VASc (Congestive heart failure, Hypertension, Age ≥ 75 years, Diabetes mellitus, prior Stroke/transient ischemic attack/thromboembolism, Vascular disease, Age 65-74 years, Sex [female]) score was 3.8, indicating a high stroke risk. The mean (standard deviation [SD] and median) hospital LOS was significantly (P < 0.001) shorter for patients treated with apixaban (5.1 [5.7], and 3 days) compared to warfarin (5.7 [5.3], and 4). Results were consistent in the hospital LOS sensitivity analysis (3.1 [4.8], 2 days for apixaban vs. 3.9 [4.1], 3 for warfarin; P < 0.001). Patients prescribed apixaban incurred significantly lower costs compared to those prescribed warfarin ($11,115 vs. $13,483; P < 0.001).

CONCLUSIONS: Among NVAF patients, apixaban treatment was associated with significantly shorter hospital length of stay (LOS) and lower costs when compared with warfarin treatment.

SPONSORSHIP: This study was funded by Bristol-Myers Squibb and Pfizer.
119 Economic Impact of Nonadherence Among Nonvalvular Atrial Fibrillation Patients Treated with Nonvitamin K Oral Anticoagulants
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BACKGROUND: Adherence to oral anticoagulants (OACs) has been reported to affect health care costs in warfarin-treated nonvalvular atrial fibrillation (NVAF) patients; however, such data are limited for patients treated with nonvitamin K antagonist OAC (NOACs).

OBJECTIVE: To assess OAC adherence and its economic impact among NVAF patients who initiated NOACs.

METHODS: NVAF patients who initiated dabigatran or rivaroxaban between October 1, 2010-July 31, 2012 without prior OAC use were identified from HealthCore Integrated Research Database. Eligible patients had continuous enrollment of 12-month before (baseline) and 12-month after (follow-up) the first NOAC fill (index date). Adherence was measured using proportion of days covered (PDC) for all OAC prescriptions during the follow-up and was defined as PDC ≥ 80%. Per-member-per-month (PMPM) all-cause hospitalization, emergency room (ER) use, office visits (OV), and total medical costs (all-cause, stroke, and bleeding-related) during follow-up were assessed.

RESULTS: A total of 4,842 patients were included in the study with a mean PDC of 0.59. Of those, 42.7% (n = 2,066) patients had PDC ≥ 0.8. Nonadherent patients were younger (mean age: 62.1 vs. 66.9, P < 0.001) than adherent patients. More nonadherent patients were hospitalized (38.7% vs. 34.6%, P = 0.003) and also with longer hospital length of stay (mean: 5.8 vs. 5.5 days, P = 0.030). The percentage of patients with an ER visit was similar between nonadherent and adherent patients (25.1% vs. 23.5%, P = 0.200), while nonadherent patients had fewer OV’s on average than adherent patients (0.95 vs. 1.02, P < 0.001). Unadjusted mean [SD] all-cause total PMPM medical costs ($1,634 [2,964] vs. $1,881 [3,928], P = 0.005) and stroke-related PMPM medical costs ($84 [963] vs. $99 [1,087], P = 0.001) were lower for adherent than nonadherent patients, but unadjusted bleeding-related medical costs (P = 0.005) for high intensity therapy respectively. Under ACC/AHA, 277 patients (50%) were recommended for treatment, with 67 (12%) and 210 (38%) recommended to receive moderate intensity or high intensity treatment, respectively. The overall mean annual cost per person was estimated to be $36 at baseline vs. $164 under ACC/AHA. In subgroup analyses, the overall mean annual cost per person was estimated to be $39 vs. $371 for those with ASCVD ≥ 7.5% and $58 vs. $338 for those ≥ 65 years old.

CONCLUSIONS: Payers will likely experience higher statin costs with adoption of ACC/AHA, which is driven in part by recommendations to use higher intensity statins. Cost increases are substantial in patients ≥ 65 years old or with ASCVD ≥ 7.5%.

SPONSORSHIP: University of Utah College of Pharmacy (Pharmacy Student Summer Research Fellowship).

122 Expected Health Care Cost Savings Resulting from Reduction in All-Cause Hospitalizations Observed in Apixaban-Treated Patients in the AMPLIFY and AMPLIFY-EXT Trials
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BACKGROUND: Results from the AMPLIFY and AMPLIFY-EXT trials demonstrated that the factor Xa antagonist oral anticoagulant apixaban was associated with a statistically significant reduction in all-cause hospitalizations in patients with acute venous thromboembolism (VTE).

OBJECTIVE: This study estimates the expected healthcare cost savings resulting from such reductions in all-cause hospitalizations by applying real-world cost data to AMPLIFY and AMPLIFY-EXT trial data on all-cause hospitalizations.

METHODS: All-cause hospitalization cost data were drawn from a previously-presented administrative claims-based study of 123,665 patients with acute VTE. Patients were followed for up to 12 months after an acute VTE event to collect information on healthcare costs. Adjusted incremental healthcare costs associated with all-cause hospitalization were calculated through multivariable regressions comparing patients with vs. without an all-cause hospitalization within 30 days, 6 months, or 12 months of follow-up. Potential cost savings resulting from reductions in all-cause hospitalizations were calculated as the estimated incremental healthcare costs multiplied by the difference in all-cause hospitalization rates between the apixaban and comparator arms in the AMPLIFY and AMPLIFY-EXT trials and adjusted to the number of months in specified follow-up.

SPONSORSHIP: This study was supported by Daiichi Sankyo.
RESULTS: In multivariable regressions comparing patients with vs. without a hospitalization within 30 days, 6 months, or 12 months of follow-up, adjusted incremental healthcare costs of all-cause hospitalization were $22,406 for 30 days of follow-up (P<0.001), $6,641 per month for 6 months of follow-up (P<0.001), and $4,808 per month for 12 months of follow-up (P<0.001). Multiplying the difference—between apixaban and its trial comparator—in the percentage of patients with ≥1 hospitalization within the AMPLIFY and AMPLIFY-EXT trials, the expected average (95% CI) per-patient cost savings of reductions in all-cause hospitalizations were $239 ($234–$244) for the AMPLIFY 30-day follow-up results (i.e., $22,406*0.017% [absolute difference in percentage of patients with ≥1 all-cause hospitalization]), $537 ($529–$545) for the AMPLIFY 6-month results, $1,430 ($1,410–$1,451) for the AMPLIFY-EXT 12-month results for apixaban 2.5 mg, and $1,902 ($1,875–1,929) for the AMPLIFY-EXT 12-month results for apixaban 5 mg.

CONCLUSIONS: Given the cost burden of all-cause hospitalizations among patients treated for acute VTE, the reduction in such hospitalizations seen for apixaban may translate to substantial healthcare cost savings.

SPONSORSHIP: Bristol-Myers Squibb and Pfizer.

123 Medical Costs Avoided with Use of New Oral Antiocoagulants Versus Standard Therapies or Placebo Among Nonvalvular Atrial Fibrillation Patients and Venous Thromboembolism Patients

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BACKGROUND: Nonvalvular atrial fibrillation (NVAF) and venous thromboembolism (VTE) are both associated with significant morbidity and substantial healthcare resource utilization and costs. Clinical trials have demonstrated that the four new oral anticoagulants (NOACs), dabigatran, rivaroxaban, apixaban, and edoxaban are efficacious alternatives for the management of NVAF and VTE.

OBJECTIVE: To evaluate differences in medical costs associated with clinical endpoints from randomized clinical trials that compared NOACs to standard therapies or placebo for management of patients with either NVAF or VTE.

METHODS: The clinical event rates of NVAF and VTE patients using NOACs and standard therapies or placebo were based on corresponding published trial data and calculated as the percentage of patients with each of the clinical events during the trial periods. Incremental medical costs to a U.S. health payer of NVAF and VTE patients with clinical events were obtained from published literature and inflation adjusted to 2013 costs. The estimated clinical event rates among NVAF and VTE patients using NOACs, standard therapies, and placebo were used to determine and compare differences in annual medical costs among NVAF and VTE patients receiving different treatments.

RESULTS: The annual total medical cost avoidances vs. warfarin were estimated at $204, $140, $495, and $340 for a NVAF patient treated with dabigatran, rivaroxaban, apixaban, and edoxaban, respectively. The annual total medical cost avoidances vs. standard therapy were estimated at $146, $482, $938, and -$344 for a patient treated for acute VTE with dabigatran, rivaroxaban, apixaban, and edoxaban, respectively. The annual total medical cost avoidances vs. placebo were estimated at $2,794, $2,948, $4,249, and -$4,244 for a VTE patient treated for an extended period with dabigatran, rivaroxaban, apixaban -2.5 mg, and apixaban -5 mg, respectively.

CONCLUSIONS: Medical costs are avoided when NOACs are used instead of standard therapies or placebo for the management of NVAF or VTE, with apixaban being associated with the greatest reduction in medical costs.

SPONSORSHIP: This study was funded by Bristol-Myers Squibb and Pfizer.

124 Cost-Effectiveness of Edoxaban Versus Warfarin for the Treatment of Venous Thromboembolism: Results Based on the Hokusai-VTE Study

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BACKGROUND: Vitamin K antagonist (VKA) therapies such as warfarin, used for venous thromboembolism (VTE) treatment and prevention, require laboratory monitoring and frequent dose adjustments, have drug and food interactions, and thus may be associated with increased healthcare use. The Hokusai-VTE trial showed that, following initial heparin lead-in, treatment with the once-daily non-VKA oral antagonist edoxaban was noninferior to warfarin for treatment and prevention of recurrent VTE but with significantly less bleeding.

OBJECTIVE: This study aimed to evaluate the cost-effectiveness of edoxaban versus warfarin from a U.S. integrated healthcare delivery system perspective.

METHODS: A Markov model evaluated the 1-year total direct healthcare costs and outcomes including VTE recurrence, major and clinically relevant nonmajor bleeding, and death in patients who had an acute VTE and were treated with edoxaban or warfarin. Given the cost burden of all-cause hospitalizations, the model used a monthly cycle with clinical event rates and healthcare resource use data from the Hokusai-VTE trial. Cost estimates were derived from the Premier Hospital Database (inpatient) and Medicare claims (outpatient). Warfarin price ($0.38 per day) was based on the wholesale acquisition cost (WAC) and pre-market edoxaban price ($9.64 per day) was assumed to be the average WAC of current non-VKA oral antagonists. To evaluate edoxaban’s cost effectiveness relative to warfarin, incremental cost per quality-adjusted life-year (QALY) gained was calculated. Per AHA/ACC guidance, a threshold of <$50K, $50K-$150K and >$150K was utilized as the therapy providing high, intermediate and low economic value, respectively.

RESULTS: Edoxaban therapy for up to one year was associated with $357.04 per patient higher total health care costs and a 0.01165 QALY increase versus warfarin. The incremental cost-effectiveness ratio (ICER) for edoxaban relative to warfarin was $30,647 per QALY gained, well below the high economic value threshold of $50K per QALY gained. One-way sensitivity analyses showed that the ICER was most sensitive to edoxaban price, warfarin monitoring cost and disutility of warfarin monitoring. Varying edoxaban daily cost by ±10% resulted in ICERs ranging from $9,615 to $51,527/QALY gained. Decreasing warfarin monitoring cost by 10% and disutility of warfarin monitoring. Varying edoxaban daily cost by ±10% resulted in ICERs ranging from $9,615 to $51,527/QALY gained. Decreasing warfarin monitoring cost by 10% and disutility of warfarin monitoring. Varying edoxaban daily cost by ±10% resulted in ICERs ranging from $9,615 to $51,527/QALY gained.

CONCLUSIONS: This study indicates that edoxaban therapy provides a cost-effective alternative to warfarin for VTE treatment.

SPONSORSHIP: The study was funded by Daiichi Sankyo.
**J00-J99 Diseases of the Respiratory System**

(i.e., Asthma, COPD, Rhinitis, RSV)

Postmarketing Survey of Satisfaction with Needle-Free Administration of Afluria Influenza Vaccine Using Novel Jet Injection Technology

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**BACKGROUND:** The CDC recommends yearly vaccination against influenza in all adults, however, current vaccination rates are below 40%. Up to 24% of adults have a significant fear of needles and 7% avoid vaccinations due to needle fears. Administration of vaccines by novel needle-free technology, such as jet injection, offers an important alternative. In August, 2014, needle-free vaccination against influenza was approved with Afluria using Pharmajet Stratis needle-free jet injection technology.

**OBJECTIVE:** The objective was to assess patient acceptance of and satisfaction with needle-free flu vaccination using Afluria delivered via the Pharmajet Stratis jet injection system.

**METHODS:** Students, staff, employees, and retirees of the University of Tennessee Health Science Center were offered vaccination against influenza as part of the 2014 campaign. Participants between 18 and 64 years of age were offered Afluria by traditional needle/syringe or administered by needle-free jet injection using Pharmajet Stratis, FDA-approved only for use with Afluria multi-dose vials. A post-administration survey was offered to all who elected needle-free vaccination. Questions addressed demographics, reasons for choosing the needle-free option, satisfaction, and likelihood of choosing and recommending needle-free vaccination again.

**RESULTS:** 500 doses of Afluria were administered using the Pharmajet (PJ) Stratis Needle-Free injector. Of those who self-selected the needle-free option, 399 (80%) agreed to participate in the study by completing a 7-question paper survey. 27% reported selecting the needle-free option out of a dislike for needles. 67% reported selecting the needle-free option due to an affinity for new technology. Overall, 96% of subjects felt satisfied, very satisfied, or extremely satisfied with needle-free influenza vaccination, and 92% indicated they would likely, very likely, or definitely choose the needle-free option next season. 92% reported that they were likely, very likely, or extremely likely to recommend the needle-free flu shot to family/friends.

**CONCLUSIONS:** In this post-marketing survey, subjects reported a high degree of satisfaction with Afluria influenza vaccination through needle-free jet injection. Over a quarter of subjects chose the needle-free option out of a dislike for needle/syringe. This data suggests that needle-free vaccination though jet injection may be widely accepted in the general adult population, may expand vaccination rates, and may contribute to reaching the CDC’s stated goal of 70% influenza vaccination coverage in adults.

**SPONSORSHIP:** BioCSL and Pharmajet.

Allergy Immunotherapy for Childhood Allergic Rhinitis Is Associated with Significant Reductions in the Frequency and Costs of Inpatient Care: Detailed Case Analyses from Large-Scale, Retrospective Claims Research

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**BACKGROUND:** Our previously published retrospective claims research examined patterns and outcomes of allergy immunotherapy (AIT) care in children with allergic rhinitis (AR). We reported that patients with AR receiving AIT had fewer pharmacy fills (8.9 vs. 12.1, P < 0.0001), outpatient visits (22.9 vs. 30.7, P < 0.0001), and inpatient stays (0.4 vs. 1.2, P = 0.02) in the 6 months preceding (pre) versus following (post) AIT. Costs for pharmacy ($60 vs. $330), outpatient ($270 vs. $735), and inpatient ($1 vs. $2,441) were also significantly reduced (all P < 0.0001) post AIT. Because hospitalizations are generally rare events, these significant inpatient-related findings were unexpected and warranted further examination.

**OBJECTIVE:** To examine characteristics of hospitalizations in the 6 months post versus pre AIT.

**METHODS:** Computerized data were obtained from Health Insurance Portability and Accountability Act-compliant Florida Medicaid (July 1, 2007–June 30, 2009) paid claims. International Classification of Diseases, 9th Revision codes identified diagnoses. Current Procedural Terminology codes identified inpatient services. Definitions: Index AR diagnosis = first AR claim; newly diagnosed AR = index AR diagnosis preceded by ≤ 1 year without AR, de novo AIT = required that first AIT claim follow (rather than precede) newly diagnosed AR; AIT discontinuation = required data availability ≥ 6 months after final AIT claim.

**RESULTS:** Among 2,718,101 Florida Medicaid child enrollees, 354 met selection criteria. Of these, 18 incurred ≥ 1 stay for any reason in the pre-AIT period; 11 had a single stay for asthma, bronchitis, croup or pneumonia; 3 had 2 stays for these disorders; and 4 had stays unrelated to respiratory illness. In the 6 months post-AIT, 3 of these children incurred 8 inpatient stays. All were for asthma (primary diagnosis). One had 3 stays over approximately 4 weeks; another, with comorbid immune deficiency, had 3 stays; and 1 child with comorbid type 1 diabetes had 2 stays.

**CONCLUSIONS:** Compared to the 6-month pre-AIT period, fewer children in the 6-month post-AIT period (3 vs. 14) experienced ≥ 1 respiratory-related hospitalization; however, these 3 children incurred multiple hospitalizations post-AIT.

**SPONSORSHIP:** Funding provided in part by Greer Labs; Stallergenes; the American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council for Allergy, Asthma and Immunology.
METHODS: 23 U.S. pollen counting sites provided grass pollen counts for 2004 through 2013. Counts were reported as pollen grain concentration per cubic meter. The start and end of the grass seasons were defined retrospectively as the dates when 2.5% and 97.5% of the cumulative total grass pollen had been collected, respectively. Spearman analyses were performed to assess relationships between latitude, longitude, and season variables.

RESULTS: Both latitude and longitude of the collection sites had significant impacts on season variables. Latitude was highly predictive of the temporal pattern of the seasons (average start date, \(P < 0.0001\); average duration, \(P = 0.003\)). The intensity of the season was highly correlated with longitude, with more severe seasons in the western locations (average daily concentration, \(P = 0.0079\)). Start and end dates varied from year to year at each location as did the maximum pollen concentration. These were likely influenced by local weather and rainfall conditions.

CONCLUSIONS: This study shows that location has a significant impact on the timing, duration, and intensity of U.S. grass pollen seasons. Understanding local characteristics of pollen seasons and the resulting disease can help health plans and disease management programs optimize resources for treating ARC.

SPONSORSHIP: Genentech.

J9 Association Between Nonadherence to Chronic Pulmonary Disease (COPD) Maintenance Medications and Medications for Other Chronic Conditions


1 Comprehensive Health Insights; 2 Boehringer Ingelheim Pharmaceuticals; 3 Humana

BACKGROUND: Patients with COPD typically have multiple comorbidities and use multiple medications. Adherence rates for maintenance COPD medications may be impacted by use of medications for other chronic conditions (non-COPD medications). It is important to assess the association between non-adherence to maintenance COPD medications and non-COPD medications.

OBJECTIVE: Evaluate the association between non-adherence to COPD medications and non-COPD medications in patients with COPD.

METHODS: A cohort of patients with evidence of COPD diagnosis was identified using Humana’s claims database. Selected patients were 40-89 years old and continuously enrolled for 12 months prior to and 24 months after the first identified COPD diagnosis (index date) during January 1, 2008-December 31, 2010. Patients were required to have ≥ 1 prescription fill for a COPD medication (Long-Acting Antimuscarinic Agents [LAMAs] or maintenance Fixed Dose Combinations [FDC] combinations) within 365 days of the index date and ≥ 1 prescription fill for a non-COPD medication (antihypertensives, statins, diuretics, beta-blockers, calcium channel blockers, anticoagulants, antidepressants, anxiolytics, nonsteroidal anti-inflammatories [NSAIDs], anti-diabetics, insulin, or bisphosphonates) within ± 30 days of the first COPD prescription. Adherence (proportion of days covered [PDC]) was measured during 365 days following the first COPD prescription. The association between non-adherence (PDC < 0.8) to COPD and non-COPD medications was determined using logistic regression, controlling for baseline patient characteristics; odds ratio (OR) and 95% confidence interval (CI) were computed.

RESULTS: A total of 14,117 patients, with a mean age of 69.9 years, met study criteria. Of these, 40.9% were male and 79.2% were non-white. The majority of patients with COPD in this study were non-adherent to COPD medications. The mean PDC for COPD medications was 0.47. Antihypertensives, statins and diuretics were the most commonly prescribed non-COPD medications with a mean PDC of 0.71, 0.67 and 0.61, respectively. Non-adherence to COPD medications was associated with non-adherence to all non-COPD medications (OR 1.38 to 1.78, all \(P < 0.01\)) except anticoagulants and anxiolytics. The strongest predictors of non-adherence to COPD medications were non-adherence to insulin (OR [95% CI]: 1.78 [1.28-2.47]), NSAIDs (1.74 [1.39-2.18]) and antidepressants (1.73 [1.50-1.99]).

CONCLUSIONS: The majority of patients with COPD in this study were non-adherent to COPD medications. Non-adherence to COPD medications was associated with non-adherence to 10 of the 12 non-COPD medications assessed.

SPONSORSHIP: This study was sponsored by Boehringer Ingelheim and Humana.

J7 Health Care Use and Costs Associated with High Versus Low HEDIS Asthma Medication Ratio

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1 Genentech; 2 Partnership for Health Analytic Research

BACKGROUND: High HEDIS asthma medication ratio (AMR) scores are considered a marker for quality of asthma care. However, healthcare use and costs associated with high vs. low AMR are poorly characterized.

OBJECTIVE: To characterize healthcare use and costs associated with high vs. low AMR.

METHODS: This retrospective cohort study identified 5-64 year old patients meeting the HEDIS definition of asthma in a commercial claims database from January 1, 2011 to December 31, 2011. We classified each patient as having either high or low AMR based on the HEDIS definition. AMR was calculated as the ratio of controller to total asthma medications. The association between non-adherence (PDC < 0.8) to COPD and non-COPD medications was determined using logistic regression, controlling for baseline patient characteristics; odds ratio (OR) and 95% confidence interval (CI) were computed.

RESULTS: A total of 14,117 patients, with a mean age of 69.9 years, met study criteria. Of these, 40.9% were male and 79.2% were non-white. The majority of patients with COPD in this study were non-adherent to COPD medications. The mean PDC for COPD medications was 0.47. Antihypertensives, statins and diuretics were the most commonly prescribed non-COPD medications with a mean PDC of 0.71, 0.67 and 0.61, respectively. Non-adherence to COPD medications was associated with non-adherence to all non-COPD medications (OR 1.38 to 1.78, all \(P < 0.01\)) except anticoagulants and anxiolytics. The strongest predictors of non-adherence to COPD medications were non-adherence to insulin (OR [95% CI]: 1.78 [1.28-2.47]), NSAIDs (1.74 [1.39-2.18]) and antidepressants (1.73 [1.50-1.99]).

CONCLUSIONS: Although HEDIS high-AMR patients had higher medication costs than low-AMR ones, their care was marked by fewer OCS bursts (indicating instances of poor asthma control), lower emergency-type (such as hospitalizations and ED visits) and higher non-emergency (office visits) healthcare use than that of low-AMR patients. Resultantly, non-medication costs of high-AMR patients were lower than that of their low-AMR counterparts.

SPONSORSHIP: Genentech.
**J10** Association Between Comorbidities and Hospitalizations Among Patients with Chronic Obstructive Pulmonary Disease (COPD)

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**BACKGROUND:** Patients with COPD typically have multiple underlying comorbidities. The relationship between existing comorbidities and hospitalizations among patients with COPD warrants further examination.

**OBJECTIVE:** Evaluate the association between comorbidities and number of hospitalizations among patients with COPD.

**METHODS:** A cohort of patients with evidence of COPD diagnosis was identified using Humana’s claims database. Patients aged 40-89 years who were continuously enrolled for 12 months prior to and 24 months after the first COPD diagnosis (index date) during January 1, 2008-December 31, 2010 were included. Comorbidities were assessed during 12 months prior and 12 months after the index date, using the Agency for Health Research and Quality Clinical Classification Software methodology. Based on prevalence and clinical expert consultation, 11 comorbidities were selected: coronary artery disease (CAD), congestive heart failure (CHF), cerebrovascular disease (CVD), chronic kidney disease (CKD), type 2 diabetes mellitus (T2DM), anxiety, depression, obesity, osteoarthritis, osteoporosis and sleep apnea. All-cause and COPD-related hospitalizations were assessed in the 24-month period after the index date. Generalized linear models with log link and negative binomial variance functions were used to determine the association between presence of comorbidities and hospitalizations, controlling for baseline patient characteristics.

**RESULTS:** A total of 52,643 patients with evidence of COPD diagnosis were identified with 92% having at least 1 comorbidity of interest; 48% had CAD, 44% osteoarthritis, 41% T2DM, 28% CHF, 27% CVD, 27% depression, 26% CKD, 23% anxiety, 20% osteoporosis, 20% obesity and 17% sleep apnea. Having a comorbidity of interest was associated with a higher number of all-cause hospitalizations compared to not having that comorbidity; CHF, CAD, and CVD had the strongest associations with all-cause hospitalizations (mean ratio ≤ 0.001). Having a comorbidity (except osteoarthritis, CKD, and obesity) was also associated with a higher number of COPD-related hospitalizations; CHF, anxiety, and sleep apnea had the strongest associations (mean ratio 2.01, 1.32, and 1.21, respectively; all P ≤ 0.001). Having a comorbidity (except osteoarthritis, CKD, and obesity) was also associated with a higher number of COPD-related hospitalizations; CHF, anxiety, and sleep apnea had the strongest associations (mean ratio 2.01, 1.32, and 1.21, respectively; all P ≤ 0.001).

**CONCLUSIONS:** Comorbidities are common in patients with COPD and are associated with higher all-cause and COPD-related hospitalizations. Assessment of comorbidities in patients with COPD, especially CHF, CAD, CVD, anxiety and sleep apnea may help identify subgroups of patients at increased risk of hospitalization.

**SPONSORSHIP:** This study was sponsored by Boehringer Ingelheim and Humana.

**J15** Budgetary Impact on a U.S. Health Plan After Adopting Umeclidinium/Vilanterol (UMEC/VI) for the Management of Moderate-to-Severe COPD

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**BACKGROUND:** A new treatment for chronic obstructive pulmonary disease (COPD), a combination of two drugs: umclidinium (UMEC), an anticholinergic agent, and vilanterol (VI), a long-acting beta agonist (LABA). UMEC/VI is indicated for once-daily maintenance of airflow obstruction in patients with COPD. Understanding the budgetary impact of including UMEC/VI on formulary while considering other COPD maintenance treatments will aid in population health-based decision making.

**OBJECTIVE:** To estimate the budgetary impact on costs and outcomes of UMEC/VI for managing COPD in a U.S. commercial and Medicare health plan population.

**METHODS:** A decision model was developed to compare COPD maintenance therapy costs and outcomes with and without formulary adoption of UMEC/VI for a hypothetical 1 million member plan over a 4-year time horizon. A disease progression model was used to follow the COPD patient population as they progressed through COPD stages over this time horizon. COPD incidence and prevalence was derived from published sources to identify the COPD population of interest. The primary outcomes of interest are total annual and per-member-per-month (PMPM) costs, which include drug and medical costs. These costs are estimated for both a status quo market mix without UMEC/VI and a projected market mix once UMEC/VI is added to formulary. The incremental budget impact on medication costs, including medication augmentation due to inclusion of UMEC/VI was estimated. Forced exhalory volume in 1 s improvement was linked to exacerbations to describe the medical cost impact. Other COPD regimens considered in this analysis include tiotropium (TIO), open dual bronchodilator therapy (TIO administered once daily and LABA administered twice daily), and no long-acting bronchodilator therapy. Drug costs were based on 2014 wholesale acquisition costs.

**RESULTS:** When UMEC/VI is not on formulary, the total PMPM (including drug and medical costs) for moderate to very severe COPD is $16.23, $19.98, $21.64, and $23.15 for 2014-2017, respectively. The addition of UMEC/VI on formulary reduces the total PMPM to $16.13, $19.74, $21.27, and $22.64, which is a reduction of $0.10, $0.24, $0.36 and $0.52 for 2014-2017, respectively. With this decrease in costs also comes a decrease in the occurrence of exacerbations within the population.

**CONCLUSIONS:** It is anticipated that including UMEC/VI on a formulary will result in a decrease in maintenance medication costs and medical costs within the population over the 4-year period following introduction.

**SPONSORSHIP:** Study funded by GlaxoSmithKline.
METHODS: Infants born July 1, 2003-June 30, 2013 were identified in the MarketScan Commercial (COM) or Multistate Medicaid (MED) databases. DRG and ICD-9-CM codes were used to identify PT (≤ 36 wGA) or FT (≥ 37 wGA) infants. RSV hospitalizations (ICD-9-CM 466.11, 480.1, 079.6) occurring >1 day after birth hospital discharge through 12 months of age were characterized. Infants with chronic lung disease, congenital heart disease, cystic fibrosis, Trisomy 21, immunodeficiencies, and organ transplants were excluded. Costs reflect 2014 US$.

RESULTS: Over 1.7 million infants from each database were identified as PT or FT, of which 14.6% MED and 12.9% COM were PT. Only 71% MED and 66% COM PT infants had gestational age (GA)-specific codes (<29, 29-30, 31-32, 33-34, 35-36 wGA). There were 29,967 MED and 16,310 COM RSV hospitalizations. Mean first-year hospitalization costs increased with decreasing GA, starting at $8,300 and $10,570 for FT, $15,839 and $19,931 for 33-34 wGA, and $39,574 and $40,813 for <29 wGA, among MED and COM infants, respectively. Length of stay (LOS; 4.3-9.2 days MED and 4.1-7.7 days COM), admission to the intensive care unit (ICU; 8%-31% MED and 9%-23% COM), and use of mechanical ventilation (MV; 2%-14% MED and 1%-9% COM) were higher for PT infants and also increased with decreasing GA. Infants that were PT and <90 days old had the greatest costs, LOS, ICU admissions, and MV use. Proportions of infants <90 days admitted to the ICU were 11%, 21%, 32%, 36%, 45%, and 58% for MED and 11%, 21%, 26%, 25%, 32%, and 33% for COM infants (FT to <29 wGA). Mean cost of ICU admissions ranged from $35,000-$89,000 among MED and COM infants.

CONCLUSIONS: The increased cost of RSV hospitalization among PT infants supports consideration of palivizumab prophylaxis, particularly when they are of young chronologic age, prophylaxis costs are low, and risk of RSV is high.

SPONSORSHIP: This study was funded by AstraZeneca.

K00-K93 Diseases of the Digestive System (i.e., Crohn's Disease, IBD, IBS)

K1 Comparing Direct Costs and Health Utilization Among Patients Using Adalimumab or Infliximab for Ulcerative Colitis (UC): A Retrospective Study

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BACKGROUND: Anti-TNFs (e.g., adalimumab [ADA] and infliximab [IFX]) have proven efficacy in inducing and sustaining clinical response and remission in patients with moderate to severe UC. Differences in real-world outcomes in patients initiating these therapies are limited.

OBJECTIVE: To compare direct health care costs and resource utilization between patients with UC initiating ADA or IFX from privately insured patients in the United States.

METHODS: Data were extracted from Truven Health MarketScan Databases (January 1, 2000-December 31, 2013) among anti-TNF naive adults with ≥2 independent diagnoses of UC initiating ADA or IFX. Patients required enrollment ≥6 months pre- and post-index date, defined as the day of ADA or IFX initiation on or after September 28, 2012 and after the first UC diagnosis date. ADA and IFX groups were matched 1:1 using a propensity score stratified by baseline variables selected as potential confounders. Outcomes included direct health care resource utilization (hospitalization, emergency department [ED] visits, outpatient visit, other medical [e.g., laboratory service, and prescription use]) and associated costs (2013 US$). Costs and resource utilization were classified as all-cause (e.g., any reason) or UC-related (where the diagnosis associated with the medical services was UC, UC-comorbidity [e.g., malnutrition] or UC-symptom [e.g., abdominal pain]). Wilcoxon rank-sum tests (continuous variables) and chi-square tests (categorical variables) were used to compare demographics, baseline comorbidities, and utilization/costs in baseline and study periods.

RESULTS: After propensity matching, baseline characteristics were similar between groups (n = 315 each). All-cause outpatient and total medical costs were lower for ADA than IFX ($4,006 vs. $5,209 [P < 0.0001] and $9,483 vs. $10,657 [P < 0.0001], respectively). No significant differences were observed between ADA and IFX groups in total prescription and total health care costs ($20,331 vs. $21,004 [P = 0.13] and $29,819 vs. $31,661 [P = 0.11], respectively). UC-related outpatient and total medical costs were lower for ADA than IFX ($2,518 vs. $3,861 [P < 0.0001], $7,141 vs. $8,618 [P < 0.0001], respectively). Total health care costs were not significantly different between ADA and IFX ($26,459 vs. $28,292 [P = 0.39]). No significant differences in costs or utilization associated with hospitalization, ER, or other medical costs were observed.

CONCLUSIONS: UC patients initiating ADA incurred lower outpatient and total medical costs than IFX patients.

SPONSORSHIP: Design, study conduct, and financial support for this study were provided by AbbVie.

K3 Medication Adherence in Patients with Inflammatory Bowel Disease: A Review of the Literature

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BACKGROUND: Inflammatory bowel diseases (IBD) can affect patients of any age and may be associated with significant burden of illness. Drug therapy for patients with IBD (Crohn’s disease [CD] or ulcerative colitis [UC]) can be complex (e.g., high daily pill burden, need for non-oral route of administration, narrow therapeutic range). A patient’s ability to adhere to a particular therapy is affected by many factors and varies by the unique characteristics of each drug regimen. Medication non-adherence can lead to suboptimal treatment outcomes resulting in disease progression, an increased risk of hospitalizations, and a need for intensification of medication therapy or surgical intervention.

OBJECTIVE: To systematically evaluate the current state of knowledge regarding adherence patterns for the various IBD medications.

METHODS: A PubMed search, using a structured search strategy for adherence and IBD, was conducted and titles and abstracts of articles were reviewed for eligibility based on inclusion/exclusion criteria. Full text articles were examined to identify any additional studies not initially included. Articles were then summarized into evidence tables that included the year of publication, author, title, study design, methods and findings. Rates of non-adherence across all studies were summarized into quartiles (Q1 [0-25%], Q2 [26-50%], Q3 [51-75%], Q4 [76-100%]).

RESULTS: The initial search yielded 554 citations. 423 articles were excluded after review of title and abstract. A total of 42 articles met inclusion criteria and were included in the analysis. Six articles studied patients with a diagnosis of UC only, 12 with CD patients only, 21 studies looked at patients with a diagnosis of either UC or CD, and 3 studies did not specify. Adherence was analyzed using a variety of methods including patient questionnaires (n = 24), pharmacy claims databases (n = 11), urinalysis (n = 3), or medication electronic monitoring (MEM) track caps (n = 9). Eleven studies measuring non-adherence were classified in Quartile 1, 22 in Q2, 4 in Q3, and 5 in Q4.
CONCLUSIONS: Based on these findings, adherence continues to be an issue of concern in IBD. Significant variation was noted in the literature in terms of study design and method of measuring medication adherence. Further research is needed to better understand adherence patterns in patients with IBD.

SPONSORSHIP: This research was conducted at Albany College of Pharmacy and Health Sciences without any external funding.

K4 The Budgetary Impact of Vedolizumab in the Management of Moderately to Severely Active Ulcerative Colitis and Crohn’s Disease in the United States

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BACKGROUND: Vedolizumab (VDZ) is a biological therapy approved in the United States (U.S.) for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn’s disease (CD).

OBJECTIVE: To assess the 5-year impact on budget and clinical outcomes of adding VDZ to a health plan’s formulary in the U.S. for adults with moderately to severely active UC or CD.

METHODS: An Excel-based model was developed to estimate the annual impact on costs (drug, medical, total) and clinical outcomes associated with adding VDZ to a 1 million-member U.S. health plan’s formulary. Treatments included biologics (VDZ, infliximab, adalimumab, golimumab, certolizumab, and natalizumab) and conventional therapy (CT: aminosalicylates, corticosteroids, immunomodulators) approved for treatment of UC or CD. Disease prevalence was taken from the published literature and the proportion of patients receiving biologics was estimated from current market share. One-year efficacy data (response and remission) were derived from placebo-controlled trials of approved biologics and CT using the Bucher method. Costs (wholesale acquisition drug costs and health state costs) were taken from published literature. Market mix and VDZ uptake were based on current market share and projections. VDZ uptake ranged from 5% to 16% in years 1 to 5 coming mostly from other biologics. Base case analyses assumed all patients received the standard-approved dose of the biologics. Results included costs (total and per-member-per-month [PMPM]) in 2014 U.S. dollars and total clinical outcomes (patients in response/remission and surgeries). Sensitivity analyses were performed varying health state costs and efficacy for each treatment within plausible ranges.

RESULTS: The model predicted that including VDZ would result in total PMPM cost savings ranging from $0.011 (0.13%) to $0.035 (0.41%) over 5 years. PMPM drug costs increased by $0.011 to $0.032, while medical costs decreased by $0.021 to $0.067. Adding VDZ led to 38 more patients in remission, 37 more in response and 2 fewer surgeries in year 5. Annual cost savings to the health plan ranged from $200,352 to $653,797 over 5 years. Results were most sensitive to VDZ efficacy and health state costs. However, VDZ remained cost saving with all parameter variation.

CONCLUSIONS: The model suggests that adding VDZ is cost-effective for the management of UC and CD in adults with moderate to severe disease. VDZ is cost-effective compared to other biologics and CT in the treatment of moderate to severe disease with the potential for cost savings in the long term.

SPONSORSHIP: Design, study conduct, and financial support for this study were provided by AbbVie.

K6 Treatment Patterns for Xifaxan (Rifaximin) in Patients with Irritable Bowel Syndrome: A Health Care Claims Analysis

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BACKGROUND: Interventions that alter the intestinal microbiota have shown promise for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The minimally absorbed antimicrobial agent, Xifaxan (rifaximin), has demonstrated efficacy in three, multicenter, randomized, placebo-controlled trials, although the extent to which patients will require repeat treatments is uncertain.

OBJECTIVE: The objective of this healthcare claims analysis was to assess treatment patterns for Xifaxan in patients with a diagnosis of IBS.

METHODS: A retrospective analysis of pharmacy and medical claims from a large health insurer was completed for patients with an index prescription fill of Xifaxan 550 mg and an IBS diagnosis (ICD-9 564.1X) between January 2010 and October 2013. Patients were required to have an IBS diagnosis within 90 days prior or 14 days after the index fill, and were required to have continuous medical and
pharmacy coverage 12 months prior to and 18 months after the index prescription fill. Prescription fills after the index fill (i.e., repeat treatments) did not require another IBS diagnosis. Patients were excluded from the analysis if they (a) filled a prescription for Xifaxan (350 mg or 200 mg) during the 12 months prior to the index fill or (b) had a diagnosis during the study period of any of a number of GI conditions (e.g., inflammatory bowel disease, diverticulitis, scleroderma, pancreatitis) other than IBS.

**RESULTS:** Patients (n = 586) with a diagnosis of IBS and an index fill of Xifaxan were primarily female (78%) and Caucasian (84%), with a mean age of 44.5 years. The mean and median number of treatments per patient over the 18-month interval was 1.3 and 1.0, respectively, with a corresponding length of therapy of 19.7 and 14 days. Overall, 84.3% of patients received a single course of therapy; among the 15.7% of patients that were retreated, 10.2%, 2.9%, and 1.0% of patients received 1, 2, or 3 repeat treatments. The mean and median number of days between the first treatment and first repeat treatment was 148 days and 85 days, respectively. For patients receiving >1 repeat treatment, the mean and median number of days between the first repeat treatment and subsequent repeat treatments was 66.9 and 34 days, respectively.

**CONCLUSIONS:** In patients with a diagnosis of IBS and an index fill of Xifaxan, <16% received more than one course of therapy during an 18-month period.

**SPONSORSHIP:** This study was supported by Salix Pharmaceuticals.

### K9 Health Care Resource Use (HCRU) and Costs Among Commercial and Medicare Advantage Health Plan Patients Initiating Treatment with Linaclotide for Irritable Bowel Syndrome with Constipation and Chronic Idiopathic Constipation

**Background:** Irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) significantly impact HCRU and costs. Linaclotide, a guanylate cyclase-C agonist FDA-approved for IBS-C and CIC treatment in U.S. adults, has been shown to improve abdominal and bowel symptoms and health-related quality of life.

**Objective:** Evaluate IBS and constipation-related HCRU and costs pre- and post-linaclotide treatment initiation.

**Methods:** Patients ≥18 years with ≥1 pharmacy claim for linaclotide between December 2012 and September 2013 were identified using medical and pharmacy claims data from a large, geographically-diverse U.S. health plan. Index date was defined as the date of the first linaclotide claim. Patients were continuously enrolled in a commercial or Medicare Advantage (Medicare) health plan for ≥6 months pre- and ≥6 months post-index. Healthcare costs included patient and health plan paid amounts standardized on a per-patient-per-month basis (PPPm). All HCRU and costs presented are IBS/constipation-related, defined using primary ICD-9 code diagnosis codes for IBS/constipation (564.1x or 564.0x, respectively) and pharmacy claims for linaclotide, lubiprostone, and prescription laxatives/stool softeners.

**Results:** A total of 2,254 patients met the inclusion criteria (1,822 commercial; 432 Medicare). Mean age (±SD) was 48 (±13) years for commercial (85% female) and 68 (±13) years for Medicare (71% female) patients. Mean PPPm office visits and costs decreased significantly pre- to post-index for both commercial (visits: 0.11 to 0.07; costs: $14 to $9) and Medicare (visits: 0.11 to 0.08; costs: $10 to $7) patients (all P < 0.001). Among commercial patients, mean PPPm outpatient (OP) facility and emergency department (ED) visits and costs also decreased significantly (OP visits: 0.04 to 0.03, P < 0.001; OP costs: $20 to $13, P = 0.010; ED visits: 0.01 to 0.00, P < 0.001; ED costs: $4 to $1, P = 0.004). Mean OP and ED treatment and costs did not change significantly for Medicare patients pre- to post-index. IBS/constipation-related outpatient resource use was negligible and unchanged for commercial and Medicare patients pre- to post-index. Mean PPPm pharmacy costs increased for commercial ($17 to $99, P < 0.001) and Medicare ($34 to $116, P < 0.001) patients.

**Conclusions:** Following linaclotide initiation, IBS/constipation-related outpatient medical resource use and costs decreased among commercial and Medicare patients. Although pharmacy costs increased, the net cost to insurers was approximately $70/month despite linaclotide’s approximately $240/month list price.

**Sponsorship:** Studies were sponsored by Forest Research Institute and Ironwood Pharmaceuticals.

### K8 The Clinical and Financial Outcomes of a Home Intestinal Rehabilitation Program

**Background:** Parenteral nutrition (PN) is often life-sustaining therapy for short bowel syndrome (SBS) patients. Intestinal rehabilitation (IR) has evolved as an important institution-based multidisciplinary approach to SBS patient management with the goal of restoring enteral autonomy to decrease PN dependency. The traditional home care model has not included IR, resulting in minimal PN weaning. Therefore, we developed a program that follows an IR approach in the home setting with the goal of reducing the routine use of PN. The interventions are provided by a dedicated nutrition support team and include (1) individualized education on SBS diet principles, (2) optimization of fluid and electrolyte balance, (3) counseling on medication management, (4) management of vitamin and mineral deficiencies, (5) assessment of bone and liver health, (6) nurse training to minimize central venous line infections, and (7) ongoing monitoring of regimen compliance.

**Objective:** Our goals were to analyze the clinical impact of our interventions on PN changes, to establish published data on PN weaning in the home setting, and to calculate the cost savings of our interventions.

**Methods:** We conducted a retrospective review of PN volume requirements of 37 SBS patients, either enrolled (n = 12) or not enrolled (n = 25) in our program at the start of care and every 6 months thereafter. Patients with an ICD-9 code of intestinal malabsorption (579.0-579.9), with a start of service date from 2008-present were included in the review. Patients’ length of therapy over this 6-year period ranged from 6 to 42 months.

**Results:** The reduction in weekly PN volume for patients enrolled in the program was, on average, 5.3 times greater than those not enrolled (3,825 mL vs. 725 mL). Moreover, 25% of enrolled patients were able to wean completely off of PN therapy by the end of the evaluation period, and 33% were able to decrease their weekly volume requirement (vs. 8% and 16% of non-enrolled patients, respectively). This resulted in average weaning of 2 days per week of PN therapy across the entire enrolled population, representing a cost savings of $21,233 per patient per year, a $254,800 total annual savings.

**Conclusions:** A home IR program can safely reduce dependence on intravenous nutrition therapy. These PN reductions lead to improvements in the patients’ quality of life and translate into significant cost savings for the payers.

**Sponsorship:** ThriveRx.
**K11 Budget Impact Analysis of Hepatitis C Treatment for Medi-Cal**

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**BACKGROUND:** An estimated 4.1 million persons (CI, 3.4 million to 4.9 million) are anti-hepatitis C virus (anti-HCV) positive, most of whom were born between 1945 and 1964.

**OBJECTIVE:** The purpose of this study was to estimate the annual budget impact and the cost per member per month of the testing and treatment of hepatitis C in the Medi-Cal population using the current testing guidelines.

**METHODS:** A budget impact analysis was constructed from a state Medicaid perspective to depict the financial consequences of implementing the testing and linkage to care guidelines recommended by the CDC, AASLD and USPSTF for persons born between 1945 and 1965. The model included disease testing and drug reimbursement cost. Of the 2,277,106 Medi-Cal beneficiaries with birthdates between January 1, 1945 and December 31, 1964, 1,894,144 are in the fee for service and not eligible for Medicare. Costs of adverse effects and non-adherence were excluded from the analysis.

**RESULTS:** The total cost in one budgetary year of testing and treating the birth cohort ranged from between $5,230,285,333.21 and $24,207,966,240.39. The cost per member per month increases from $0.55 to between $77.76 and $337 if the birth cohort testing recommendation is implemented.

**CONCLUSIONS:** In the base case analysis, the birth cohort testing increases the overall cost by over 100% from the current risk-based testing and treating strategy. Furthermore, sensitivity analysis shows a 78% increase from the base case estimates if adjustments are made for additional risks in the birth cohort. Treatment of genotype 3 has the biggest budget impact followed by the treatment of genotype 1 interferon ineligible persons.

**SPONSORSHIP:** None.

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**L1 Evaluation of Signs and Symptoms and Health-Related Quality of Life in Cured Versus Improved Patients in an Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Phase 3 Trial**

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**BACKGROUND:** Healthcare providers (HCPs) are under increased scrutiny to lower re-admission rates and improve patient satisfaction scores. When treating ABSSSIs, a HCPs decision to stop antibiotics is empirical. Limited data exists on the outcome of patients who are cured (complete resolution of all baseline signs and symptoms) versus improved (some symptoms remain, but no further antibiotics are necessary) after antibiotic discontinuation. An assessment of signs and symptoms (S&S) and health-related quality of life (HRQL) in skin infections may challenge HCPs assumptions about outcomes after antibiotics are stopped.

**OBJECTIVE:** To evaluate S&S and HRQL in patients with a positive clinical response (cured and improved) during an ABSSSI phase 3 trial.

**METHODS:** Adult patients diagnosed with ABSSSI were enrolled in a prospective phase 3, randomized, double-blind study to evaluate antibiotic treatment. Investigators were asked to assess patients with a positive clinical response as cured or improved at the end of treatment (EOT), follow up (FU, study day 14 ± 1) and late follow up (LFU, study day 21-28). An analysis was conducted to understand the difference between cured and improved patients with respect to S&S, pain score, and patient reported HRQL as measured by Extremity Soft Tissue Infection (ESTI) Score, a 20 question survey with a 5 point Likert scale (5 being the highest degree of importance/impairment to patients) measured symptoms, daily functioning, emotional functioning, and social interactions.

**RESULTS:** 660 patients were enrolled in this study and 589 patients had data for inclusion in this analysis. Overall, improved patients had persistent S&S, greater pain scores, and more difficulty with HRQL measures than cured patients. Approximately 20% of the improved patients at EOT did not proceed to cure by LFU. The ESTI Score was higher at LFU in improved patients than cured (39.9, 25.7, \( P = 0.000 \)). At LFU improved patients were more likely than cured patients to report having continued difficulty performing a job (27.8%, 8.8%, \( P < 0.0001 \)) and earning an income (29.1%, 10.8%, \( P < 0.0001 \)).

**CONCLUSIONS:** Patients who are improved at EOT may have persistent S&S and HRQL issues that require further utilization of health care resources and potentially lower patient satisfaction ratings. Additional research is needed to determine the potential economic impact of this data.

**SPONSORSHIP:** This study was funded by Melinta Therapeutics.

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**L00-L99 Diseases of the Skin and Subcutaneous Tissue (i.e., Psoriasis, Pressure Ulcers)**

**L2 Potential Predictors of Using Ustekinumab 90 mg Versus Other Biologic Treatments in Patients with Moderate-to-Severe Plaque Psoriasis**

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1Kantar Health; 2Janssen Scientific Affairs

**BACKGROUND:** Various considerations apply to treatment selection and use in treating moderate to severe plaque psoriasis (PsO).

**OBJECTIVE:** This study examines potential drivers of choice of injectable biologic among PsO patients.

**METHODS:** Data were collected from 400 U.S. dermatologists who randomly selected five charts each for patients with PsO (n = 2,000) from four treatment groups: adalimumab (ADA; n = 447), etanercept (ETA; 539), ustekinumab (UST) 45 mg (311), and UST 90 mg (303). Physicians had to have been in practice 2-30 years, managing 10+ patients (5+ with biologics for PsO). Generalized estimating equation (GEE) binary logistic models, weighted according to inverse probability of patient selection and accounting for correlation of patients within physicians, examined each treatment vs. UST 90 mg, as a function of patient-related measures.

**RESULTS:** Weight >100 kg was a significant, independent predictor of UST 90 mg use vs. UST 45 mg (odds ratio \( OR = 6.08 \)), ETA (6.18), and ADA (2.92), controlling for other variables, as was patient change in weight (\( OR = 6.74, 7.34, \) and 6.44, respectively). Prior experience with biologics predicted UST 90 mg use vs. ETA (\( OR = 7.32 \)) for 1 prior biologic or 20.57 for 2 biologics) and ADA (2.91 or 6.57, respectively). Prior PsO severity (i.e., ‘moderate to severe’ vs. clear) predicted UST 90 mg use vs. ETA. Convenient administration, ease of administration, better dosing schedule, and faster improvement in symptoms were significant reasons for choosing UST 90 mg vs. ETA. Feet, toes, and toenails, as locations affected prior to current treatment, predicted UST 90 mg vs. ETA. Use of administration also predicted choosing UST 90 mg vs. ADA (3). Stopping progression of psoriatic arthritis...
predicted UST 90 mg use vs. UST 45 mg or ETA. Ease of insurance approval, longer time on market, and more experience with the current drug predicted ETA over UST 90 mg.

CONCLUSIONS: Among PsO patients treated with biologics, weight >100 kg, baseline severity, and biologic experience predicted use of UST 90 mg vs. ADA, ETA, or UST 45 mg. Convenience and ease of administration/dosing and faster symptom improvement predicted choosing UST 90 mg over ETA. Yet, ease of insurance approval, longer time on market, and more experience with the current drug predicted choosing ADA or ETA over UST 90 mg. This study reveals potential drivers of biologic choice in PsO and helps inform access and reimbursement decisions.

SPONSORSHIP: This study was fully supported by Janssen Scientific Affairs.

L3 Frequency of Increased Maintenance Doses of Adalimumab, Etanercept, and Ustekinumab
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BACKGROUND: Psoriasis (PsO) and psoriatic arthritis (PsA) are immune-mediated systemic inflammatory diseases. Among other options, therapeutic management may include the use of biologic agents, such as adalimumab (ADA), etanercept (ETN), and ustekinumab (UST). As recommended in FDA labels for PsO, patients initiated on these agents should receive a higher loading dose followed by a regular maintenance dose. However, in clinical practice, some patients, e.g., those with higher body weight, may receive increased doses during the maintenance phase of treatment. Given linear pricing of these medications, commonly used higher maintenance doses may significantly increase payer costs.

OBJECTIVE: To assess the proportion of patients treated with ADA or ETN for PsA, and ADA, ETN, or UST for PsO who receive an increased maintenance dose.

METHODS: Continuously enrolled adult patients with at least 2 outpatient diagnoses for PsA (ICD-9 code: 696.0) or PsO (ICD-9 code: 696.1) were selected from the Symphony FTD Claims Database if their first biologic prescription date, defined as the index date, fell between May 2010 and April 2013. Patients were included if (1) full access was available to all pharmacy claims ≥12 months prior and ≥12 months after their index date, and (2) patients were treatment-naive to the agent of interest pre-index, although treatment with a different biologic pre-index was not considered reason for exclusion. The dosing analysis was assessed over 12 months post-index. Regular maintenance dosing was defined as ADA 40 mg bi-weekly starting 1 week post-index, ETN 50 mg weekly starting 3 months post-index, and UST 45 mg every 12 weeks starting 3 months post-index. Increased maintenance dosing were defined as doses exceeding the FDA label recommendation of ADA >40 mg bi-weekly and ETN >50 mg weekly. For UST, increased maintenance doses were defined as >45 mg every 12 weeks.

RESULTS: In total, 15,400 unique patients for PsA and 40,545 unique patients for PsO met the inclusion criteria. The number and proportion of patients using increased maintenance doses for PsA was: ADA: 1,603, or 18%; ETN: 1,300, or 17%. The number and proportion of patients using increased maintenance doses for PsO was: ADA: 3,187, or 14%; ETN: 5,201, or 32%; and UST: 3,136, or 45%.

CONCLUSIONS: A large subgroup of patients treated with commonly used biologic agents is maintained on increased maintenance doses. Given linear pricing, this practice may significantly increase costs to U.S. managed care payers. The specific impact of increased dosing on cost could be explored in future research.

SPONSORSHIP: This research was funded by Celgene Corporation, Warren, NJ.

L4 Rethinking Costs of Psoriasis: 10% of Patients Account for Nearly 40% of Health Care Expenditures Among Enrollees with Psoriasis in a U.S. Health Plan
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BACKGROUND: Psoriasis (PsO) is a chronic, recurrent, immune-mediated disease of the skin, affecting as many as 7.5 million Americans. PsO is associated with increased healthcare utilization and costs. In order to improve decision-making and cost-containment, it is important to understand which PsO patients are incurring the highest costs in order to identify and address the factors that contribute to these costs.

OBJECTIVE: To examine patient characteristics, health service utilization, and costs, and treatment among U.S. patients with PsO who have high medical costs.

METHODS: Patients with 2 or more medical claims with a diagnosis of PsO who were continuously enrolled in a large, geographically diverse, U.S. health plan in 2011-2013 were identified. Total paid 2012 health care costs (excluding biologics) were used to identify patients in the top 10% of expenditures (T10). Demographics, comorbidities, medications, healthcare utilization and costs in 2012 were compared between T10 patients and the bottom 90% (B90). Logistic regression was used to identify factors associated with high medical costs.

RESULTS: The study included 18,653 patients with mean age 48 years and 49% female. T10 patients accounted for 26% (2011), 39% (2012), and 26% (2013) of all-cause costs (excluding biologics) and 13% (2011), 18% (2012), and 11% (2013) of PsO-related costs. Mean (median) per patient 2012 total costs were $58,029 (41,979) for T10 vs. $10,295 (5,304) for B90 ($10,475 [610] vs. $5,301 [218] for PsO-related costs). Biologic use was similar for T10 vs. B90 (any use: 23% vs. 24%; mean: 1.5 vs. 1.7 prescriptions/year, mean cost: $4,959 vs. $5,095/year). T10 patients filled more prescriptions compared to B90 (15 unique medications/year vs. 7) and were more likely to use corticosteroids (57% vs. 31%). Compared with B90 patients, T10 patients were more likely to have any hospitalization (43% vs. 3%; 14% vs. 1% for PsO-related events) or ER visit (53% vs. 21%; 3% vs. 1% for PsO-related). Characteristics significantly associated with T10 status were female gender (54% [T10] vs. 49% [B90]; odds ratio [OR]: 1.26, 95% confidence interval [CI]: 1.13-1.39), older age (54 year vs. 48 year; OR: 1.03, 95% CI: 1.02-1.03), having renal disease (14% vs. 2%; OR: 2.05, 95% CI: 1.65-2.54), depression (22% vs. 8%; OR: 1.96, 95% CI: 1.70-2.27), cardiovascular disease (25% vs. 5%; OR: 1.88, 95% CI: 1.61-2.19), psoriatic arthritis (21% vs. 13%; OR: 1.57, 95% CI: 1.37-1.80), and diabetes (28% vs. 11%; OR: 1.50, 95% CI: 1.32-1.71).

CONCLUSIONS: The top 10% of patients accounted for nearly 40% of overall healthcare expenditure. Biologic use did not account for differences in healthcare costs between the top 10% and bottom 90% of patients. Top 10% patients had significantly higher comorbid medical conditions, higher inpatient admissions, and ER visits.

SPONSORSHIP: Research funding for this study was provided to Optum by Novartis.

L5 Recent Cost Trends Among Patients Using Biologic Agents for the Treatment of Psoriatic Arthritis
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Psoriasis (PsO) is a chronic, recurrent, immune-mediated disease of the skin, affecting as many as 7.5 million Americans. Among PsO patients treated with biologics, weight >100 kg, baseline severity, and biologic experience predicted use of UST 90 mg vs. ADA, ETA, or UST 45 mg. Convenience and ease of administration/dosing and faster symptom improvement predicted choosing UST 90 mg over ETA. Yet, ease of insurance approval, longer time on market, and more experience with the current drug predicted choosing ADA or ETA over UST 90 mg. This study reveals potential drivers of biologic choice in PsO and helps inform access and reimbursement decisions.
BACKGROUND: Psoriatic arthritis (PsA) is a type of arthritic inflammation that affects some people with psoriasis. A number of therapeutic classes are available to treat PsA, including biologic drugs. Although the wholesale acquisition cost of biologic drugs has increased in recent years, there is little published evidence documenting cost trends from the U.S. managed care perspective.

OBJECTIVE: To assess cost trends for patients using biologic therapy for PsA from the U.S. managed care perspective.

METHODS: Continuously enrolled adult patients with at least 2 outpatient diagnoses for PsA (ICD-9 code: 696.0) were selected from the MarketScan Commercial and Medicare Supplemental databases if their first biologic claim (index date) occurred between July 1, 2008, and July 31, 2013. Patients were included in the study if (1) full access was available to all medical and pharmacy claims for at least 6 months prior to and at least 12 months after their index date, and (2) patients were biologic-naive prior to index. Health care costs were assessed from the payer perspective and based on annual reimbursed amounts for 6 patient cohorts that initiated biologic therapy from 2008-2013. Results were stratified by all-cause vs. PsA-related costs and within these 2 categories further subdivided into medical inpatient, medical outpatient, emergency room, and pharmacy costs.

RESULTS: In total, 25,565 patients met the inclusion criteria. All-cause health care costs in the 6 annual cohorts were: 2008: $26,981, 2009: $28,534, 2010: $31,797, 2011: $33,873, 2012: $38,050, 2013: $41,317, an increase of 63.6%, with an average annual increase of 10.6% (or $2,867). PsA-related annual costs were estimated at 2008: $18,344, 2009: $19,061, 2010: $21,591, 2011: $23,300, 2012: $26,923, 2013: $30,021, an increase of 63.6%, with an average annual increase of 12.7% (or $2,335). Although cost increases in all categories of interest were observed over time, the major driver of the observed increase of 12.7% (or $2,335). Although cost increases in all categories of interest were observed over time, the major driver of the observed increase of 12.7% (or $2,335). Although cost increases in all categories of interest were observed over time, the major driver of the observed increase of 12.7% (or $2,335). Although cost increases in all categories of interest were observed over time, the major driver of the observed increase of 12.7% (or $2,335). Although cost increases in all categories of interest were observed over time, the major driver of the observed increase of 12.7% (or $2,335).

CONCLUSIONS: At week 12, ADA, ETN, and GOL had the lowest incremental CPR for ACR20 and ADA, GOL, and IFX had the lowest CPR for PASI75. ADA had the lowest CPR for both ACR20 and PASI75. The design, study conduct, and financial support for this study/trial were provided by AbbVie.

SPOONSHORP: This research was funded by Celgene Corporation, Warren, NJ.

L7 Cost Per Responder Associated with Biologic Therapies for Psoriasis

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BACKGROUND: Psoriasis (Ps)—a chronic, autoimmune disorder with prevalence of 2.1% among U.S. adults—is characterized by red, raised, scaly skin lesions and also affects joints. A prior study reported differences in the relative efficacy and cost per responder of adalimumab (ADA), etanercept (ETN), infliximab (IFX), and ustekinumab (UST) in Ps. However, the oral treatment apremilast (APR) has been approved and the cost per responder has not been evaluated.

OBJECTIVE: To compare costs per responder associated with reported response rates in randomized clinical trials (RCTs).

METHODS: Phase 3 RCTs of ADA, APR, ETN, IFX, or UST were identified via a PubMed database literature search. Studies were selected if they followed patients for ≥10 weeks and included placebo in the trial. FDA-approved dosing schedules were evaluated: ADA 80 mg at week 0 and 40 mg every other week starting at week 1, ETN 50 mg twice weekly for 3 months and 50 mg once weekly thereafter, UST 45 mg or 90 mg at week 0 and then every 12 weeks starting at week 4; IFX 5 mg/kg at weeks 0, 2, and 6 and 5 mg/kg every 8 weeks thereafter; APR 10 mg on day 1, with an additional 10 mg added every day until day 6, 60 mg on day 7, and 30 mg twice daily thereafter. Published response rates were estimated, with response defined as ≥75% improvement in Psoriasis Area and Severity Index (PASI) at 12 weeks. For studies that did not report the daily response rate at 12 weeks, we used the rate closest to 12 weeks between 10 and 16 weeks. A network meta-analysis was conducted to identify randomized clinical trials for FDA-approved biologics and a PDE-4 inhibitor for PsA. Clinical efficacy was measured using both ACR20 and PASI75. The relative probability of achieving ACR20 and PASI75 at week 12 and 24 with each drug was obtained via a Bayesian NMA. All arms of the NMA included approved dosage, which was 40 mg EOW for adalimumab (ADA), 25 mg BIW for etanercept (ETN), 5 mg/kg for infliximab (IFX), 50 mg Q4W for golimumab (GOL), 200 mg Q2W or 400 mg Q4W for certolizumab (CZP), 45 mg or 90 mg for ustekinumab (UST), and 30 mg twice daily for APR. Number needed to treat (NNT) was calculated as the reciprocal of incremental response rate of each biologic versus placebo. Comparisons were made in terms of cost per incremental ACR20 and PASI75 responder, separately. Drug costs at week 12 and 24 were based on approved dosage using WAC price and IFX 4 hour infusion cost was obtained from Medicare Current Procedural Terminology payment information.

RESULTS: A total of 16 publications were identified, all of which included ACR20 at week 12. The NNT for ACR20 at week 12 were 2.5 (95% credible interval [CrI] 1.9-3.3) for ADA, 2.1 for ETN (1.6-2.9), 1.8 for IFX (1.5-2.4), 2.0 for GOL (1.5-2.9), 3.8 for CZP (2.6-6.3), 5.1 for UST 45 mg (3.8-8.5), 5.6 for UST 90 mg (3.8-9.9), and 6.1 for APR (4.5-9.1). The NNT for PASI75 at week 12 were 2.1 (1.5-3.3) for ADA, 5.8 for ETN (2.2-∞), 1.4 for IFX (1.2-1.7), 2.2 for GOL (1.6-3.5), 4.5 for CZP (2.9-8.2), and 5.5 for APR (3.3-11.3). PASI75 data for week 12 were not available. The 12-week ACR/PASI75 CPR were estimated at $20,071/$16,767 for ADA, $16,716/$46,782 for ETN, $20,687/$15,741 for IFX, $17,473/$19,367 for GOL, $47,203/$55,591 for CZP, $31,953/$28,962 for APR, and $74,933 and $166,102 for UST 45 mg and 90 mg for ACR20, respectively. At week 24, ADA had the lowest CPR for both ACR20 and PASI75.

CONCLUSIONS: At week 12, ADA, ETN, and GOL had the lowest incremental CPR for ACR20 and ADA, GOL, and IFX had the lowest CPR for PASI75. ADA had the lowest CPR for both ACR20 and PASI75 at week 24. The design, study conduct, and financial support for this study/trial were provided by AbbVie.
meta-analysis was used to indirectly derive response rates. For each treatment, number needed to treat (NNT) for an additional responder was calculated as the reciprocal of the incremental derived response rate vs. placebo for that treatment. Drug costs at week 12 were based on the WAC price (June 2014). Cost per incremental responder was calculated for each therapy based on the expected 12-week per patient drug multiplied by the estimated NNT, 95% credible intervals (CrIs) for the NNT and cost per responder were also calculated.

RESULTS: 12 studies were included in the analysis. Across a 12-week time horizon, cost (95% CrI) per additional responder was lowest for ADA ($15,716; $13,614, $17,718), followed by IFX ($16,518; $14,766, $18,269), APR ($20,301; $15,291, $26,094), UST 45 mg ($23,981; $21,746, $26,662), ETN ($34,840; $30,141, $39,702), and UST 90 mg ($44,166; $40,313, $48,020).

CONCLUSIONS: In this analysis, ADA was associated with the lowest cost per responder compared to IFX, ETN, UST, and APR in Ps.

SPONSORSHIP: Genentech.

L16 The Burden of Chronic Hives from the Patient’s Perspective as Compared with Psoriasis

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BACKGROUND: Although many persons with chronic hives (CH) remain symptomatic despite standard therapy, evidence on disease burden is scarce.

OBJECTIVE: This study sought to address this gap by assessing burden of illness (BOI) of CH relative to a clinically well-defined disease, psoriasis (PsO), among adults in the U.S.

METHODS: This retrospective cross-sectional study used self-reported data from the (U.S.) National Health and Wellness Survey (NHWS) (January 2010-August 2012). BOI was defined by health-related quality of life (SF12/36 v2; SF6D), work productivity impairment (WPAI-GH) and healthcare resource use (prior 6 months). Comorbidity was measured using Charlson Comorbidity Index (CCI). Self-report of physician diagnosis included CH (n = 747) or PsO (n = 5,107); persons with both conditions were excluded. PsO severity was based on percent (%)) body coverage (Mild: 3%, n = 3;648; Moderate: > 3-10%, n = 1,336; Severe: > 10%, n = 303). ANOVA was used to compare indicators for CH across levels of PsO severity.

RESULTS: Comorbidity burden was highest for CH (CCI = 1.05) and similar to Severe PsO (CCI = 1.01). More CH than PsO persons reported anxiety (41.6%), depression (38.8%), and sleep difficulties (49.4%) and more CH persons reported positive health indicators: 46.1% never smoked; more were of normal weight (29.1%) and reported exercise in the prior month (64.5%; 79 mean days). Physical and Mental Component Summary (PCS; MCS) scores were below the population standard average (50); CH scores (PCS: 43.8; MCS 44.7) were similar to PsO Moderate and PsO Severe as were health utility scores (0.667 CH vs. 0.671 PsO Moderate; 0.651 PsO Severe). Less than 60% were active in the work force. CH persons reported work productivity impairment similar to PsO Moderate and PsO Severe: Absenteeism: 8.6% CH vs. 8.8% PsO Severe; Presenteeism: 26.6% CH vs. 27.6% PsO Severe; Overall Work Impairment: 28.9% CH vs. 26.4% PsO Moderate; Activity Impairment: 38.8% CH vs. 36.8% PsO Moderate. More CH than PsO persons reported healthcare provider visits (77.1%; 714 visits on average); ER use: 20.7% CH vs. 14.5% PsO Severe; and hospital use: 11.4% CH vs. 9.6% PsO Severe.

CONCLUSIONS: BOI for those with CH is similar to or exceeds that of those with moderate and severe PsO, even in light of positive health behaviors among CH persons. Attention to this high BOI may impact providers to alter their approaches to CH disease management.

SPONSORSHIP: Novartis Pharmaceuticals, East Hanover, NJ.
Regional Variation in Rheumatoid Arthritis Quality Measures

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BACKGROUND: Rheumatoid arthritis (RA) is an inflammatory disorder of the joints affecting 1.5 million patients in the U.S. In recent years, measures have been developed to monitor the quality of RA care offered by health plans and providers. For example, CMS incorporates a RA quality metric to the star ratings of Medicare Advantage (MA) plans. Despite these efforts, it is unclear whether the quality of care RA patients receive depends on where the patients live.

OBJECTIVE: Assess the geographic differences in the quality of RA care in the U.S.

METHODS: We used a large commercial claims database from July 2008 to June 2013 to measure quality of RA care across metropolitan statistical areas (MSAs), in terms of: (a) the share of RA patients prescribed a disease-modifying antirheumatic drug (DMARD), and (b) the share of patients screened for tuberculosis (TB) during the 6 months prior to initiating biologic DMARD therapy. Additional metrics examined were: RA prevalence, defined as the share of the population with RA, and the share of RA patients visiting a rheumatologist annually. Using logistic regression adjusting for age and gender and applying population weights, we measured average quality metric by MSA. We assessed geographic variation using standard deviation (SD) and interquartile range (IQR). The MA star rating for DMARD use was employed for benchmarking.

RESULTS: There were 381,488 patients who met the inclusion criteria. In the average MSA, 64.8% (SD: 11.2%, IQR: 59-72%) of RA patients received a DMARD, and 40.3% (SD: 6.5%, IQR: 36-45%) of RA patients were screened for TB prior to initiating a biologic DMARD. RA prevalence was 0.63% (SD: 0.39%, IQR: 0.50-0.72%), and 49.7% (SD: 17.0%, IQR: 39-62%) of RA patients visited a rheumatologist annually. Based on these results, 9.4% of MSAs would qualify as 4 or 5 stars (SD: 17.0%, IQR: 39-62%) of RA patients visited a rheumatologist annually. Using logistic regression adjusting for age and gender and applying population weights, we measured average quality metric by MSA. We assessed geographic variation using standard deviation (SD) and interquartile range (IQR). The MA star rating for DMARD use was employed for benchmarking.

CONCLUSIONS: P = 0.01) and RA-related costs ($27,141 vs. $18,261; P < 0.001) were observed for patients who initiated IFX and switched to ETN, versus those who switched to ETN. Patients switched to IFX had 5 more office visits in the 12 months post-switch compared to those switched to either ADA or ETN (P = 0.001). No significant differences in costs or healthcare utilization was observed for patients who initiated IFX and switched to ETN or ADA (P = 0.835).

SPONSORSHIP: The design, study conduct, and financial support for this study/trial were provided by AbbVie.

Real-World Treatment Patterns During and After an Emergency Room or Acute Care Facility Visit for Gout

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BACKGROUND: Clinical guidelines recommend NSAIDs, systemic corticosteroids (SCs), or colchicine for the treatment of acute gout. However, little is known about the real-world acute treatment of gout.

OBJECTIVE: To describe real-world treatment patterns of patients receiving branded colchicine or other treatments during an emergency room or acute care facility visit (ER/ACF) visit for gout.

METHODS: An online questionnaire collected chart data on 500 patients with an ER/ACF visit for gout after October 22, 2009. 250 patients who received branded colchicine (Colchicine Cohort) and 250 patients who received NSAIDs, SCs, narcotics, allopurinol, leflunomide, pegloticase, and Costs in Patients with Rheumatoid Arthritis (RA)

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BACKGROUND: The availability of several TNF inhibitors has raised the question of whether switching among these drugs will lead to different outcomes.

OBJECTIVE: To compare healthcare costs and resource utilization among RA patients on anti-TNF therapy who switched to a subsequent TNF inhibitor.

METHODS: Adults with RA diagnoses from January 2005-December 2009 were identified in the MarketScan Database. Patients were included if they initiated adalimumab (ADA), etanercept (ETN), infliximab (IFX), golimumab (GLM), or certolizumab (CZP) following the RA diagnosis and switched to another anti-TNF. Additional requirements were no prior biologic in the 12-month period prior to initial anti-TNF and continuous eligibility for 12 months pre-/post-switch. Healthcare cost and resource utilization were evaluated in the 12 months pre- and post-switch and compared between treatment sequences. Generalized linear models were adjusted for differences in patient demographics and clinical characteristics, including the Charlson Comorbidity Index and Severity Index for Rheumatoid Arthritis (SIFRA).

RESULTS: Among 2,421 patients included, 1,205 initiated ETN and switched to ADA (78.2%) or IFX (21.8%), 899 initiated ADA and switched to ETN (72.9%) or IFX (27.1%), and 317 initiated IFX and switched to ADA (53.3%) or ETN (46.7%). CZP and GLM were not included due to small patient numbers. Patients switched to IFX had increased RA disease severity and methotrexate use at baseline compared to those switched to ADA or ETN. After adjusting for baseline differences, patients initiated on ETN and switched to ADA versus IFX incurred lower all-cause healthcare costs ($33,976 vs. $41,766; P = 0.001) and RA-related costs ($19,743 vs. $28,121; P < 0.001) 1 year after switching. Similarly, higher all-cause ($38,270 vs. $29,488; P < 0.001) and RA-related costs ($27,141 vs. $18,261; P < 0.001) were observed for patients who initiated ADA and switched to IFX, versus those who switched to ETN. Patients switched to IFX had 5 more office visits in the 12 months post-switch compared to those switched to either ADA or ETN (P = 0.001). No significant differences in costs or healthcare utilization was observed for patients who initiated IFX and switched to ETN or ADA (P = 0.835).

CONCLUSIONS: Following treatment with a TNF inhibitor, a switch to ADA or ETN resulted in lower all-cause and RA-related health care costs than switching to IFX.

SPONSORSHIP: The design, study conduct, and financial support for this study/trial were provided by AbbVie.
probenecid, or sulfinpyrazone (Other Cohort) during the ER/ACF visit (Period 1 [P1]). Data were collected from 45 U.S. rheumatologists and 63 primary care physicians. Patient characteristics and treatment during P1, from ER/ACF discharge to the first follow-up visit (P2), and from the first follow-up visit to end of treatment (P3) are reported.

RESULTS: The mean age was 51 years and 74.8% were male. In P1, 16.0% of patients were newly diagnosed; 40.2% had been diagnosed for ≤ 1 year, and 43.9% for > 1 year. All patients were treated in P1 with 46.0% and 47.2% of patients receiving monotherapy in the Colchicine and Other cohorts, respectively. The most common treatments received in the Other Cohort were NSAIDs (59.6%), SCs (45.2%), narcotics (33.2%), and allopurinol (14.8%). The 500 patients contributed 307 distinct treatment patterns from P1 to P3. Of the 20.6% (n = 103) patients not prescribed a treatment in P2, 60.2% were restarted on a treatment in P3. Of the 393 treated patients in P2, 36.1% had a treatment change (add-on, switch, or dose increase) in P3. The treatment change was justified by inadequacy of the treatment for maintenance therapy, insufficient dosage, or failure to achieve satisfactory response in 67.6% of these patients. In the Colchicine Cohort, 60.8% of patients were prescribed colchicine consistently from P1 to P3, while in the Other Cohort, only 26.8% and 17.7% of patients were consistently prescribed NSAIDs and SCs from P1 to P3, respectively.

CONCLUSIONS: Treatment guidelines recommend several treatment options for acute gout flares. In practice, we observed a substantial number of distinct patterns and frequent subsequent treatment adjustments by treating physicians for patients who were admitted to the ER/ACF for gout. These findings suggest that further studies are warranted to better understand and identify the optimal treatment patterns for acute gout flares.

SPONSORSHIP: This study was funded by Takeda Pharmaceuticals International.

M4 Identification of Infliximab Infusions Using Veterans Affairs Structured Pharmacy and Procedure Data and Unstructured Clinical Notes

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BACKGROUND: The Veterans Health Administration (VHA) contains multiple data-marts, which include the Corporate Data Warehouse (CDW), Pharmacy Benefits Management (PBM), Decision Support Systems (DSS) now managed by the Corporate Data Warehouse (CDW), and Medical SAS Datasets. These data-marts have different rules for extracting VHA data from local VistA systems. Early work found that data on outpatient infused medications was not consistently identifiable in pharmacy dispensing data.

OBJECTIVE: The objective was to compare the accuracy of different data sources and combinations to identify infliximab administration date and infused dose against a reference standard established from the Veterans Affairs Rheumatoid Arthritis (VARA) registry.

METHODS: Infliximab administration dates and infused doses were determined using eight approaches: CDW HCPCS/CPT codes alone, CDW clinical notes, CDW IV package (inpatient pharmacy dispensing), PBM IV package, DSS, and combined approaches. Natural Language Processing (NLP) algorithms were validated to extract infliximab infusion doses and dates from clinical notes. F-measure is the harmonic mean of precision and recall. Mean estimated infused doses were compared to VARA using two-tailed t-test with P = 0.05.

RESULTS: DSS performed the best with an F-measure of 92.9%, the combined CDW HCPCS/CPT plus NLP on clinical notes performed the second best with an F-measure of 90.5%. CDW IV package had an F-measure of 64.1% and CDW HCPCS/CPT alone had a score of 66.5%. The mean dose for the VARA reference standard was 432.9 mg with a standard error of 3.34 mg. DSS, CDW NLP clinical notes and the combined CDW IV plus NLP on clinical notes were not significantly different from the VARA reference standard. The CDW HCPCS/CPT performed the worst at identifying the actual infused dose with a mean dose of 337.0 (P < 0.0001).

CONCLUSIONS: In a previous paper we reported that NLP was required to accurately identify infliximab and other outpatient infused medications. When we conducted the original study we did not include DSS or PBM data since they were considered legacy and was in the process of being phased out. DSS data was retained to MCA and it now appears that it will remain available to VHA researchers. Furthermore, CDW IV package was not available when we initiated the study and is still in the raw (not officially acknowledged by CDW) domain and not considered production data. Researchers should consider the use of DSS data to identify infliximab, and other outpatient infused medications, when conducting studies that involve the infusion of outpatient medications.

SPONSORSHIP: VA Informatics and Computing Infrastructure (VINCI) and Salt Lake City COIN were the primary funders of this work.

M5 Variation in Disease-Modifying Antirheumatic Drug (DMARD) Initiation Among Newly Diagnosed Rheumatoid Arthritis (RA) Patients by State and Drug Plan

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BACKGROUND: The National Quality Forum recommends patients diagnosed with RA have at least one outpatient prescription for a DMARD, conventional or biologic, within 12 months of diagnosis.

OBJECTIVE: This study evaluated DMARD initiation rates for newly diagnosed RA patients and variations by state and prescription plan.

METHODS: Adults with newly diagnosed RA were identified between January 2009 and December 2012 in the Truven Health MarketScan Commercial and Medicare Research Databases. Patients were required to have 12 months of continuous health plan enrollment before and after the first RA diagnosis (index date), have a second RA diagnosis after the first RA diagnosis (index date), have a second RA diagnosis among Newly Diagnosed Rheumatoid Arthritis (RA) Patients by State and Drug Plan

BACKGROUND: The National Quality Forum recommends patients diagnosed with RA have at least one outpatient prescription for a DMARD, conventional or biologic, within 12 months of diagnosis.

OBJECTIVE: This study evaluated DMARD initiation rates for newly diagnosed RA patients and variations by state and prescription plan.

METHODS: Adults with newly diagnosed RA were identified between January 2009 and December 2012 in the Truven Health MarketScan Commercial and Medicare Research Databases. Patients were required to have 12 months of continuous health plan enrollment before and after the first RA diagnosis (index date), have a second RA diagnosis within 120 days of the first, and were excluded if they used a DMARD in the 12 months prior to index date. DMARD initiation rates were described separately at the state and prescription plan (plan)-level. While all plans were included in the patient-level and state-level analyses, plans were required to have at least 25 newly diagnosed RA patients to be included in the plan-level analysis.

RESULTS: Among newly diagnosed RA patients (n = 40,040), 55.5% initiated DMARD therapy within 12 months. Mean time to initiation was 39.1 days (SD = 64.8) and 87% initiated a DMARD within 90 days of a new diagnosis. DMARD initiation rates were similar in 2009, 2010, 2011 and 2012, increasing modestly from 53.3% to 56.8%. Although initiation rates were similar across region (range: 51.95% in Northeast to 58.1% in South), there was variation across states (Interquartile range [IQR]: 54%, 66%), with a range of 43.5% to 61.1% among the ten states with the greatest number of newly diagnosed RA patients (66% of study sample). A total of 57 prescription drug carrier plans were included in the plan-level analysis. Nearly 25% of plans had between 500 and 11,000 RA initiators. 39% had 100 to less than 500 and the remaining plans between 25 to less than 100. Among plans, the median DMARD initiation rate was 56.9% (IQR: 49%, 65%), DMARD initiation rates ranged from 42.6% to 63.5% among the eight largest prescription carriers in the analysis, which comprised 75% of the study sample and varied by 10 percentage points between the two largest plans in the analysis.
CONCLUSIONS: In this commercially insured population, DMARD initiation rates varied substantially by both state and health plan with only over half of the RA patients initiating DMARDs within 12 months of diagnosis. This has significant patient outcome implications and poses a challenge to managed care in order to meet quality of care guidelines for RA.

SPONSORSHIP: Research was funded by ImmuneX and Wyeth.

**M6 Impact of a Clinical Outreach Program on CMS Star Rating for Rheumatoid Arthritis Treatment**

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Magellan Rx Management

BACKGROUND: To assist payers in improving the quality of care delivered to their beneficiaries, Magellan Rx Management has developed and implemented clinical programs designed to specifically address the quality standards incorporated into the CMS Star Rating measures. One of these measures is C19-Rheumatoid Arthritis (RA) Management.

OBJECTIVE: To measure the impact of a clinical program on measure C19—the percentage of RA patients on disease-modifying antirheumatic drug (DMARD) therapy within a regional Medicare Advantage plan.

METHODS: The RA Management population consists of all members with two or more outpatient or nonacute inpatient visits with a diagnosis for RA between January and November 2014. Members are considered compliant when they have a pharmacy or medical claim for a DMARD. The treatment rate is calculated by taking the numerator (compliant members) divided by the denominator (compliant + non-compliant members). A clinical program was implemented to increase the treatment rate, which was to be accomplished through telephonic outreach by clinical staff to providers, pharmacies, and patients. Outreach was prioritized according to concurrent diagnoses, claims history, and prescriber specialty. The focus of this outreach was recommending use of a DMARD and/or removing inappropriately diagnosed members from the denominator.

RESULTS: Between January and November 2014, 550 members were identified as part of the RA Management measure, with a total of 326 non-compliant cases. 232 non-compliant cases were able to be resolved, 180 resulted in a claim for a DMARD; 27 resulted in identification of an inappropriate RA diagnosis; 25 resulted in clinical and non-clinical rationale for non-compliance. As of November 2014, the 180 additional members with a claim for a DMARD and 27 denominator removals resulted in a treatment rate of 79.9% (+ stars). Since additional members with inappropriate RA diagnoses can continue to be removed from the population through February 2015, full results for 2014 will be available in March 2015.

CONCLUSIONS: As of November 2014, the clinical program has resulted in a 2.9% increase in the treatment rate compared to the same time period in 2013. Without denominator removals and cases that transitioned from non-compliant to compliant post-outreach, the treatment rate in November 2014 would have been 63.0%, which would have resulted in a 2-star decrease for the measure. The treatment rate for 2014 should continue to increase as members inappropriately diagnosed with RA are identified and removed from the measure.

SPONSORSHIP: This research was conducted by Magellan Rx Management, Newport, RI, without external funding.

**M7 Short-Acting Opioid Utilization Patterns Can Aid in Clinical Program Development**

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Prime Therapeutics

BACKGROUND: More than 70% of drug overdose deaths in 2012 involved opioids. Insurers have started limiting quantities dispensed and days supply to address the problem (e.g., a maximum of 30 days supply in a 3-month period). Insurers need to understand their members’ opioid utilization to develop successful programs.

OBJECTIVE: Describe utilization patterns, quantities, and duration of use among short-acting opioid users to guide clinical program development.

METHODS: We queried administrative pharmacy claims data for 12 million commercial members from 14 plans across the U.S. between July 1, 2013 through September 30, 2014. Members were included in the analysis if they had a short-acting opioid claim between July 1, 2013 and December 31, 2013 and were continuously enrolled 120 days prior to their first (index) claim through September 30, 2014. Opioid measures included new start (no opioid supply 120 days prior to their index claim), count of claims, median days supply and quantity dispensed, count of unique prescribers and pharmacies, percentage of time a member had opioid supply during the study period, and sum of days supply for non-liquid formulations over 3-month periods in 2014 (January to March, April to June and July to September). Descriptive statistics were used to report results; medians were reported due to outlying values.

RESULTS: Between July 1, 2013 and December 31, 2013, 1,074,264 members had at least 1 claim for any opioid and 990,682 (93%) members had only short-acting opioid claims. 769,561 (78%) members had new starts to short-acting opioids. 583,016 (59%) members had only 1 short-acting opioid claim with no refills. During follow-up, median number of opioid claims per member was 2 (average 4); median sum of days supply was 9 (average 61) and median quantity was 50 (average 254). 68,018 (7%) filled their short-acting opioids at 4 of more pharmacies and 20,237 (2%) members used 4 or more prescribers. 84,259 (9%) members had opioid supply for over half of their follow-up period. The median short acting opioid days supply for each 3 month period in 2014 ranged from 26 to 30. 120,288 (12%) members had more than 30 days supply of short-acting opioids January to March 2014, followed by 119,803 (12%) from April to June, and 119,973 (12%) members from July to September.

CONCLUSIONS: While most members used short-acting opioids for small periods of time with small quantities, a concerning 9-12% appear to be using them chronically with over a 6 month supply during the 12-month follow-up or more than 30 days supply in 3 month periods. Understanding utilization patterns can direct new managed care pharmacy program development to ensure safe opioid use.

SPONSORSHIP: Prime Therapeutics.

**M11 One-Year Treatment Patterns and Health Care Resource Use Among Patients with Rheumatoid Arthritis Newly Initiating Treatment with Biologic DMARDs**

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Pfizer

BACKGROUND: Biologic DMARDs have improved care of patients with rheumatoid arthritis (RA).

OBJECTIVE: To assess treatment patterns and impact on healthcare resource use (HCRU) following prescription/administration of a biologic DMARD alone or with a conventional synthetic (cs) DMARD.

RESuLtS: Between July 1, 2013 and December 31, 2013, 1,074,264 members had at least 1 claim for any opioid and 990,682 (93%) members had only short-acting opioid claims. 769,561 (78%) members had new starts to short-acting opioids. 583,016 (59%) members had only 1 short-acting opioid claim with no refills. During follow-up, median number of opioid claims per member was 2 (average 4); median sum of days supply was 9 (average 61) and median quantity was 50 (average 254). 68,018 (7%) filled their short-acting opioids at 4 of more pharmacies and 20,237 (2%) members used 4 or more prescribers. 84,259 (9%) members had opioid supply for over half of their follow-up period. The median short acting opioid days supply for each 3 month period in 2014 ranged from 26 to 30. 120,288 (12%) members had more than 30 days supply of short-acting opioids January to March 2014, followed by 119,803 (12%) from April to June, and 119,973 (12%) members from July to September.

CONCLUSIONS: While most members used short-acting opioids for small periods of time with small quantities, a concerning 9-12% appear to be using them chronically with over a 6 month supply during the 12-month follow-up or more than 30 days supply in 3 month periods. Understanding utilization patterns can direct new managed care pharmacy program development to ensure safe opioid use.

SPONSORSHIP: Prime Therapeutics.
METHODS: In this retrospective cohort analysis, patients aged >18 years with an RA diagnosis (ICD-9:714.XX) and prescribed/administered DMARD (2007-2011) were selected from de-identified electronic health records (EHR, Humedica). Index date was first biologic DMARD prescription/administration. Patients received no biologic DMARD for ≥6 months pre-index and were followed for ≥1-year post-index. Patients were categorized by index biologic monotherapy (Bmono) or combination therapy with biologic and cs-DMARD (B + CScombo). Regression analyses for switch (new biologic/cs-DMARD prescription/administration, no index biologic drug ≥120 days) and RA-related costs were based on patient demographics and characteristics. RA-related costs were derived from a patient subset with linked Optum claims data and applied to RA visits and pharmacy use in EHR.

RESULTS: Of 2,119 patients initiating a biologic DMARD, 70.6% had Bmono and 29.1% had B + CScombo. For Bmono and B + CScombo patients, mean age (58.7 vs. 58.8 years), percentage of females (75.2% vs. 78.3%) and mean number of RA prescriptions 6 months pre-index (2.96 vs. 2.39) were similar between cohorts (all \(p > 0.05\)). Compared with B + CScombo patients, Bmono patients were more likely to be treated by a rheumatologist (31.9% vs. 60.7%, \(p < 0.0001\)) and had a higher Charlson comorbidity index (0.61 vs. 0.94, \(p < 0.0001\)) but were less likely to have cardiovascular disease, hyperlipidemia, hypertension and renal disease (all \(p < 0.01\)). Most Bmono (79.4%) and B + CScombo (92.4%) patients were prescribed a TNF inhibitor. During 1-year follow-up (FU), B + CScombo patients were less likely to switch vs. Bmono patients (odds ratio 0.37, 95% confidence interval 0.27-0.51, \(p < 0.0001\)). In total, 36.3% (544/1497) of Bmono patients switched, with most of the 544 patients (81.4%) switching to a cs-DMARD, 11.8% (73/617) of B + CScombo patients switched, with 53.4% of patients switching biologic and 46.6% switching cs-DMARD of the B + CScombo regimen. Compared with Bmono patients, B + CScombo patients had lower mean RA-related office (6.0 vs. 4.9) and outpatient (2.1 vs. 0.8) visits, but more prescriptions (6.2 vs. 7.8, all \(p < 0.0001\)). Total RA-related costs were 30% lower for Bmono vs. B + CScombo patients (\(p < 0.001\)).

CONCLUSIONS: Overall, 70.6% of patients had Bmono. B + CScombo patients were less likely to switch from index in 1-year FU and had lower RA-related medical HCRU vs. Bmono patients but greater total costs.

SPONSORSHIP: This study was sponsored by Pfizer.

M12 Early Experience with Tofacitinib: Patient Characteristics, Treatment Adherence, and Costs in a Health Care Claims Database

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BACKGROUND: Tofacitinib is an oral Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis (RA). Tofacitinib can be administered as monotherapy or in combination with conventional synthetic (cs) disease-modifying antirheumatic drugs (DMARDS). Limited data are available to describe the characteristics of patients with RA receiving tofacitinib in clinical practice.

OBJECTIVE: To describe the characteristics of patients with RA initiating tofacitinib and evaluate adherence and costs using data from a U.S. administrative claims database.

METHODS: This was a retrospective cohort analysis of patients aged >18 years with an RA diagnosis (ICD-9:714.XX) and ≥1 tofacitinib claim in the Truven MarketScan Commercial and Medicare healthcare claims databases. The index date was the first tofacitinib fill date (November 2012–June 2014). Patients were continuously enrolled for ≥12 months pre- and ≥6 months post-index. Tofacitinib adherence was assessed using proportion of days covered (PDC). Differences in 6 months pre- and post-index RA-related and all-cause costs were evaluated. Outcomes are reported for patients receiving tofacitinib alone (not filled cs-DMARD≤90 days of tofacitinib initiation) or with a cs DMARD.

RESULTS: 871 patients were included with mean (standard deviation [SD]) age 55.9 (11.5) years; 81.1% were women. In the 12 months pre-index, 70.8% of patients had ≥1 biologic with mean (SD) 2.1 (3.4) TNF inhibitors (TNFi) and 1.0 (2.8) non-TNFi biologic, and 8.6% of patients had ≥1 hospitalization with an RA diagnosis (any diagnosis position). In the 6 months pre-index, 72.0% of patients used a cs-DMARD. Upon initiating tofacitinib, 48.7% of patients received monotherapy, 34.6% received tofacitinib with methotrexate (MTX) and 16.8% received tofacitinib with a non-MTX cs-DMARD. Six-month median PDC was 0.83 overall (monotherapy vs. combination therapy mean difference: -0.0001 [95% confidence interval (CI) -0.0431, 0.0428], \(p = 0.9955\)). Change from pre-index to post-index periods in 6-month mean RA-related medical and overall costs were -$596 and -$4,635, respectively. Difference in change in RA-related costs was not significantly different for monotherapy vs. combination therapy (mean difference -$25.50 [95% CI 2,229, 2,178], \(p = 0.98\)).

CONCLUSIONS: Almost half of patients received tofacitinib monotherapy and most had prior biologic use. Six-month median adherence was >0.80 overall and similar for monotherapy and combination therapy. Difference in change in RA-related costs was not significantly different for tofacitinib monotherapy vs. combination therapy.

SPONSORSHIP: This study was sponsored by Pfizer.

M13 The Real-World Effectiveness and Cost Per Responder of Biologic Therapies Among U.S. Veterans with Rheumatoid Arthritis

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1Dallas VA and University of Texas Southwestern Medical Center; 2Salt Lake City VA and University of Utah, 3AbbVie

BACKGROUND: Several tumor necrosis factor (TNF) inhibitors are available and understanding the real-world comparative effectiveness of these agents will guide policy development.

OBJECTIVE: The purpose of this study was to compare the real-world effectiveness and cost per responder for adalimumab (ADA), etanercept (ETN), and infliximab (IFX) in the Veterans Affairs Rheumatoid Arthritis (VARA) registry, a longitudinal observational cohort of rheumatoid arthritis (RA) patients.

METHODS: Patients enrolled in the VARA registry initiating their first VA-based anti-TNF (ADA, ETN, or IFX) after 6 months of VA enrollment between March 2003 to September 2011 were included and followed for up to 15 months. A responder was defined by a 12-month (>0.80 overall and similar for monotherapy and combination therapy. Difference in change in RA-related costs was not significantly different for tofacitinib monotherapy vs. combination therapy.

SPONSORSHIP: This study was sponsored by Pfizer.

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METHODS: Patients enrolled in the VARA registry initiating their first VA-based anti-TNF (ADA, ETN, or IFX) after 6 months of VA enrollment between March 2003 to September 2011 were included and followed for up to 15 months. A responder was defined by a 12-month (>0.80 overall and similar for monotherapy and combination therapy. Difference in change in RA-related costs was not significantly different for tofacitinib monotherapy vs. combination therapy.

SPONSORSHIP: This study was sponsored by Pfizer.
(91% male), race, and tobacco use. Disease characteristics were also similar between groups: mean time to biologic was 9.9, 9.7, and 9.5 years for ADA, ETN, and IFX, mean baseline DAS28 was 5.0, 4.9, and 5.3, respectively. These differences were not statistically significant.

After 1 year of drug exposure, the response to treatment was 44±% for ADA, 35.8±% for ETN, and 27.3±% for IFX. Total mean (±SD) annualized outpatient costs for up to 15 months of observation were $19,699 (6,041) for ADA, $19,468 (7,937) for ETN, and $19,566 (11,124) for IFX. The cost per responder was $44,322 for ADA, $54,347 for ETN, and $71,742 for IFX.

CONCLUSIONS: While differences in response rate to ADA, ETN, and IFX were observed, the overall direct medical costs were similar. Thus, in a real-world setting, differences in effectiveness resulted in a cost per responder that was lower for ADA relative to both ETN and IFX.

SPONSORSHIP: The design, study conduct, and financial support for this study were provided by AbbVie.

M14 Patient Preferences Associated with Therapies for Rheumatoid Arthritis Among Humana Medicare Members: A Conjoint Analysis

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BACKGROUND: Health professionals are encouraged to involve patients in treatment decisions, recognizing patients have a unique knowledge of their own health. However, little is known about the relative importance of product attributes that shape affinities for treatments.

OBJECTIVE: To learn relative patient preferences associated with route of administration (ROA) and other attributes associated with biologic DMARDs (bDMARDs) and targeted synthetic DMARDs (tsDMARDs), including Janus kinase inhibitors, in the treatment of rheumatoid arthritis (RA).

METHODS: A choice-based conjoint (CBC) survey was mailed to 1,400 randomly selected Humana Medicare members diagnosed with RA (≥2 medical claims with an ICD-9-CM diagnosis code of RA [714.0], May 1, 2012-April 30, 2013) and no current or prior use of a bDMARD or tsDMARD indicated for RA. Attributes included ROA, monthly out-of-pocket cost, frequency of administration (FOA), ability to reduce daily joint pain and swelling, likelihood of serious side effects (SSE), improvement in the ability to perform daily tasks and activities, and medication burden (methotrexate co-administration). Mean attribute importance scores (AIS) were calculated and ranked ordered after adjusting for member demographic and clinical characteristics. Part-worth utilities were used to simulate preference shares of currently marketed bDMARDs and tsDMARDs.

RESULTS: A total of 361 Medicare members (response rate 25.8%) returned the survey (mean ± standard deviation [SD] age 68.7 ± 7.9 years, 27% had a history of joint surgery due to RA, 70.6% female). Medicare members’ ranking of attribute importance was in decreasing order (mean AIS ± SD): cost 32.4 ± 15.97, ROA 21.58 ± 12.37, FOA 11.98 ± 5.12, joint pain reduction 10.67 ± 4.79, SSE 8.94 ± 3.63, improvement in daily tasks 7.59 ± 3.42, and medication burden 6.84 ± 3.13. Within the ROA attribute, oral formulation was the level with the highest part-worth utility (preference) values compared with subcutaneous and intravenous routes of administration. A market simulation using these utility values estimated that 52.9% of RA patients in the sample would prefer oral therapy.

CONCLUSIONS: Out-of-pocket costs and route of administration are important considerations to Medicare members diagnosed with RA. Gaining a better understanding of the attributes important to patients may help inform decisions in selecting therapies that could lead to higher patient satisfaction and improved adherence.

SPONSORSHIP: This study was funded by Humana and Pfizer.

M15 Cost Per Effectively Treated Patient of First-Line Biologics for Rheumatoid Arthritis in a Managed Care Population

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1HealthCore; 2Amgen

BACKGROUND: The lack of clinical outcomes information for rheumatoid arthritis (RA) in administrative claims databases has limited their use in comparative effectiveness research. A validated claims-based algorithm has been developed to estimate the effectiveness of biologics for RA.

OBJECTIVE: The objective was to implement this algorithm in a U.S. managed care database and compute the one-year cost per effectively treated patient among first-line biologics approved for moderate-to-severe RA (abatacept [ABA], adalimumab [ADA], certolizumab pegol [CER], etanercept [ETN], golimumab [GOL], infliximab [INF]).

METHODS: This is a retrospective cohort study using administrative data for individuals receiving managed care from the HealthCore Integrated Research Database (HIRD). The cohort included patients with ≥1 claim for the first-line biologics for RA between July 1, 2009 and January 31, 2013. Patients also had to be aged 18-63, had ≥1 claim for RA, had no prior exposure to biologics for RA 6 months pre-index or other conditions for which the aforementioned biologics were approved to treat, and be continuously enrolled between 6 months prior to and 12 months post-index. The first biologic use following 6 months of enrollment defined the index event and date. Costs were obtained from paid amounts on claims for biologic drug and administration.

RESULTS: The cohort comprised 4,844 patients (mean age 48.6, 76.4% female). Average first-year cost ranged from $14,795 (GOL) to $19,520 (ABA). Average first-year cost per effectively treated patient was lowest for ETN ($50.217), followed by GOL ($56.427, P = 0.027 vs. ETN), ADA ($56.879, P < 0.001 vs. ETN), CER ($76.427, P < 0.001 vs. ETN), and INF ($95.126, P < 0.0001 vs. ETN).

CONCLUSIONS: Per the validated claims-based algorithm, ETN had the lowest one-year cost per effectively treated patient among first-line biologics used for RA.

SPONSORSHIP: Research funded by Immunex Corporation, a wholly owned subsidiary of Amgen.

M18 The Economic Benefit of Bupivacaine Liposome Injectable Suspension in the Management of Total Knee Arthroplasty (TKA) Patients

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BACKGROUND: Increased use for TKA is placing increasing demands on health systems and providers to be more efficient and effective.

SPONSORSHIP: This study was funded by Humana and Pfizer.
OBJECTIVE: The study objective was to determine the economic benefit of utilizing a local infiltration analgesia, bupivacaine liposome injectable suspension (LB group), compared to usual care (control group) in TKA patients.

METHODS: This evaluation measured the impact of the LB group following TKA on post-operative pain, pain medication utilization, ambulation, physical therapy assessment, length of hospital stay (LOS), and total procedure cost. From September 2013 to April 2014, consecutive recruitment of 134 TKA cases that received local infiltration with 20 mL of LB and 30 mL bupivacaine 0.25% with epinephrine were enrolled. A historical cohort of 134 control patients (October 2011-August 2013), who received elastomeric pump were propensity score matched by their clinical and demographic characteristics. Variables in the analysis included demographic, pain scores (numeric pain rating), comorbidity, analgesic technique used, pain medication dose, distance ambulated, and length of stay. Sample size was powered 0.80 and alpha 0.05 for each outcome. This study has IRB approval.

RESULTS: For the 268 patients included in the analysis, between group mean pain scores were similar, both groups were <3 on the day of surgery and ≤4 on the first day after surgery (P > 0.05). Compared to the control group, the LB group had significantly (P < 0.001) lower NSAID use on the day of surgery (411.7 ± 145.5 vs. 336.3 ± 145.5) and the first day after surgery (291.1 ± 144.0 vs. 188.1 ± 144.2). There was no between group differences in opioids. After surgery, the LB group walked significantly earlier (walked on the day of surgery 22% vs. 3%, P < 0.05) and farther (mean distance 30 ± 88 vs. 10 ± 15 feet, P < 0.05) and was more likely to be discharged from the hospital in < 3 days (19% vs. 50%, P < 0.05) than the control group. A cost-benefit ratio favored the LB group, for each $1 investment per patient there was a $2.60 benefit and a net benefit (benefit – cost) of $457.27 per patient.

0.05) than the control group. A cost-benefit ratio favored the LB group, for each $1 investment per patient there was a $2.60 benefit and a net benefit (benefit – cost) of $457.27 per patient.

SPONSORSHIP: Pacira Pharmaceuticals provided funding assistance for production and printing of poster.

M19 Predictors of Switch Behavior Among Maintenance Adalimumab Users
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BACKGROUND: The immunomodulator class is one of the highest spend categories for UnitedHealthcare Employer & Individual (UHC). Although utilization has increased, price escalations have been the primary spend driver. By using a tiered formulary, UHC provides financial incentive for members to choose higher value products. Copay coupons undermine this management tool by decreasing patients’ out-of-pocket expense. On January 1, 2013, UHC stopped processing coupons for select Tier 3 products, including adalimumab. As a result, some members switched to lower cost biologic options.

OBJECTIVE: To identify baseline characteristics that may predict switch behavior among maintenance adalimumab users impacted by the coupon policy.

METHODS: A retrospective claims analysis was conducted using UHC commercial data. Members aged 18-64 with an adalimumab claim were identified. The index date was the last adalimumab claim between September 1, 2012 and December 31, 2012. Members were required to be continuously enrolled for six months pre-index through June 30, 2013 and have three consecutive adalimumab claims in the pre-index period. The identified outcomes included: (1) switched to another biologic immunomodulator or (2) remained on adalimumab. Logistic regression was used to evaluate the impact of each characteristic on switch behavior.

RESULTS: A total of 3,541 members met the inclusion criteria. Overall, 18.3% (n = 648) switched and 71.8% (n = 2,544) remained on adalimumab. Members aged 36-45, 46-55, and 56-64 were 52% (P = 0.01), 44% (P = 0.03), and 38% (P < 0.01) more likely to switch than those aged 18-35. Females were 25% (P = 0.02) more likely to switch than males. Members living in the Northeast were significantly less likely to switch compared to those living in other regions (P < 0.01). Members with an arthritis-related diagnosis were 275% more likely to switch (P < 0.01) than those with a gastrointestinal related diagnosis. Members with household incomes ≤ $50,000/year were more likely to switch (P < 0.05) compared to those with higher incomes. Specialty copay tiers significantly impacted switch behavior (P < 0.01). Members taking ≥1 non-biologic DMARD in the baseline period were 33% more likely to switch than those without a non-biologic DMARD claim (P = 0.01).

CONCLUSIONS: The analysis shows that certain baseline characteristics significantly influence switch behavior. These results may be used to more accurately predict potential outcomes of similar strategies.

SPONSORSHIP: Research was conducted by UnitedHealthcare, without external funding.

M21 Longitudinal Treatment Patterns and Associated Outcomes in Patients Newly Diagnosed with Systemic Lupus Erythematosus in the United States
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BACKGROUND: Systemic lupus erythematosus (SLE) is a chronic autoimmune disease of unknown etiology with diverse clinical manifestations.

OBJECTIVE: This study estimated longitudinal treatment patterns of incident SLE patients in a commercially insured U.S. population and associated clinical and economic outcomes.

METHODS: This retrospective, observational cohort study grouped treatment patterns of incident SLE patients over four years after diagnosis from 2002 to 2012 in MarketScan claims database, using a k-means cluster analysis with ten clusters. Multivariable regression analyses compared clinical outcomes (severe SLE and number of severe flares) and health care resource use and costs across treatment clusters, controlling for baseline age, gender, care by specialists vs. PCPs, health plan types, regions, and Charlson comorbidity index (CCI).

RESULTS: 1,611 incident SLE patients were identified with 91% being female, mean age 44.5 years (SD: 9.5), and mean CCI 1.0 (SD: 1.3). Corticosteroids, hydroxychloroquine, mycophenolate mofetil, azathioprine, and methotrexate were included in the cluster analysis. Over four years after diagnosis, 43.8% of the patients were minimally treated with any therapy, 11.2% received corticosteroids monotherapy, 34.0% received hydroxychloroquine monotherapy, 7.8% received corticosteroids plus hydroxychloroquine, and 4.2% received methotrexate or azathioprine with some corticosteroids and hydroxychloroquine. After controlling for covariates and relative to the minimally treated patients, corticosteroid monotherapy patients showed the worst outcomes among all patients, with the risk of severe disease and severe flares ranging from 5 to 9 higher and total medical costs about 2 times higher. Corticosteroids + hydroxychloroquine patients were significantly worse in both clinical outcomes (3-4 times higher) and in some economic outcomes. Hydroxychloroquine monotherapy patients...
showed either similar or better clinical and economic outcomes. Adding methotrexate to corticosteroids and hydroxychloroquine showed significantly worse outcomes in some economic outcomes. Adding azathioprine to corticosteroids and hydroxychloroquine showed worse clinical outcomes (3-4 times higher). Care by specialists vs. PCPs was associated with a benefit in almost all clinical and economic outcomes (0.7-0.9 risk ratio).

CONCLUSIONS: These findings indicate substantial opportunities for improving SLE treatment rate, treatment appropriateness especially for patients receiving corticosteroid monotherapy for four years, and potential benefits of involving specialists.

SPONSORSHIP: GlaxoSmithKline.

M22 Indirect Treatment Comparison of Adalimumab, Etanercept, Certolizumab, Golimumab, and Infliximab for the Treatment of Ankylosing Spondylitis

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BACKGROUND: Biologic therapies have improved the clinical management of ankylosing spondylitis (AS); however, few head-to-head studies have directly compared these agents.

OBJECTIVE: The aim of this study was to conduct a cost per responder (CPR) analysis of biologics for treatment of active AS.

METHODS: A systematic literature review was conducted to identify randomized clinical trials for FDA-approved biologic treatments for active AS. The clinical efficacy of biologic therapies was evaluated versus placebo using ASAS20. The relative probability of achieving ASAS20 at week 12 with each biologic was obtained via a Bayesian network meta-analysis. All arms of the network meta-analysis included approved dosage, which was 40 mg EOW for adalimumab (ADA), 25 mg BIW or 50 mg QW for etanercept (ETN), 5 mg/kg for infliximab (IFX), 50 mg Q4W for golimumab (GOL), and 200 mg Q2W or 400 mg Q4W for certolizumab (CZP). Number needed to treat (NNT) was calculated as the reciprocal of incremental response rate of each biologic versus placebo. Comparisons were made in terms of cost per incrementally ASAS20 responder. Drug costs at week 12 were based on approved dosage using WAC price and IFX 3 hour infusion cost was obtained from Medicare Current Procedural Terminology payment information.

RESULTS: A total of 13 publications were identified, all of which included ASAS20 at week 12. In active AS, the median response rates for ASAS20 at week 12 were 71% (95% credible interval [CrI] 59-82%) for IFX, 63% for ADA (52-73%), 61% for ETN (52-71%), 60% for GOL (47-72%), 50% for CZP (33-68%), and 28% for placebo (25-31%). Incremental drug costs for 12 weeks of therapy were $7,508 for ADA, $8,132 for GOL, $8,102 for ETN, $11,186 for IFX, and $11,077 for CZP. The 12-week CPR was estimated at $21,067 (95% credible interval [CrI] 16,810-29,641) for ADA, $25,102 ($18,638-40,634) for GOL, $23,991 ($19,073-33,147) for ETN, $25,616 ($20,750-35,493) for IFX, and $48,715 ($28,861-182,213) for CZP at week 12. The ASAS40 CPR was $21,322 ($15,241-33,785) for ADA, $29,647 ($17,574-72,962) for ETN, $29,755 ($19,888-59,275) for IFX, $32,535 ($19,622-72,372) for CZP, and $51,738 ($34,789-211,893) for GOL.

CONCLUSIONS: ADA had the lowest incremental cost per responder based on ASAS20 and ASAS40 response and provided a cost savings of $2,924 for ASAS20 over 12 weeks compared to ETN, which was the next most cost-effective option.

SPONSORSHIP: The design, study conduct, and financial support for this study/trial were provided by AbbVie.
METHODS: An internet based survey of post-menopausal women in the U.S. who have been diagnosed with osteoporosis was conducted. Participants were recruited from the Harris Poll consumer panel consisting of adults who have self-selected into the panel. Respondents were asked about current and past osteoporosis treatment, reasons for discontinuing osteoporosis treatment, and willingness to engage in the step-therapy process. Statistical analyses included descriptive statistics and bivariate comparisons for differences between groups.

RESULTS: 432 respondents who self-reported that they had previously taken oral osteoporosis therapy in the past were included in this study. 169 of 432 respondents (39%) indicated that they were not at all willing to reinitiate treatment with an oral osteoporosis medication in order to gain access to coverage of additional treatments. 130 (30%) indicated they were somewhat willing and 133 (31%) ranged from willing to extremely willing. These groups did not differ significantly with regard to demographic characteristics however, those who were unwilling to engage were significantly more likely than those who were willing to reinitiate to experience side effects (P < 0.001). Those who were more willing were significantly more likely to express concerns around costs (P < 0.02).

CONCLUSIONS: While results are limited, osteoporotic patients seem unwilling to engage in the step-therapy process; cost and side effect concerns may be primary drivers. Understanding barriers to access is important for developing policy which ultimately results in appropriate osteoporosis medication use.

SPONSORSHIP: Study funding was provided by Merck & Co.

M26 Association of Osteoporosis Therapy Dosing Regimen with Persistence and Compliance Among Women in a Commercially Insured Population in the United States

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BACKGROUND: Persistence and compliance with osteoporosis therapy are generally suboptimal and may be affected by frequency and route of administration. Limited real-world persistence and compliance data exist for the range of available regimens.

OBJECTIVE: To evaluate persistence and compliance over a 12-month period with different dosing regimens for osteoporosis therapies in a large U.S. claims database.

METHODS: Adult females initiating a new osteoporosis therapy between January 1, 2012 and March 31, 2012 were identified from the MarketScan Commercial and Medicare databases (index date = qualifying claim date). Patients were required to have continuous enrollment with medical and pharmacy benefits for ≥ 24 months pre-index and ≥ 12 months of post-index. Patients were grouped according to frequency and route of administration associated with the index therapy as follows: daily oral, daily injectable, weekly oral, monthly oral, 3-month injectable, and 6-month injectable. Propensity score weighting was used to adjust for differences in baseline demographic and clinical characteristics across the dosing schedules. Study outcomes assessed during the post-index period included: (1) persistence, defined as continuous use of the index therapy without a gap >60 days; and (2) compliance, defined as a medication coverage ratio (proportion of days covered) ≥ 0.80. Multivariable logistic regression was used to compare persistence and compliance across regimens adjusting for baseline characteristics.

RESULTS: A total of 10,863 women (mean [SD] age: 66.1 [11.4] years) were included in the study. Propensity score weight-adjusted 12-month persistence was highest in patients initiating an injectable administered every 6 months (68.0%), followed by daily injectable (60.0%), daily oral (42.0%), weekly oral (35.5%), monthly oral (34.0%), and every 3 months injectable (18.0%; overall P < 0.001). Similarly, the adjusted 12-month compliance was highest in patients initiating a therapy injected every 6 months (71.0%), followed by daily injectable (53.0%), daily oral (38.0%), weekly oral (31.0%), monthly oral (31.0%), and every 3 months injectable (23.0%; overall P < 0.001). The adjusted odds of being persistent and compliant across regimens favored the 6-month dosing schedule (odds ratios from 1.5 to 10.2, P < 0.001 for persistence, 2.3 to 9.7, P < 0.001 for compliance).

CONCLUSIONS: In a U.S. setting, persistence and compliance with osteoporosis therapies over 12 months were higher among patients initiating a 6-month injectable dosing regimen compared to those initiating more frequent regimens.

SPONSORSHIP: This study was sponsored by Amgen.
with inpatient costs accounting for almost 50%. Given its substantial impact, efforts to reduce renal impairment in this population, including potential avoidance of nephrotoxic agents, should be carefully considered.

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

**N2** Treatment Gap Between Clinical Guidelines and the Utilization of Renin-Angiotensin-Aldosterone System Inhibitors in Patients with Heart Failure and/or Chronic Kidney Disease: The Role of Hyperkalemia

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**BACKGROUND:** Renin-angiotensin-aldosterone system inhibitors (RAASi) are recommended in patients with chronic kidney disease (CKD) and/or heart failure (HF). However, these medications can provoke hyperkalemia, potentially leading to serious cardiac arrhythmias.

**OBJECTIVE:** This study investigated RAASi dosage and changes made to RAASi prescriptions in response to laboratory reports of elevated serum potassium (K+).

**METHODS:** Medical records (2007-2012) from a large U.S. population of patients aged ≥5 years with at least 2 serum K+ measurements were evaluated (N = 1.7 million). Inclusion criteria required at least 1 RAASi prescription and 12 months data prior to July 1, 2009 (index period). All persons were classified by disease comorbidity (CKD stages 3-4) and/or HF, age < or ≥ 65 years, and last prescription dose level as of June 30, 2009. RAASi prescriptions were classified by dose level (supramaximum, maximum, submaximum, or discontinued). In addition, all laboratory-reported events of K+ ≥ 5.1 mEq/L were classified by severity (mild 5.1-5.4 mEq/L; moderate/severe ≥ 5.5 mEq/L). Dosage of RAASi was evaluated before and after each hyperkalemia event.

**RESULTS:** 195,327 patients were evaluated during the index period. 19.9% of patients (38,812) were prescribed maximum RAASi doses, 65% (126,955) were prescribed submaximum doses, 14.5% (28,309) were discontinued from RAASi, and 0.6% (1,251) were prescribed supramaximum doses. Distributional differences in dosage were apparent between patients with comorbidities and a control group of patients without comorbidities, as well as between patients aged < 65 years and those aged ≥ 65 years (P < 0.0001). Dosing patterns were evaluated before and after 218,813 hyperkalemia events. In patients on maximum doses of RAASi, 47% of moderate/severe hyperkalemia events and 38% of mild events led to decreases in RAASi doses to submaximum levels or to discontinuation of RAASi. In patients on submaximum doses of RAASi, 55% of moderate/severe hyperkalemia events resulted in dose maintenance, while 27% of events led to RAASi discontinuation. For patients in both dosage categories, RAASi doses were more likely to be decreased or discontinued after moderate/severe vs. mild hyperkalemia events (P < 0.0001).

**CONCLUSIONS:** Relatively few patients are prescribed maximum recommended doses of RAASi despite the presence of serious comorbidities. Prescribing patterns of RAASi are adversely impacted by hyperkalemia, leading to suboptimal or discontinued therapy in many patients.

**SPONSORSHIP:** Funding support was provided by Relypsy.

**000-099 Pregnancy, Childbirth, and the Puerperium (i.e., Abortion, Eclampsia, and Maternal Care)

**01 Use of Prescription Medications During Pregnancy in Regione Emilia-Romagna, Italy, 2004-2013

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**BACKGROUND:** Medication use during pregnancy constitutes a risk of teratogenicity to the developingetus and should only occur if the benefit to the mother outweighs this risk.

**OBJECTIVE:** We sought to describe prescription medication utilization during pregnancy over a 10-year period (2004-2013) in Regione Emilia-Romagna (RER), Italy.

**METHODS:** We performed a retrospective analysis of the RER longitudinal administrative healthcare database for hospital deliveries between January 1, 2004 and December 31, 2013. Medications used in the 270 day period prior to delivery were stratified by trimester of use, pregnancy risk categorization, and anatomical classification. Pregnancy risk categorization was assigned based upon the FDA classification system and, when not specified in the product labeling, the Australian prescribing medicines in pregnancy database and the Briggs classification system were used. A trend analysis by year was performed to identify changes in utilization over time.

**RESULTS:** Among 393,082 deliveries during the 10-year study period, 72.1% of women were exposed to at least 1 prescription medication during pregnancy and 53.2% were exposed to prescription drugs excluding vitamin and mineral products. The most common medication class used during pregnancy was anti-infectives, which represented 6 of the 16 medications with a prevalence of greater than 1%. Progesterone (9.7%) was the most prevalent drug used among all pregnancies. At least 1 prescription for a known teratogen was dispensed to 31,545 pregnant women (8.0%) during the study period. Excluding hormones, 0.45% of women were exposed to the absolutely contraindicated category X medications during pregnancy and 0.33% were exposed during the first trimester. Paroxetine and statins were among the most common category X drug exposures. The prevalence of maternal prescription drug utilization in all deliveries increased from 59.9% of all pregnancies in 2004 to 78.9% in 2013 (45.6% vs. 59.1%, respectively, excluding vitamins and minerals). Notably, exposure to contraindicated medications during pregnancy decreased from 0.71% of women in 2004 to 0.39% in 2013.

**CONCLUSIONS:** In alignment with population-wide trends of increasing drug utilization, the proportion of pregnant women in RER exposed to prescription medications rose markedly during the study period. Encouraging, maternal exposure to contraindicated medications has decreased in RER since 2004. Effective dissemination of teratogenicity risk is imperative in order to facilitate appropriate decisions weighing the risks and benefits of medication use during pregnancy.

**SPONSORSHIP:** None.
BACKGROUND: Respiratory syncytial virus (RSV) is a viral pathogen that causes acute respiratory infections in infants and younger children. Palivizumab is a humanized monoclonal antibody used as a prophylaxis treatment to reduce the incidence of lower respiratory tract disease caused by RSV in high-risk children.

OBJECTIVE: A comparative analysis of three different palivizumab reimbursement models focusing on clinical projection of infant weight gain over a RSV season and its influence on total drug cost.

METHODS: This study was based from medical benefits claims data and through PharMedQuest’s propriety medical benefit management platform (ARC) from October 2012 to April 2014. The study included 83 infants requiring prophylaxis treatment of palivizumab as defined by the 2012 American Academy of Pediatrics. Patients were excluded if they only received one injection and/or did not have a recorded baseline weight. Patient drug utilization and drug cost were projected from recorded baseline weight and compared between three models: (1) California’s Children Services (CCS) 1 kg per month linear growth model, (2) World Health Organization’s (WHO) logarithmic growth curve based on age and weight, and (3) weight monitoring through a model, employed to account for potential medication overflow. A sensitivity analysis was employed to account for potential medication overflow.

RESULTS: The total drug cost of palivizumab based on the clinical pharmacy model ($952,213.48, P<0.01) and WHO model ($963,362.20, P<0.01) yielded decrease in total drug cost when compared to the CCS model ($917,699.22, P<0.01). A 5% sensitivity analysis incorporating a need for additional guidance for tapering patients off of opioids. This study provides a quantitative analysis on the chronic opioid guidelines.
S00-T98 Injury, Poisoning, and Certain Other Consequences of External Causes
(i.e., Adverse Events, Side Effects)

T1 A Budget Impact Analysis of Genotyping-Based Treatment Decisions in Patients with Chronic Pain

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BACKGROUND: Genotyping-based treatment decisions may optimize treatment response and minimize adverse drug events (ADEs) in patients with chronic pain.

OBJECTIVE: To estimate the financial impact of genotyping-based treatment decisions in patients with moderate to severe chronic pain in a managed care setting.

METHODS: A budget impact model was built with a one-year time horizon to estimate costs of genotyping-based treatment decisions in a 1,000 patient cohort. The model includes drug costs, type and cost of adverse events (AEs), distribution of treatments used, and genotyping costs. Event rates and healthcare costs were derived from primary literature. Three patient cohorts were assessed with and without genotyping-based treatment decisions: no genetic testing; 50% genetic testing; and 100% genetic testing. Sensitivity analysis was carried out varying costs, adherence and the percentage of patients treated according to genotyping results.

RESULTS: Medical and AE costs varied by patient severity and genotyping rates. Without genotyping, drug and AE costs ranged from $1,106,517 to $23,086,881. With genotyping-based treatment, total costs ranged from $2,329,888 to $18,792,334. Sensitivity analysis carried out varying costs, adherence and genotyping rates suggested genotyping improves outcomes and is cost saving in patients with chronic pain.

CONCLUSIONS: Genotyping-based treatment costs are offset by reduced medication utilization and adverse event costs. Genotyping should be considered for patients with chronic pain in clinical practice and within clinical trials.

SPONSORSHIP: Pathway Genomics.

U3 Improving Medication Adherence by Addressing Member Convenience: Year Three of an Ongoing Dual-Eligible Medicare Plan’s Efforts

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BACKGROUND: Since 2012, iCare, a Medicare Advantage Prescription Drug plan, implemented various strategies to improve adherence to medication used to treat diabetes, hypertension and hyperlipidemia. The prior programs included targeting members to receive care management and a coordinated effort with a mail order provider who also delivered adherence information (program results previously published). Evidence of lower medication adherence among Special Needs Plans (SNP), like iCare, as compared to other non-SNP Medicare contracts is well known. While public assistance is available for iCare beneficiaries, their 100% low income subsidy (LIS) membership continues to experience challenges with access and transportation to a pharmacy. Convenience with filling medications can be offered with a greater supply of medication (i.e., 30- vs. 90-day benefit) at alternative fulfillment options (i.e., retail vs. mail).

OBJECTIVE: To assess the effectiveness of adding a new 90-day benefit and a prescriber-directed, retail-centered campaign intended to increase awareness and improve medication adherence.

METHODS: On January 1, 2014 iCare implemented a new benefit plan allowing a 90-day supply of medications at retail and mail. Prescribers of the most recent 30-day retail prescription for eligible members received a letter (via fax or mail) containing a pre-populated 90-day
prescription. Prescribers could write for a new 90-day prescription if deemed appropriate for their patient. Medications targeted aligned with the Centers for Medicare & Medicaid Services Star Rating adherence measures. The proportion of 90-day fills was calculated and member- and contract-level adherence rates, using the proportion of days covered (PDC) methodology, were measured and compared from January to November of 2013 and 2014. Prescriber approval and denial rates and the proportion of 90-day retail and mail claims were evaluated.

RESULTS: A total of 7,824 unique prescriber letters were sent, representing 2,843 members and 1,196 providers. Of the total unique letters sent, the prescriber approval rate was 40% and denial rate was 7%. The proportion of 90-day claims increased to 35%-40% for the target medication categories. The average PDC increase was 3.3%.

CONCLUSIONS: Persistent efforts are necessary to change member behavior in challenging populations. A variety of approaches to improve adherence and address common barriers should be employed including offering a 90-day benefit at retail and mail. Physician-directed campaigns can additionally be used to increase awareness and provide fulfillment options that facilitate member convenience.

SPONSORSHIP: No funding was received for this research.

Identifying Unused Medications and Disposal Patterns at Home: Findings from a Medicare Patient Survey and Claims Data

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BACKGROUND: Unused medications are often thrown in household trash or flushed down the toilet. The safety and appropriateness of such practices have not been established, and no drug-specific data currently exist to quantify their potential impact.

OBJECTIVE: This study examined the following three questions: (1) what kinds of drugs are most frequently left unused by patients; (2) how much is left unused; and (3) how these drugs are disposed.

METHODS: A dataset combining the pharmacy claims data of a regional health plan with its member telephone survey data was constructed. The dataset included 721 Medicare Advantage members who had Part D coverage through the plan as of December 31, 2013 and completed the phone survey in May of 2014. From the claims database, the complete lists of drugs that each member had purchased during 2013 were obtained.

RESULTS: Of the 2,994 drugs in the dataset, 247 (8%) were reported being left unused by the patients. Of the 247, the most common drugs were medications for pain (15%), hypertension (14%), antibiotics (11%), and psychiatric disorders (9%). Approximately 13% of the unused drugs were controlled substances. The reasons for being unused varied by drug type (e.g., for pain medications, adverse side effects and over-prescribing were the most commonly cited reasons; for hypertension medications, “Dosage Changed by Doctor” was the most common). Also, most commonly 25%-50% of the unused drugs remained unused. Only about 11% was disposed via drug take-back programs, while the majority was kept in cabinet (55%), thrown in trash (14%) or flushed down the toilet (9%).

CONCLUSIONS: A lack of patient adherence alone does not explain unused medications and their improper disposal. Community-level interventions designed to improve prescription efficiency and patient awareness of appropriate disposal methods—particularly of controlled substances—are necessary to reduce the potentially harmful effects of improper disposal of unused medications.

ing to medication costs, nurse support, injection training, pen disposal, and medication reminders. Whether these resources impact costs associated with healthcare utilization has not been assessed.

**OBJECTIVE:** To quantify the relationship between participation in any component of the PSP and resource costs (medical and total).

**METHODS:** Longitudinal, patient-level data on the utilization of AbbVie’s PSP were linked with Source Healthcare Analytics administrative claims data for patients initiating ADA treatment from January 2008 to June 2014. The sample included patients aged ≥18 years with a diagnosis of Crohn’s disease, ulcerative colitis, rheumatoid arthritis, psoriasis, psoriatic arthritis, or ankylosing spondylitis who were anti-tumor necrosis factor naïve prior to initiation of ADA. Patients enrolled in the PSP (PSP cohort) were matched to those who did not enroll (non-PSP cohort) based on age, sex, year of ADA initiation, comorbidities, diagnosis, and initiation at a specialty pharmacy. For the PSP cohort, the index date was the date of enrollment into the PSP program and their time to enrollment following initiation was used to assign index dates for the non-PSP cohort. All patients were required to have evidence of medical and pharmacy coverage for 6 months before/after their first ADA claim and for 12 months after the index date. Medical costs associated with emergency department, inpatient, physician, and outpatient visits (all-cause and disease-related) and total costs (medical costs plus drug costs) were compared at 12 months following the index date using t-tests and generalized linear models adjusting for key baseline variables. Patients with costs exceeding 5 times the standard deviation of the mean were excluded as outliers (52 for PSP, 64 for non-PSP).

**RESULTS:** A total of 1,199 PSP patients and 1,187 non-PSP patients were included. Baseline characteristics were similar between cohorts. During the follow-up period, unadjusted analyses showed PSP patients had significantly lower 12-month medical costs than non-PSP patients by 23% ($18,322 vs. $23,679; P = 0.003). Disease-related medical costs were 22% lower for PSP patients compared to non-PSP patients ($8,001 vs. $10,201, P = 0.045). Total costs were 10% lower for PSP patients than non-PSP patients ($35,741 vs. $39,713, P = 0.03). Adjusted analyses yielded similar findings.

**CONCLUSIONS:** AbbVie’s free-to-patient PSP was associated with lowering medical costs (all-cause and disease-related) and total healthcare costs.

**SPONSORSHIP:** Design, study conduct, and financial support for this study were provided by AbbVie.

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**U8** Comparison of Annual Treatment Costs for Patients Treated with Infusion Versus Injectable Biologics

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**BACKGROUND:** Biologics have increased therapeutic options for patients with chronic conditions but often entail non-trivial costs. Infusion and self-injectable biologics differ across multiple dimensions besides administration route, including drug price and predominant method of benefit reimbursement. These may influence overall treatment costs.

**OBJECTIVE:** To compare annual treatment costs among patients with autoimmune disorders for infusion vs. self-injectable biologics.

**METHODS:** Patients aged ≥18 years treated with an approved biologic, administered by either infusion (infliximab, rituximab, natalizumab, and tocilizumab) or injection (adalimumab, etanercept, certolizumab, golimumab, ustekinumab, and anakinra), were identified from the Truven Health MarketScan claims database (July 1, 2009 to June 30, 2013). Patients were required to have ≥1 diagnosis for rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, or Crohn’s disease, continuous eligibility for 6 months pre-index (with no claims for the study biologic of interest) and 12 months post-index, and initiation of a study biologic on index date. The key outcome was 30-day average drug costs (2013 USD) while on the study biologic. Unadjusted comparisons between the infusion and injection cohorts were made using univariate statistics. Regression analyses were also conducted for the cost comparisons, adjusting for demographics (age, sex, and region), insurance type, index indication, Charlson Comorbidity Index (CCI), index year, and baseline indication-related costs.

**RESULTS:** There were 7,197 and 25,174 patients in the infusion and injection cohorts, respectively, with mean ages of 45.4 and 46.0 years. Mean baseline CCI was 0.87 and 0.71 for the infusion and injection cohorts, respectively. Unadjusted analysis demonstrated the average 30-day total drug plus administration cost was $3,571 and $2,533 for the infusion and injection cohorts, respectively (P < 0.0001). Adjusted analysis confirmed the unadjusted results, with the adjusted average 30-day drug cost alone being $1,058 more for the infusion cohort than the injection cohort ($3,549 vs. $2,491, P < 0.0001).

**CONCLUSIONS:** Autoimmune disorders patients treated with injectable biologics incurred lower drug costs than those treated with infusion biologics.

**SPONSORSHIP:** Design, study conduct, and financial support for this study were provided by AbbVie.

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**U9** Factors Influencing Self-Reported Perceptions of Adherence, Satisfaction, and Benefits in Patients Receiving Adalimumab Therapy

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**BACKGROUND:** Adalimumab (ADA) is a self-injected biologic therapy that is approved for multiple chronic autoimmune disorders. Although patients’ perceptions of various medication-related factors can affect health outcomes, data examining patients’ perceptions of ADA therapy are limited.

**OBJECTIVE:** To identify factors impacting satisfaction with therapy, potential non-adherence related to injection-site pain, and perceived benefits of therapy in patients treated with ADA.

**METHODS:** An invitation to participate in an online survey was sent to a randomly selected sample of 2,000 patients that had received ADA. Constructs of adherence, satisfaction with therapy, perceived benefits of therapy, were each measured on a 5-point likert scale (1 = strongly agree, 5 = strongly disagree). Patients were also asked about factors such as therapy information source (physicians, Internet, and other), knowledge of therapy (5-point scale), years on therapy, and enrollment in a myHumira patient support program (PSP), which includes patient services such as medication cost support, injection training, or nurse support, among others (yes/no). Least squares regressions models were used to assess whether these factors predicted patients’ intention of adherence to ADA, satisfaction with therapy, and perceived benefits of therapy.

**RESULTS:** Of 335 invitation respondents, 299 had completed responses for analysis. Respondents were on average 47 years old, and 67% were women. Among the respondents, 36% had rheumatoid arthritis, 24% had Crohn’s disease, 22% had psoriasis, 22% had psoriatic arthritis, 9% had ulcerative colitis, and 7% had ankylosing spondylitis.
(percentages not mutually exclusive). All multiple-item measures had high reliability (Cronbach’s alpha > 0.7). Common positive predictors for the 3 dependent variables were knowledge of therapy, length on therapy, and current enrollment in myHumira PSP (all P < 0.01). Patients currently participating in myHumira PSP were less likely to report intent to non-adhere to ADA (3.6 vs. 3.2, P < 0.001), more likely to be satisfied with therapy (4.1 vs. 3.5, P < 0.001), and more likely to perceive the therapy as beneficial (3.6 vs. 3.2, P < 0.001) compared with patients not enrolled.

CONCLUSIONS: Knowledge of therapy, length on therapy, and current enrollment in myHumira PSP were important factors influencing patients’ intended adherence to ADA, satisfaction with therapy, and perceived benefits of therapy. Participation in a PSP may improve patients’ perceptions of a therapy’s benefits and overall satisfaction with their therapy and encourage greater adherence.

SPONSORSHIP: Design, study conduct, and financial support for this study were provided by AbbVie.

U11 The Future of Wellness and Medicare Part D: The Impact of Mergers and Acquisitions
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BACKGROUND: Healthcare reform has led to increasing hospital and insurance partnerships. Under the Medicare Shared Savings Program, reductions in cost will be shared with Medicare. Hospitals and insurance companies opted to partner with a goal of distributing the risk and resources to increase care coordination. Furthermore, the Affordable Care Act (ACA) encouraged implementation of employee wellness programs.

OBJECTIVE: The objectives of this study were to (1) summarize the literature on Medicare reimbursement associated with mergers, (2) provide examples of successful mergers, and (3) describe the pros and cons of developing health plan driven health and wellness programs.

METHODS: A systematic review was conducted to identify successful mergers and best practices of health and wellness programs. Articles after 2008 were compiled using search engines PubMed, Galileo, Ebscohost, and Google Scholar. Key terms used were “corporate,” “health and wellness program,” “health plan,” “insurance plan,” “hospital,” “vertical,” and “merger.” Exclusion criteria to identify successful wellness programs were articles involving forms of consolidation and wellness programs not tied to insurance plans. Notable characteristics were summarized in tables.

RESULTS: A total of 29 relevant articles were retrieved. Findings revealed that despite rising healthcare costs, mergers prevent hospitals from trading-off healthcare quality and services for cost reductions. Medicare reimbursement related to mergers includes a “shared risk” payment model. These arrangements make providers eligible for bonuses if they keep costs below a certain threshold. Examples include Blue Cross Blue Shield, Aetna, and Anthem/WellPoint. The partnership between Piedmont and WellStar health care systems of Georgia allowed for the formation of a new insurance plan for coverage. Administrators believed merging would allow the companies to meet ACA standards for improving clinical outcomes at reduced costs. Before the ACA, some employers had wellness programs, but these programs were not standardized and did not need to produce measurable results. The ACA encouraged improvement of employee wellness programs by providing funding for expanded health services and mandated quality reporting. Successful workplace health and wellness programs have varying incentive structures, but all included monetary incentives.

CONCLUSIONS: The ACA’s Medicare reforms have incited rapid growth of mergers and health and wellness programs. Medicare shared savings incentives can represent a unique opportunity for health plans to promote health and wellness.

SPONSORSHIP: None.

U12 Predicting the U.S. Market on Biosimilars Based on Sales Figures for the European Union
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BACKGROUND: Biosimilars can file as interchangeable with the reference product, or non-interchangeable, which will affect their market share and prescribing behaviors. Currently there are 16 biosimilar products approved in the European Union, with varying market shares in different countries. Biosimilars are often 30% cheaper than the reference product, which in many cases is over $10,000 for treatment. Thus, biosimilars represent an enormous cost saving opportunity to healthcare globally. Some countries have entirely saturated their markets with biosimilar products because of the financial benefits.

OBJECTIVE: To predict the market for the Remicade biosimilar.

METHODS: This project will utilize online sales figures for existing biosimilars, and their reference products in the European Union and United States in order to make projections on the markets in the United States. There will also be a comparison of how the United States and European Union current regulations affect the existing market share and predictions of market share for the next 5 years by looking at their online guidances for filing of biosimilar products, what data they require for acceptance, if there are any product specific guidances, how long the biosimilar product would have patent exclusivity if approved.

RESULTS: Our prediction is that, based on existing sales figures for how biosimilars have penetrated the markets in the European Union, biosimilars in the United States stand to gain 30% of the market. This depends on how they are filed. The product can be filed as interchangeable or non-interchangeable with the reference product. Our hypothesis is that Biosimilars cost 30% less than the reference product, and would also achieve 30% of the market share in the first 2 years post approval.

CONCLUSIONS: Biosimilar present a tremendous opportunity for health care savings in the United States, and have been shown as safe and effective alternatives for expensive reference products. However, the FDA guidances on biosimilars have been not been concise. The current analyses shows that at the current sales growth rate of Infliximab the biosimilar would have to have a 20% market share to lower the sales growth of Remicade. If the sales growth rate for Remicade is half the historical average the biosimilar would need a 10% market share to reduce the sales of Remicade.

SPONSORSHIP: Temple University School of Pharmacy.

U15 The Justification, Design, and Implementation of a Pharmacy Network Continuing Participation Verification Process for a Large Managed Care Organization
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PROBLEM DESCRIPTION: Through a limited scope, pharmacy credentials review; numerous issues with pharmacy network providers were identified due to outdated demographic, ownership and liability
information. This review confirmed the existence of gaps in the credentialing details of network pharmacies.

**GOAL:** To develop and implement a scheduled credentials monitoring process of participating network pharmacies. This process once implemented will provide current and accurate data on network pharmacies. This will lead to more robust contract monitoring, tracking of pharmacies, their owners, pharmacists and pharmacy contacts.

**PROGRAM DESCRIPTION:** A limited review was initiated and identified pharmacies were requested to submit the following documents for verification purposes: a listing of pharmacy owners, copies of the dispensing pharmacists licenses and a copy of the pharmacies certificate of liability insurance. Analysts working in the Pharmacy Network area reviewed the submitted documents for accuracy and appropriateness according to network contract.

**OBSERVATIONS:** 45 issues with pharmacy credentials were identified in 32 of the 73 pharmacies reviewed. This represents a 62% rate of issue occurrence in the pharmacies audited. Issues identified in the submitted documents included outdated list of board members, NPI taxonomy code changes, change of ownership detail not on file, non-current certificate of insurance/liability, contact information for the pharmacy not up to date, and the documentation on the pharmacists on duty is not up to date. The results provided justification to institute a continuing participation verification program to verify each pharmacy in the pharmacy network on a rolling two-year basis.

**FINDINGS/RECOMMENDATIONS:** It is imperative to maintain and ensure that current pharmacy network participants are meeting their contractual and credentialing requirements. A limited review found a high rate of noncompliance in credentialing documentation. This lack of continual oversight potentially exposes our membership to untoward action that could result in safety related issues. These findings have lead to instituting a continued participation verification process that will provide for the most current and accurate data on a health plan’s pharmacy network. While early in its development, further review and analysis will be conducted as data is collected about the process.

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

**U24 Education and Training in U.S. Pharmacy Schools: Meeting the Needs of the Pain Population**

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**PROBLEM DESCRIPTION:** High-risk medication (HRM) use among elderly populations is responsible for increased hospitalizations, poor outcomes, and is measured under various quality rating programs. Current methods of alerting pharmacies about opportunities for face-to-face patient consultations are not integrated within the pharmacy workflow. A large regional health plan, HealthPartners, and a national PBMs, MedImpact, developed and implemented an innovative program within an existing pharmacy’s adjudication system to encourage point-of-sale (POS) consultation of patients filling HRMs.

**GOAL:** To describe and assess the effectiveness of a patient consult program designed to educate members using potentially inappropriate medication.

**PROGRAM DESCRIPTION:** A 14-week pilot program (July 28, 2014–October 31, 2014) targeted commercially insured members aged >62 attempting to fill select HRMs at five health plan-owned pharmacies. Six commonly prescribed HRM classes representing approximately 82% of national HRM use were included. A hard stop POS edit required pharmacists to provide consultation and submit specific response codes indicating occurrence of consultation. Training materials included potential risks, a list of appropriate alternatives and scripted talking points. Pharmacy staff was asked to document their time spent and final action taken including offer to speak with their provider, referral to MTM, request follow-up with their provider or fill HRM. To measure the program effectiveness HRM discontinuation rates were calculated approximately 2-4 months after the consultation date for participating and non-participating pharmacies. Use of alternatives was evaluated for the participating pharmacies.

**OBSERVATIONS:** A total of 33 patients were consulted during the 14-week intervention. The most common consultation was for zolpidem (11). The majority of consultations lasted 2-5 minutes. Seven patients indicated they were unaware of medication risk. The HRM discontinuation rate was greater among members visiting participating pharmacies (63% vs. 45%) yielding an estimated 18% intervention effect. Ten percent of targeted members received an alternative.

**FINDINGS/RECOMMENDATIONS:** Members targeted by this program benefited from a HRM consultation at the point-of-sale. This program offers an innovative and effective method to address HRM use within the pharmacy workflow. Similar programs could be employed to address other clinical opportunities including medication adherence, synchronization and gaps in care. Application of this program for Medicare and with other retail pharmacies should be pursued.

**SPONSORSHIP:** This research was conducted by MedImpact HealthCare Systems, San Diego, CA, without external funding.
The mean number of hours spent teaching pain topics ranged from 0.4 to 4.4 hours; empathic communication (3.1 h), anatomy and physiology of pain (3.7 h), and headache pain (4.4 h) had the highest mean hours. Chi-squared analysis revealed no association ($P>0.05$) between institution characteristics and subjects covered.

CONCLUSIONS: Findings revealed several areas of weakness in pain management curriculums across the U.S. Little time was spent teaching pediatric, obstetric/gynecological, orofacial, or spine pain. It is evident that more needs to be done to standardize pain education in pharmacy schools.

SPONSORSHIP: PRIUM Medical Cost Management Services sponsored the completion of this project.

U26 Characterization of an Elderly Population with Potential for Drug–Gene Interactions to Determine the Value of Pharmacogenetic Risk Screening

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BACKGROUND: Genetic testing for drug metabolizing enzyme (DME) coding genes has the potential to optimize medication prescribing, dosing, monitoring, patient outcomes, health resource utilization (HRU) and costs. Elderly patients may realize a greater benefit from genetic testing as they are at higher risk for polypharmacy and adverse drug events.

OBJECTIVE: The objective of this study was to describe baseline characteristics and HRU of a cohort of elderly patients that may benefit from such testing.

METHODS: A retrospective cohort study of patients age ≥65 years were identified through Inovalon’s MORE2 registry; a healthcare data warehouse with national medical/pharmacy claims. Patients with continuous enrollment, taking ≥3 prescription drugs (at least one metabolized by a polymorphic DME), between July 2012 and March 31, 2013 were included. Patient demographics and clinical characteristics were assessed on index date (defined as the date of first claim for ≥1 drugs with pharmacogenetic [PGx] implications) from a predefined list of drugs with either pharmacokinetic in vivo evidence, pharmacodynamic evidence, FDA label/dosing guidance, or the most frequent combinations thereof requesting YouScript (DME screening test). Counts of HRU, including hospitalizations, emergency room and clinic visits were assessed at 9 months post-index date.

RESULTS: There were 1,185,239 individuals identified ≥65 years of age with continuous enrollment between January 1, 2012 and December 31, 2013 of which 602,336 (51%) were on ≥1 of the targeted drugs for genetic testing. Of these, a total of 252,184 patients met the full eligibility criteria. The mean age was 74 ± 6, 41% were male and 72% were white race (35% reported). The majority had Medicare (83%). Of the study population, the Charlson Comorbidity Index was 0 (29%), 1 (33%), 2 (16%), 3 (9%), and ≥4 (14%). The distribution of HRU events at 9 months post-index was 0 (52%), 1 to 5 (16%), 6-10 (12%), and 11 + (20%), respectively. Of the study population, 86% had no hospitalizations in the study period and 10% had 1 to 5 hospitalizations.

CONCLUSIONS: Over 50% of elderly patients are taking at least one prescription drug metabolized by a polymorphic DME. Of these patients 20% experienced more than 10 HRU events in a 9-month period. Stratification of these patients by PGx risk can identify associations of risk with greater HRU events, and is planned as future research. Results from such studies will help determine the value of incorporating PGx risk scores in routine clinical practice.

SPONSORSHIP: Genelex unrestricted research grant.

U27 Application of Pharmacogenomics Screening into a Specialty Drug Management Program

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BACKGROUND: Pharmacogenomics refers to drug treatment that is specific to an individual based on their DNA. Implementation of genetic testing and analysis provides key information, allowing for a personalized approach to drug treatment, and ensuring patient’s receive the most appropriate medication for their condition. Additionally, the presence of certain biologic markers allows physicians and patients to select optimal therapy options and prepare for monitoring and prevention from the start, avoiding the frustration of “trial-and-error” prescribing. Due to strong evidence showing biologic markers are associated with improved treatment response and side effect avoidance, pharmacogenomics information is included on approximately 10% of drug product labels approved by the FDA.

OBJECTIVE: To evaluate the impact of integrating pharmacogenomics screening criteria within a specialty drug management program in targeted, self-funded employer groups.

METHODS: As part of an overall specialty drug management program, a collaborative approach was developed between self-insured employer groups and a pharmacy benefit manager to manage and ensure appropriate utilization of specialty drug products. Prior authorization with additional screening criteria requiring pharmacogenomics testing was implemented as part of the utilization management program for 26 identified specialty products. Prescription drug claims and prior authorization records were evaluated retrospectively so a comparison of the baseline period and intervention period could be made, therefore quantifying the impact of the new pharmacogenomics criteria.

RESULTS: Self-insured employer groups saw overall savings through increased avoidance of medication costs due to the incorporation of pharmacogenomics criteria into the specialty management program. Additionally, an increased number of patients did not meet the specified pharmacogenomics criteria, allowing them to avoid unnecessary therapy and the related financial burden.

CONCLUSIONS: Application of pharmacogenomics screening criteria into an existing specialty drug management program demonstrated an approximate 10% increase in prior authorization requests not meeting established criteria and a subsequent increase in cost avoidance. It also provided plan sponsor specialty savings of 2% and avoided unnecessary medication regimens.

SPONSORSHIP: None.

U28 Prescription Patterns of Patients Meeting Opioid Overutilization Criteria

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BACKGROUND: The CMS Overutilization Monitoring System mandates that Part D sponsors identify patients who meet opioid overutilization criteria, which include receiving RXs from ≥4 prescribers and ≥4 pharmacies. Similarly, the Pharmacy Quality Alliance has drafted an overutilization measure based on the proportion of opioid patients receiving RXs from ≥4 prescribers and ≥4 pharmacies.

OBJECTIVE: To describe the prescription patterns of patients who met the ≥4 prescriber, ≥4 pharmacy overutilization criteria in 2013.

METHODS: Medical and pharmacy claims from the IMS Integrated Data Warehouse for non-cancer patients (≥18 years of age) with ≥2
Rxs for opioids in calendar year 2013 were analyzed. Patients with claims from ≥4 prescribers and ≥4 pharmacies were classified over-utilizers (OU); all other patients were classified non-over-utilizers (N-OU). Demographic and clinical characteristics were compared between the two cohorts. The proportions of patients on short-acting opioids (SAOs) only, long-acting opioids (LAOs) only and both SAO & LAO were compared between cohorts using chi square tests, as was the proportion of patients with Rxs for a category comprised of commonly abused non-opioid medications (e.g., benzodiazepines, stimulants, and sedatives). For each cohort, the mean number of Rxs by opioid molecule was evaluated.

RESULTS: Of the study population (5.2 million), the mean age was 54 years, the majority were female (63.3%) and 65,861 (1.3%) of patients met the overutilization criteria. Compared to N-OUs, OUs were more frequently diagnosed with back and neck pain (60.4% vs. 36.8%), alcohol abuse (15.0% vs. 3.6%), liver disease (9.4% vs. 6.0%), and mental health conditions (45.7% vs. 24.0%, all P<0.001). The majority of OUs (70.2%) and N-OUs (90.4%) used “SAOs only,” and “both SAO and LAO” use was seen in 29.7% and 8.9% of the two cohorts, respectively. A majority of OUs (59.8%) filled Rxs for commonly abused non-opioids, while 37.4% of N-OUs did <0.001. The mean number of opioid Rxs in 2013 was 16.8 for OUs and 6.4 for N-OUs (P<0.001). Among OUs, the mean number of Rxs for products containing the following opioids was hydrocodone (5.9), oxycodone (5.9), tramadol (1.8), oxymorphone (0.2) and tapentadol (0.1).

CONCLUSIONS: Patients meeting opioid overutilization criteria more frequently had claims for both long- and short-acting opioid therapy and for commonly abused non-opioid medications than those not meeting the criteria. Better understanding of overutilization can help identify and appropriately treat patients overusing opioid medications.

SPONSORSHIP: This research was funded by Janssen Scientific Affairs.

U30 Pneumococcal Vaccination Coverage in Adults with Chronic Medical Conditions in the United States

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BACKGROUND: The U.S. Advisory Committee on Immunization Practices (ACIP) recommends pneumococcal vaccination for adults younger than 65 with chronic medical conditions, with a coverage goal of 60% called by the Healthy People 2020 objectives. Yet there are limited real-world data on pneumococcal vaccination coverage in adults with these chronic medical conditions.

OBJECTIVE: To examine pneumococcal vaccination coverage and associated factors in four large U.S. managed care populations with chronic medical conditions included in the ACIP recommendations.

METHODS: In this retrospective observational cohort study, adults aged 19-64 years with newly diagnosed chronic medical conditions from 2007-2010, and with continuous enrollment for at least 3 years in four administrative claims database (MarketScan Commercial, MarketScan Medicaid, Clinformatics Data Mart, and Humana Research Databases) were identified and followed until the end of enrollment or 2011. Outcomes of interest included pneumococcal vaccination coverage, and time to pneumococcal vaccination from the initial diagnosis of the chronic medical condition. Descriptive and regression analyses were applied to examine pneumococcal vaccine coverage and factors associated with pneumococcal vaccination coverage.

RESULTS: The overall pneumococcal vaccination coverage among U.S. managed care adult population with chronic medical conditions was 7.5%, 6.2%, 6.9%, and 7.0%, based on MarketScan Commercial, MarketScan Medicaid, Clinformatics Data Mart, and Humana Research Database, respectively. Pneumococcal vaccination coverage in adults with HIV/AIDS, diabetes, chronic lung disease, or chronic renal disease. On average, these adults visited pharmacy most often (41 times), followed by doctor’s office (29 times) and outpatient hospital (8 times) during the follow-up period. However, among those who received pneumococcal vaccination, the average time to vaccination from initial diagnosis was 454 days, with the majority vaccinated in the doctor’s office. Multivariable logistic regression analysis showed that older age, male, increased healthcare encounters, more chronic medical conditions, enrollment in an HMO health plan, and influenza vaccination were significant predictors of receiving pneumococcal vaccination (all P<0.001).

CONCLUSIONS: Pneumococcal vaccination coverage in four U.S. managed care populations with chronic medical conditions was shown to be consistently far below the Healthy People 2020 objectives. Findings highlight the need for better interventions to improve pneumococcal vaccination in this high-risk adult population.

SPONSORSHIP: Merck & Co.

U31 Differences in the Quality of Medication Use—An Insight for the Medicare Star Rating System

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BACKGROUND: The Medicare Star Ratings system provides incentives to Medicare plan sponsors based partly on the medication-use quality of their beneficiaries. As health plan sponsors seek to further engage their network pharmacies to improve performance, it is important to consider the impact of environmental factors on the differences in the performance of the pharmacies.

OBJECTIVE: The objective of our study was to examine the impact of environmental factors, such as region, population characteristics and healthcare access in the counties in which the stores are located, on differences in pharmacy performance.

METHODS: We used the EQuIPP database, which contains performance information for pharmacies covering 11,700,000 Medicare beneficiaries. Pharmacies with less than 10 patients for a measure were excluded. The following 4 performance measures were examined: (1) proportion of days covered (PDC) for non-insulin oral diabetes medications, (2) PDC for renin angiotensin receptor antagonists, (3) PDC for statins and (4) high-risk medication use in elderly. County-level data was obtained from the Area Health Resource database. A logistic regression model was developed with performance as the dependent variable and regions and environmental factors as independent variables. Performance and the environmental factors were classified as high and low based on a median cut-off.

RESULTS: A total of 28,950 pharmacies had an eligible population (>10 patients) for at least one of the performance measures. Pharmacies in the “East North Central” were the least likely to have low performance for all measures, except PDC statins. Pharmacies were less likely to have low performance if they were located in counties with high median income, or high proportions of urban population, elderly males, elderly Whites, elderly Hispanics and elderly > 84 years of age. Independent pharmacies as well as pharmacies in counties with a high proportion of African-Americans were more likely to have low performance.

CONCLUSIONS: Environmental factors, such as income, age, ethnicity and urban concentration at a county level, play a role in explaining some of the differences in performance of network pharmacies for Medicare beneficiaries. Further research is needed to explore whether
such factors can be overcome through differentiated intervention or if risk adjustment procedures for the measurement system need to be considered.

**SPONSORSHIP:** This research was sponsored, as part of a fellowship, by Pharmacy Quality Solutions.

**U32 How Are Medicare Part D Plans in California Performing? A CMS Star Ratings Quality Metrics Data Analysis**

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**BACKGROUND:** Star ratings are of utmost importance when used to identify improvements in Medicare quality. Medication adherence and safety outcomes measures, including measures of high-risk medications in the elderly, use of angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) in patients with diabetes, and measures of medication adherence for oral diabetes medications, ACE inhibitors/ARBs and statins show that pharmacists’ intervention may play a huge role in improvement of Medicare quality, thus leading to an increase in Star ratings for various health plans.

**OBJECTIVE:** The primary goal was to analyze the performance of California health plans derived from the CMS Star ratings system quality metrics. The secondary purpose was to identify the number of consistently low and high performing health plans across the 3 years demonstration project for CMS Star ratings.

**METHODS:** Based on both the overall percentages and the Star ratings, there were 5 major measured categories of interest: high risk medications, diabetes treatment, adherence of oral diabetes medications, adherence of hypertension medications, and adherence of cholesterol medications.

Data collection procedure initially began with compilation of all the health plans in California from multiple resources. The plan ID numbers were available on Medicare.gov and matched accordingly with the ones on the CMS website.

**RESULTS:** The average percentage data looked relatively similar across the 3 years for each of the 5 measured category. High risk medications category was the only one with a decreasing trend; the other 4 categories had an increasing shift with diabetes treatment as the one with the highest average percentage data. However, for all the measured categories the minor change was slightly different of only a couple.

As a whole, health plans in California showed improvement based on the Star ratings quality metrics. The percentage of health plans with less than 3 stars continued to decrease from 2012 to 2014 while the percentage of 5-star health plans progressively rose over the same time frame.

**SPONSORSHIP:** None.

**U33 Physician Perception of Medication Adherence in a Cohort of Medicare Advantage Plans in Texas**

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**BACKGROUND:** Prescription medication adherence is a known health-related barrier for elderly patients, leading to insufficient disease control and negative health outcomes. The Centers for Medicare and Medicaid Services (CMS) have placed significant emphasis on medication adherence revolving around treatment for chronic disease states such as hypertension, diabetes and hyperlipidemia. However, it is unclear if physicians fully grasp the extent of non-adherence within their patient populations regarding these medications, specifically those enrolled in Medicare Advantage Part D (MAPD) plans.

**OBJECTIVE:** To determine physicians’ perception of medication adherence among their patients enrolled in MAPD and compare it to actual adherence rates obtained from claims data.

**METHODS:** A survey was developed and administered to primary care physicians (PCPs) contracted with a MAPD plan in Texas. Surveys were distributed during an all-PCP quarterly meeting to increase completion and return rates, and were collected prior to the meeting’s conclusion. PCPs were requested to indicate what percentage of their patients they believed to be adherent to each of the CMS Part D medication classes, which included statins, oral diabetics products and renin-angiotensin system (RAS) antagonists. Adherence was defined as patient consumption of the medication >80% of the time. The percent of adherent patients was indicated using a 0-100% scale in intervals of 25%. The PCPs’ perceived percentages of adherent patients were compared to calculated percentages of patients meeting the adherence threshold from pharmacy claims data for the 3 medication classes in each PCP’s patient population using proportion of days covered (PDC).

**RESULTS:** A total of 239 PCPs (78%) completed and returned the survey. PCPs who indicated >75% of their patients were adherent to medications used for Star measures (taking >80% of prescribed doses) were as follows: statins 38%, RAS antagonists 50% and oral diabetes agents 56%. Average percent of adherent patients calculated based on claims data (PDC>80%) were as follows: 71% statins, 76% RAS antagonists and 77% for oral diabetes agents.

**CONCLUSIONS:** MAPD PCPs may be imprecise in their estimation of patient medication adherence. Pharmacist interventions to inform and provide feedback regarding medication adherence may encourage PCPs to take proactive approaches to improve patient care.

**SPONSORSHIP:** This study was conducted without funding.

**U36 APilot Study Investigating Unit-of-Analysis Error in Studies of Pharmacist-Led Interventions for Hypertension**

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**BACKGROUND:** Unit-of-analysis error (UAE) occurs when investigators analyze individual patient data independent of behaviors or interventions conducted by providers (i.e., physicians, pharmacists, or nurses). Because most studies of this type typically include more patients than providers, assuming patient outcomes are independent of provider behaviors can erroneously inflate the power and statistical significance of findings. Several published analyses exist identifying the problem of UAE in medical literature. However, no previous studies examined presence of this error with regard to pharmacist-led interventions.

**OBJECTIVE:** To determine if UAE occurs in studies of pharmacist-led interventions. As a pilot, only studies on pharmacist-led interventions in the management of patients with hypertension published in three pharmacy journals were examined.

**METHODS:** Studies published between January 1, 2012 and November 1, 2014 in the Journal of Managed Care and Specialty Pharmacy, American Journal of Health-System Pharmacy, and Journal of the American Pharmacists Association were included. Three reviewers, using previously published UAE criteria, abstracted and analyzed identified articles.
RESULTS: Of the 67 articles identified, 15 included a pharmacist-led intervention, 4 of which were studies involving hypertension management. All 3 reviewers agreed unanimously on the UAE status of the 4 articles; UAE criteria were met for 3 out of the 4 studies.

CONCLUSIONS: To our knowledge, this pilot is the first evaluation of UAE in studies of pharmacist-led interventions. We found 3 of the 4 identified studies included UAE, indicating this may be a prevalent methodological problem in pharmacist-led intervention research. Since UAE can result in falsely low (e.g., significant) P values for intervention studies, this has important implications for interpretation when deciding whether or not to adopt a reported intervention in day-to-day practice. Based on the results of this pilot, additional investigation is warranted and abstractions are currently underway to assess UAE frequency and implications in studies on pharmacist-led interventions for other conditions.

SPONSORSHIP: There was no external funding for this research.

**U37 Medication Adherence Among Mail-Order Pharmacy Users Versus Retail Pharmacy Users with 90-Day Supply Prescription Fills**

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BACKGROUND: Medication adherence is an important aspect in the management of chronic diseases. Evidence from recent studies indicates that compared with patients who obtained medication refills at local pharmacies, patients using mail-order pharmacy are more likely to have better adherence. Now many health plans allow patients to fill 90-day supply of maintenance medications at retail pharmacies, but few studies have examined the impact of 90-day supply fills on medication adherence.

OBJECTIVE: To compare medication adherence among patients who filled 90-day supply of maintenance medications through mail-order pharmacies versus retail pharmacies.

METHODS: Using administrative pharmacy claims data, we conducted a retrospective cohort study on patients who newly initiated treatment with any of the 5 therapeutic medication classes—antidiabetics, beta-blockers, calcium channel blockers, other antihypertensives (renin-angiotensin system inhibitors, anti-adrenergics) and statins—between July 1, 2012 and December 31, 2012. The analysis included patients who filled 90-day supply prescriptions for the study medications exclusively through the OptumRx mail-order pharmacy or retail pharmacies and were continuously eligible during the 12-month measurement period following the index date. The primary outcome of interest was adherence to each medication class during the measurement period, which was measured using the proportion of days covered (PDC). Mail-order pharmacy users and 90-day retail pharmacy users were stratified by health plan type (Commercial vs. Medicare) and therapeutic class and then 1:1 matched via propensity scoring, controlling for patient's demographic and clinical characteristics.

RESULTS: Compared with patients filling 90-day supply at retail pharmacies, mail-order pharmacy users demonstrated a significantly higher PDC for all 5 medication classes (antidiabetics: 76.9% vs. 72.4%; beta-blockers: 76.6% vs. 72.6%; calcium channel blockers 79.2% vs. 73.3%; other antihypertensives: 78.2% vs. 73.9%; statins: 73.3% vs. 68.3%; all P < 0.001). More patients in the mail-order pharmacy group were adherent (defined as PDC ≥ 80%) with their medications as compared to the retail pharmacy group (antidiabetics: 56.4% vs. 48.8%; beta-blockers: 55.2% vs. 50.2%; calcium channel blockers: 62.6% vs. 54.3%; other antihypertensives: 59.2% vs. 52.9%; statins: 48.9% vs. 42.5%; all P < 0.001).

CONCLUSIONS: Patients using mail-order pharmacies appear to have better adherence to maintenance medications than patients filling 90-day supply at retail pharmacies.

SPONSORSHIP: This study was supported by OptumRx.

**U38 Characterizing Health Care Resource Utilization and Costs Following Patterns of Immediate-Release Hydrocodone Use**

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BACKGROUND: Immediate-release (IR) hydrocodone is among the most widely prescribed opioid analgesics in the United States. To assess healthcare resource utilization (HRU) and costs among IR hydrocodone patients by days of supply and average pills/month in the prior year.

METHODS: A retrospective analysis using healthcare claims from Truven MarketScan commercial, Medicare supplemental, and Medicaid multistate databases was performed. Patients prescribed IR hydrocodone during the 6-month baseline (July 2011-December 2013) period, and with continuous enrollment during baseline and the 12-month follow-up (2012) periods were selected. HRU and per-patient-per-month (PPPM) costs (2013 U.S. dollars) were assessed at follow-up. Descriptive analyses were conducted to compare outcomes at follow-up by days’ supply (<60 vs. ≥ 60 days) and average pills/month (≥ 60 vs. > 60 pills/month) at baseline. Multivariate regressions were employed to estimate the association between the days’ supply, average pills/month and outcomes (HRU and costs), adjusting for differences in patient demographics and clinical characteristics.

RESULTS: In baseline, 1,698,831 commercial, 264,036 Medicare, and 151,063 Medicaid IR hydrocodone patients were identified. During follow-up, commercial patients with ≥ 60 days’ supply had a higher proportion of patients with inpatient hospitalizations (13.1% vs. 7.6%), outpatient hospital visits (69.0% vs. 37.2%), office visits (97.6% vs. 91.1%), emergency room (ER) visits (28.1% vs. 21.5%), and higher PPPM total costs ($1,489 vs. $858) than the <60 days supply subgroup (all P < 0.05). After adjusting for confounding factors, among commercial patients the adjusted odds ratio for ≥ 60 days’ supply of IR hydrocodone versus < 60 days’ supply was 1.60, 1.32, 2.55 and 1.47 (all P values < 0.05) for inpatient admissions, outpatient hospital visits, office visits, and ER visits, respectively. Adjusted all-cause total costs were higher ($1,284 vs. $864, P < 0.05) among commercial patients with longer days’ supply than those with shorter days’ supply. Trends were similar with average pills/month subgroups (≥ 60 vs. > 60 pills/month) and across all plan types.

CONCLUSIONS: Extended length of days’ supply and higher pills/month in the prior year for IR hydrocodone are associated with higher HRU and costs in the following year. Utilization patterns of IR hydrocodone may help to predict future costs, providing an opportunity to flag patients likely to become expensive and improve quality of care.

SPONSORSHIP: Purdue Pharma.

**U40 Outcomes-Based Contracting for Pharmaceutical Products in the United States: Payer and Manufacturer Experience and Outlook**

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BACKGROUND: Over the past 15 years, outcomes-based contracts (OBCs), a type of performance-based risk sharing (PBRS) arrangements, have emerged as a promising avenue for payers to share...
pharmaceutical risk and for manufacturers to improve access. Very limited public information exists on U.S. OBC activity.

**OBJECTIVE:** The aim of this study was to explore historical OBC activity, payers and pharmaceutical decision makers’ perceptions of OBCs, and the future outlook for OBC activity in the U.S.

**METHODS:** Our study combined 2 approaches: a targeted literature review and primary research with U.S. stakeholders. Key sources for the literature review included the University of Washington’s PBRS Database, payer news releases, Factiva, PubMed, and congress abstracts. Only schemes relating to pharmaceuticals were included. Eighteen experts were also interviewed using a structured questionnaire: 10 Commercial/Medicare Part D payers, 2 accountable care organization (ACO) leaders, 2 CMS advisors, and 4 manufacturers’ U.S. pricing or market access executives.

**RESULTS:** There appears to have been limited U.S. OBC activity to date. Over the past 5 years, the literature review identified 3 OBC drug schemes in the U.S. (11 from 1994 to 2014). While this understates the true level of U.S. OBC activity (e.g., some U.S. payers reported enacting up to 4 OBCs in the past 5 years), OBC activity in the U.S. remains a small and discrete proportion of overall contracting activity. Cost/risk reduction was a key focus for payers, while achieving access, building partnerships, and future ACO contracting considerations were the focus for manufacturers. In addition, many payer and manufacturer management executives appear interested in OBCs to showcase value for manufacturers. In addition, many payer and manufacturer partnerships, and future ACO contracting considerations were the focus for manufacturers. While this understates the true level of U.S. OBC activity (e.g., some U.S. payers reported enacting up to 4 OBCs in the past 5 years), OBC activity in the U.S. remains a small and discrete proportion of overall contracting activity. Cost/risk reduction was a key focus for payers, while achieving access, building partnerships, and future ACO contracting considerations were the focus for manufacturers. In addition, many payer and manufacturer management executives appear interested in OBCs to showcase value to their customers (e.g., employers for payers, payers for manufacturers), while staff in charge of pharmaceutical contracting expressed skepticism regarding implementation feasibility given data infrastructure requirements, negotiation complexity, and organizational costs anticipated with OBCs. Based on our stakeholder research, the outlook indicates moderate growth in U.S. OBC activity over the next 5 years, with significant growth expected by some payers and manufacturers. Clear and uncomplicated OBC frameworks will likely need to be developed to support this growth.

**CONCLUSIONS:** OBCs present a valuable opportunity for payers and manufacturers. This research provides an overview of the experience and outlook for OBCs, based on payer and manufacturer insights and perceptions that have thus far been largely unavailable to the general public.

**SPONSORSHIP:** This study was funded by Novartis Pharmaceuticals, East Hanover, NJ.

**U43 Trends in Medication Adherence: The Payer Perspective**

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Xcenda

**BACKGROUND:** In the U.S. market, medication non-adherence leads to healthcare losses between $100 billion and $300 billion annually. Payers are in a unique position to influence medication adherence by supporting adherence programs.

**OBJECTIVE:** To evaluate trends in payer perspectives regarding barriers to implementation and interest in adherence/compliance programs.

**METHODS:** Survey question content was fielded to payer advisors through Xcenda’s proprietary PayerPulse survey subscription service. To observe trends, Xcenda Managed Care Network advisors were queried in April 2011, May 2013, and July 2014. Respondents were asked, whether they will partner with manufacturers, share claims data to improve compliance, and whether adherence programs can influence formulary placement. Respondents were also assessed on current adherence strategies in use, barriers to program development, and benefits for implementing programs.

**RESULTS:** Respondents from 2011 (N = 59), 2013 (N = 60), and 2014 (N = 56), represented between 100,000,000 and 160,000,000 lives each year. In 2014, 55% of respondents selected total cost savings as a reason for participating in compliance programs, and 59% already use automated reminders. The greatest barriers were cost (48%), and lack of integration (57%). The predominant benefit for cardiology/diabetes and multiple sclerosis programs was cost savings (86% and 57%, respectively). Improved quality measures were chosen for high cholesterol (75%), and improved patient satisfaction for arthritis (43%). Over all three years, manufacturer adherence programs gained in popularity. There was a growing trend in willingness to partner with a manufacturer to improve compliance (37% to 48%).
67% and 73% of payers were unwilling to share medical claims with manufacturers. In contrast, a majority of payers were willing to share prescription data to improve compliance (88%-63%). Respondents chose the medication possession ratio as most impactful for formulary decision-making (53%-77%). For outcomes, payers selected decreased hospitalizations (83%-93%) and decreased ER visits (80%-91%) as the most important data they would like to see to inform implications of compliance from the medical claims side.

CONCLUSIONS: While payers are in theory supportive of compliance programs due to the potential cost savings, they see barriers to the return on investment in implementing these programs. Our research suggests that by proving value through decreasing hospitalizations and ER visits, payers will become more involved in compliance monitoring.

SPONSORSHIP: Xcenda.

U44 Six-Month Total Morphine Equivalent Dose and Pharmacy Costs of Opioid Therapy for Chronic Pain Patients Treated with Tapentadol ER, Oxycodone CR, and Oxyxone ER

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BACKGROUND: Examining utilization patterns and costs associated with long-acting opioid (LAO) and short-acting opioid (SAO) therapy in chronic pain patients can help to inform managed care decision making and management of the opioid category.

OBJECTIVE: To compare the 6-month dosing and pharmacy costs of all opioid prescriptions for non-cancer patients with chronic pain initiating therapy with tapentadol extended-release (TAP-ER), oxycodone controlled-release (OXC-CR), and oxymorphone extended-release (OXM-ER).

METHODS: Claims from March 2011-July 2013 in the Symphony Health Solutions database were analyzed for non-cancer adult patients dispensed ≥30 days supply of TAP-ER, OXC-CR, or OXM-ER. The first 30 days were considered a titration period, with day 31 defined as the index date. Patients not meeting the definition of chronic pain (≥180 days supply of index LAO in the 6 months post-index), or having multiple LAOs in the titration period, were excluded. All opioid (LAO and SAO) dosing and pharmacy costs observed for 6 months post-index were compared as mean daily dose in morphine equivalent dose (MED) units and as cost per patient per month (PPPM) for index LAOs, SAOs and total opioids. Adjusted total opioid regimen costs, PPPM were compared using ordinary least squares regression models to adjust for baseline characteristics. To account for multiple comparisons, a P < 0.001 was considered statistically significant.

RESULTS: A total of 25,803 LAO users (TAP-ER: n = 2,637, OXC-CR: n = 19,273, OXM-ER: n = 3,893) were included. The observed mean daily dose in MED units of TAP-ER (114.9) appeared similar to OXC-CR (115.0, P = 0.952) and lower than OXM-ER (141.4, P < 0.001). The TAP-ER cohort had lower mean SAO daily dosing (36.6) compared to both OXC-CR (63.8, P < 0.001) and OXM-ER (60.4, P < 0.001). Adjusted total opioid daily doses (TAP-ER: 153.8) were compared to OXC-CR (204.6, P < 0.001) and OXM-ER (181.1, P < 0.001). Unadjusted mean total opioid PPPM costs were lower for the TAP-ER cohort ($402) vs. OXC-CR ($660, P < 0.001) and OXM-ER ($521, P < 0.001). After adjustment for baseline differences, mean total opioid costs PPPM were lower for TAP-ER patients by $49 and $101 than for OXC-CR and OXM-ER patients, respectively (P < 0.001 for both comparisons).

CONCLUSIONS: Chronic pain patients on TAP-ER had lower total utilization of LAO and SAO medication and lower pharmacy costs than patients using OXC-CR or OXM-ER. The results of this study can help payers manage their utilization of opioids for members with chronic pain.

SPONSORSHIP: This research was funded by Janssen Scientific Affairs.

U46 Evaluating the Risk of the Individually Insured Population in ACA-Compliant Health Plans in Comparison to Transitional Health Plans

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BACKGROUND: The introduction of the Affordable Care Act (ACA) has produced a change to the individually insured population in the United States. Many Americans, both previously insured and uninsured, have signed up for ACA-compliant health plans. Although the new population in ACA-compliant health plans is thought to be comprised of higher utilizers of healthcare services (i.e., higher risk), the risk level has not been quantified.

OBJECTIVE: To quantify the risk of ACA-compliant plan membership using clinical risk groups (CRG) scores and to evaluate the differences of the individually insured population in ACA-compliant plans versus the individually insured population in transitional plans.

METHODS: A retrospective analysis was performed by identifying individually insured members in a midwestern health plan. These members were broken into two groups for analysis: those with transitional plans and those with ACA-compliant plans. Weighted CRG scores of active members for the calendar year 2014 were calculated using pharmacy and medical claims data and demographic information. The health plan’s book of business was used as the benchmark in the calculations. All results were calculated using chi square and t-tests.

RESULTS: Transitional policy membership (n = 46,952) carried an average CRG weight of 0.766, while ACA-compliant membership (n = 36,132) carried an average weight of 1.132 (P ≤ 0.001). “Healthy” and “Non-User” CRGs made up 60.0% of the transitional plan population and 52.1% of the ACA-compliant population, respectively (P ≤ 0.001). “Complex Chronic” and “Critical” CRGs made up 4.0% of the transitional plan population and 10.9% of the ACA-compliant population, respectively (P ≤ 0.001). Furthermore, transitional plan membership was younger (average age 33.66 vs. 38.14, P < 0.001) and was composed of more males (53.5% vs. 48.1%, P < 0.001) than ACA-compliant membership.

CONCLUSIONS: The ACA-compliant health plan population has proven to be one with very high risk. When compared to the composition of members in transitional plans, the values of the CRGs indicate the ACA-compliant population is expected to be about 1.5 times more expensive than the transitional plan membership. The higher expected expense of the ACA-compliant population is supported by having more “Complex Chronic” and “Critical” members, while having less “Healthy” and “Non-User” members than transitional plans. These findings represent tangible values for the risk associated with the individual ACA-compliant population that can be used for future planning.

SPONSORSHIP: No external funding was provided.

U49 Assessment of Opioid Prescribing Trends Related to the Hydrocodone Class Rescheduling

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BACKGROUND: Recently, the U.S. Drug Enforcement Administration (DEA) rescheduled hydrocodone combination products (HCPs) from schedule III to schedule II of the Controlled Substances Act (CSA) in response to increasing concerns of drug addiction and overdose. This change went into effect on October 6, 2014. Hydrocodone is a strong analgesic and it is the most prescribed drug for pain in the U.S., mostly in combination with acetaminophen, making the potential for abuse a public health concern. The more restrictive schedule II means prescribers must hand write the prescription or e-prescribe, and can no longer fax or orally communicate the prescription or contain refills.

OBJECTIVE: To analyze opioid medication prescribing trends following the hydrocodone rescheduling, specifically of HCPs, codeine/acetaminophen, oxycodone containing products, and tramadol, and to assess the different healthcare prescribers before and after the rescheduling.

METHODS: This retrospective analysis utilized claims data from a prescription benefits manager (PBM), to identify members enrolled in a county health plan over a 60-day period before and a 60-day period after rescheduling, who were prescribed any HCPs, codeine/acetaminophen, oxycodone-containing products, or tramadol, after rescheduling, who received prescriptions for an opioid pain medication. The prescribers were categorized into 3 groups: General Practitioner (including family med, internal med), Specialist, and Other (including dentists, nurses, and student doctors).

RESULTS: Using chi-square analysis, there was a decrease in overall prescribing of HCPs after the rescheduling (P = 0.0023) and a decrease in the number of general practitioners who prescribed HCPs (P = 0.0163). General practitioners also had a decrease in overall prescribing of opioid products compared to specialists and other prescribers (P = 0.03).

CONCLUSIONS: The group of patients following the rescheduling of HCPs received fewer prescriptions for HCPs compared to the group of members before the rescheduling. This may be due in large part to the lack of ease in prescribing HCPs compared to other, less restrictive opioid medications. Finally, there is also a shift away from general practitioners to specialists and other practitioners for the overall prescribing of opioid medications. The role of general practitioners involved in prescribing opioid prescriptions may decrease as specialists are becoming more involved with pain management.

SPONSORSHIP: None.

**U51 Evaluation of Eligibility Criteria Used to Identify Members for Medication Therapy Management Services in a Medicare Advantage Part D Population**

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OptumRx

BACKGROUND: Current eligibility criteria used by the Centers for Medicare & Medicaid Services (CMS) to identify members for medication therapy management (MTM) services include ≥ 3 chronic conditions, ≥ 8 chronic drugs, ≥ $3,144 in annual drug costs. CMS recently proposed to lower threshold values of each criterion. However, the performance of these criteria and their thresholds used to identify valuable MTM members is unknown.

OBJECTIVE: (1) To evaluate the performance of MTM eligibility criteria when using varied criteria thresholds; and (2) to identify additional risk factors significantly associated with the number of drug therapy problems (DTPs) for potential use as eligibility criteria.

METHODS: All members in the Medicare Advantage Part D population who had pharmacy eligibility as of December 31, 2013 were included in the study. For each member, at least 6 months of prior pharmacy and medical claims data were retrospectively examined for DTPs. Members with at least 1 DTP were defined as “valuable” and used as the gold standard when calculating the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for current and new eligibility criteria. Quartile values of the 3 MTM criteria were used to test the performance of potential new MTM criteria thresholds. To identify additional risk factors, a Poisson model was used with the number of DTPs per member as the outcome variable. In addition to disease count, drug count, and annual drug spend, the model included socio-demographic variables and prior healthcare utilization as independent variables.

RESULTS: Of the 2,578,336 members included in the study, about 46% were identified with at least 1 DTP. The sensitivity, specificity, PPV, and NPV of current MTM criteria was 12%, 97%, 77%, and 56%, respectively. Both sensitivity and PPV improved when the drug count threshold increased from 8 to 10, and when the annual drug cost decreased from $3,144 to $2,239 or less. The rate of DTPs was significantly greater among members with higher drug and disease counts, annual drug spend, and prior ER or outpatient or hospital visits. Members with higher median household incomes who are male, younger, white, or live in the west (compared to the south) had significantly lower rates of DTPs.

CONCLUSIONS: The performance of MTM eligibility criteria can be improved by increasing the threshold values for drug count while decreasing the threshold value for annual drug spend. Furthermore, additional risk factors, such as recent hospital visit, may be considered as potential MTM eligibility criteria.

SPONSORSHIP: None.

**U52 Impact of Expanding Medication Therapy Management Identification Criteria in a Medicare Advantage Part D Population**

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OptumRx

BACKGROUND: The Centers for Medicare & Medicaid Services recently proposed changes to criteria used to identify members for medication therapy management (MTM) services. These changes would expand the eligible membership size for MTM and have great impact to payers.

OBJECTIVE: To evaluate the impact of changing MTM identification criteria on eligible membership size, demographic and clinical mix of members, and the cost per identified drug therapy problem (DTP).

METHODS: Members in the Medicare Advantage Part D population of approximately 2.6 million were retrospectively identified on a quarterly basis using pharmacy and medical claims as being eligible for MTM in 2013. Cohort 1 members were identified using the 2013 criteria (≥ 3 chronic conditions, ≥ 8 chronic drugs, ≥ $3,144 in annual pharmacy costs). Cohort 2 members were identified using the expanded criteria (≥ 2 chronic conditions, ≥ 8 chronic or acute drugs, ≥ $620 in annual pharmacy costs). Up to 1 year of claims data were used to measure baseline member characteristics. The most recent 6 months prior to when a comprehensive medication review (CMR) would be provided were used to identify DTPs, such as drug-drug interactions and non-adherence. The cost of providing MTM services was evaluated from the payer perspective and included estimated mailing costs and the cost of providing a CMR found from the literature. We assumed that all eligible members would receive a CMR. The cost per DTP was calculated by dividing the annual cost of providing MTM services by the total number of identified DTPs.
**RESULTS:** The expanded criteria increases the number of eligible MTM members by 470% from 189,233 to 1,078,965. In comparison to cohort 1, cohort 2 was older, and more likely to be male and have higher household incomes. Cohort 2 was also more likely to be white and have fewer comorbidities and emergency room and hospital visits. About 78% of cohort 1 was identified with at least one DTP in comparison to 63% of cohort 2. The total annual cost of MTM increased by 470% from $14.1M to $80.7M after expanding the identification criteria, which resulted in a cost per DTP of $56 in cohort 1 and $82 in cohort 2.

**CONCLUSIONS:** Expanding identification criteria will significantly increase the number of eligible members, while decreasing the clinical severity of members and the proportion of members identified with at least one DTP. Payers should anticipate that expanding MTM criteria will increase the cost per DTP and consider further prioritizing members using additional clinical criteria to increase the value of MTM services.

**SPONSORSHIP:** None.

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**U53 Identifying the Potential Differences in Management Strategies Between Hospital and Commercial Payers Regarding Biosimilars: A National Survey**

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**BACKGROUND:** Biologics have accounted for the majority of rising healthcare expenditures; it is projected to be about 25% of drug spending worldwide by 2018. With biosimilars emerging in the U.S. drug market, it’s uncertain how commercial and hospital payers may change their policies to implement these less expensive biologics into their benefit design. Though market sales rates may vary in relation to biosimilars and generics, it is vital to understand how payers will accommodate to these changes.

**OBJECTIVE:** To identify the potential differences in management strategies between hospital and commercial payers within the biosimilar market.

**METHODS:** An electronic survey (Sawtooth software) was e-mailed in November 2014 to 204 representatives of managed care organizations (MCOs) and hospital systems. Data was processed using standard analytics software.

**RESULTS:** 95 respondents from the managed care organization (n = 41) and hospital systems (n = 54) completed the online survey. All respondents are involved in P&T committee decisions for their respective organizations (58 pharmacy directors/VPs, 18 medical directors/VPs, 17 clinical pharmacists, and 2 P&T members). Results showed that 98% of MCOs and 94% of hospital systems are interested in using biosimilars due to low cost as well as 76% of MCOs and 72% of hospital systems interest due to interchangeability. The most important factors that organizations take into consideration when utilizing biosimilars are efficacy, safety, price of treatment, and interchangeability. Efficacy and safety were the highest rated factors. It was also shown that the greatest therapeutic need for biosimilars is within the autoimmune disorder and oncology areas. The vast majority of organizations would include a biosimilar first for treatment-naive patients (88% MCOs; 81% hospital systems) as well as treatment-experienced patients (90% MCOs; 80% hospital systems). Most MCOs would need a cost savings of 20 to 39% to require switching an existing patient to a biosimilar product, while that value is lower for most hospital systems (<30%). In addition, cost-savings thresholds are lower for new patients compared to existing patients.

**CONCLUSIONS:** Commercial and hospital payers will have similar management strategies in regards to biosimilars. Moreover, both payer groups feel that cost and interchangeability are the most important factors when considering the utilization of biosimilars. Though most MCOs and hospital systems plan to manage biosimilars as they would biologics, new tools may be warranted in the future.

**SPONSORSHIP:** MediMedia Managed Markets.

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**U55 Pharmacoeconomic Impact of Generic Price Increases of Tetracycline Antibiotics Across a Self-Insured Population**

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**BACKGROUND:** Generic medications are intended to be more cost-effective alternatives to their brand name counterparts. Over the past several years, the cost of generic medications has increased and thus have caused an increased financial burden on employers. Recent analyses concluded relatively half of all generic medications on the market rose in cost in the past year. Tetracycline antibiotics (TAB) are one example of generic medications that have seen significant price increases.

**OBJECTIVE:** To evaluate the cost impact of generic price increases of tetracycline antibiotics across a self-insured population.

**METHODS:** Retrospective analysis of TAB pharmacy benefit claims from the following date range: January 1, 2011–October 31, 2014. Primary outcome measure: percent (%) increase in cost of generic TABs. Secondary outcomes measures: number of pharmacy benefit claims, average ingredient costs, annual increase in costs. Exclusion criteria: any dosage form other than an oral capsule or tablet; quantity dispensed greater than 30 dosage units (DUs); and any brand name TAB.

**RESULTS:** Out of 23,342 claims, a total of 5,648 claims met the inclusion criteria. Claims represented 26 different TAB products: 54% had experienced a price increase. Of the TAB products that saw an increase in ingredient cost, 50% had a price increase greater than 100%. Significant price increases occurred after the year 2012. Tetracycline 250 mg and 500 mg oral capsules had the greatest price increase.

**CONCLUSIONS:** The self-insured population has been affected by the increase in generic drug costs, especially in the TAB class. Definitive causes of TAB price increases are considered multifactorial and unclear at this time. Generic TAB have been on the U.S. market for decades, but does not mean that they are necessarily still the most cost effective therapies. Plan design and tier placement may need to be modified, such as a split tier generic strategy or a percentage copayment.

**SPONSORSHIP:** None.

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**U57 The Relationship of Member Out-of-Pocket Costs on Primary Prescription Abandonment of Electronically Transmitted Prescriptions Filled in 2011-2012 and 2013**

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**BACKGROUND:** Primary prescription abandonment is a frequently occurring undesirable event that may lead to suboptimal clinical outcomes. There is a paucity of published data comparing changes in abandonment over time within levels of member out-of-pocket costs.

**OBJECTIVE:** To assess member cost share for abandoned electronically-transmitted prescriptions (eTRxs) across different calendar years (CY).
METHODS: This study utilized Medicare and commercial claims data from January 1, 2010 to June 30, 2014 for 18-89 year-olds with continuous eligibility 6 months pre- and post-index. Index date was a new eTRx without a paid claim for the same drug in the prior 6 months. Abandoned prescriptions had no corresponding paid claim and no dose or drug class switch within 120 days of index. Prescriptions filled in CY2011-12 and CY2013 were analyzed separately.

RESULTS: In CY2011-12, 26.3% of 17,440,564 total prescriptions were eTRxs and 12.1% of those were abandoned, while in CY2013, 38.5% of 10,188,310 were eTRxs and 13.1% were abandoned (P<0.001 for 12.1% vs. 13.1%). A positive correlation was observed between abandonment and member cost share for both time periods. In CY2011-12, abandonment ranged from 9.5% for eTRxs costing $0-10 to 31.1% for eTRxs $51+. In CY2013, it ranged from 10.1% to 37.6%, with statistically significant increases in abandonment observed for each cost share range from CY2011-12 to CY2013. Of top 20 most commonly prescribed eTRxs drug classes in CY2011-12, twelve, primarily chronic medications, increased in abandonment in CY2013. Seven of the eight decreasing in abandonment were anti-infectives. The most highly abandoned classes were vaginal combination contraceptives (50.5%) in CY2011-12 and impotence agents (45.0%) in CY2013. Other highly abandoned classes across both time periods included anti-hyperlipidemics, diabetic control agents, and smoking deterrents.

CONCLUSIONS: Increased use of e-prescribing provides insight on true rates of primary prescription abandonment. Although the 1% absolute (8% relative) increase in overall abandonment from CY2011-12 to CY2013 is noteworthy, the 6.5% absolute (21% relative) increase seen for eTRxs costing patients $51+ is of particular concern. Increased patient and provider awareness of plan coverage and member cost share may allow live workshop engaged learners with case presentations and peer critique. Upon completion, learners assessed their ability to evaluate CER studies and use the data in day-to-day decision making using a Likert scale (1 = strongly disagree, 5 = strongly agree). Follow-up evaluations occurred at 2 and 6 months.

RESULTS: Eighteen of the 20 learners enrolled completed the program on schedule (90% completion rate). At completion, learners indicated high confidence in their CER evidence assessment abilities (mean = 4.1). Learners reported a 29-61% improvement in capabilities to evaluate various CER studies and identify study design flaws (mean evaluation prior to CCP scores = 2.0-2.7 and post-CCP scores = 3.9-4.3). Additionally, 61% of learners indicated they expected to increase their use of evidence from CER studies in one to two problem decisions per month. The two-month follow-up survey indicated that eight of 13 respondents had incorporated findings from CER studies in at least two CER-related problem decisions per person.

CONCLUSIONS: As data from CER study designs become available, it will need to be matched by an increased knowledge and skill by decision makers to be incorporated into formulary and clinical decision making and ensure optimal patient outcomes. The CCP was found to improve healthcare decision makers’ self-reported abilities in assessing and applying CER in their work settings.

SPONSORSHIP: Funding was provided by the CER Collaborative, a collaboration of the Academy of Managed Care Pharmacy, the National Pharmaceutical Council, and the International Society for Pharmacoeconomics and Outcomes Research.

U62 Pharmacy and Drug-Impacted Medical Costs Savings for MCOs and PBMs Through MTM/Prescription Planning, Adherence Intervention, and Untapped Generics Usage in Medicare, Medicaid, and Commercial Populations

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BACKGROUND: Managed care organizations (MCOs) are looking for their pharmacy benefit manager (PBM) to reduce pharmacy and drug impacted medical costs.

OBJECTIVE: To analyze savings and efficiency opportunities by leveraging a collaborative MCO/PBM model in Medicare, Medicaid, and Commercial populations by offering MTM/prescription planning, medication adherence, and expanded brand prescription substitution with generics.

METHODS: Pharmacy, medical claims and co-pay of 100K Medicare, 100K Medicaid and 250K commercial members of an MCO for the year 2013 were analyzed for savings: (a) MTM/prescription planning: costs for patients who fell in coverage gap and were also nonadherent were identified and net savings calculated assuming $400 of intervention cost per member per quarter; (b) medication adherence: cost differential of nonadherent (proportion of days covered <80%) members with 3+ CMS defined chronic diseases versus adherent members—intervention cost of $50 per nonadherent member were used to calculate savings; and (c) generics savings: prescription claims for brand drugs with generic alternatives were analyzed.

RESULTS: Medicare: (a) 21.4% of members reached the coverage gap in Q1 to Q3 and over half of these members (12.1%) were nonadherent. This coverage gap/nonadherent population cost $10,644 per member than a member outside the coverage gap for a total annual cost of $59.7M. Potential annual savings post intervention was $50.7M. (b) 17.2% of members had 3+ chronic diseases of which 69% were nonadherent costing $28,081 (medical cost was $23,746 and pharmacy cost was $4,345) versus $17,447 (medical cost was $12,215 and pharmacy cost was $5,232).

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cost was $5,232) for an adherent member. Net annual savings from converting nonadherent members to adherent was $108.9M. (c) 2.97M claims were analyzed of which 15.6% were brand claims with substitutes for 19.1% for savings of $16.0M. Medicaid: (a) 3.0% members had 3+ chronic diseases; 81% were nonadherent with total potential savings of $14.0M. (b) Of 1.6M claims, 16.3% were brand claims with generic substitutes for 4.8% of these brand claims resulting in savings of $2.5M. Commercial: (a) 2.2% members had 3+ chronic diseases; 72% were nonadherent with total potential savings of $15.9M. (b) 2.28M claims were analyzed of which 20.0% were brand claims with substitutes for 11.0% of these brand claims resulting in savings of $9.5M.

CONCLUSIONS: MCOs and PBMs can attain substantial cost savings across all three lines of businesses by expanding MTM/Prescription planning, medication adherence, and increased use of generics.

SPONSORSHIP: The research was funded by RxAdvance.

**U65 Reduction of 30-Day Hospital Readmissions After Patient-Centric Telephonic Medication Therapy Management (MTM) Services**

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BACKGROUND: The Hospital Readmission Reduction program requires CMS to reduce payments to hospitals with excess readmissions. Pharmacist mediated post-discharge telephonic outreach has demonstrated decreased hospital readmission rates in multiple hospital systems. Health plans also have the goal to reduce hospitalizations and emergency room visits with the aim of improved patient outcomes and decreased medical costs.

OBJECTIVE: To evaluate the effectiveness of pharmacist-facilitated telephonic MTM services on reducing hospital readmissions from an academic medical facility.

METHODS: A retrospective chart analysis (n = 314) was performed for patients whom received MTM services following hospital discharge between February 23, 2014 and July 4, 2014. The primary outcome was 30 day readmission. The secondary outcomes were identification of pharmacist interventions related to medication-related problems and discrepancies between patients reported medication list versus hospital discharge medication list. Patients who met the inclusion and exclusion criteria were offered MTM services within 72 hours following hospital discharge. The services, modeled after the 5 core elements of MTM, included a medication therapy review with the patient via telephone, a medication action plan and personalized medication list mailed to the patient, intervention with providers on identified medication-related problems, and follow-up with the patient via telephone within 14 to 30 days after the medication review. Hospital readmission rates for the patient population were compared to a control group using time series analysis. Secondary outcomes were manually categorized and totaled.

RESULTS: Of the 314 total charts, 267 charts were included in the analysis of the primary outcome after further exclusion criteria were applied to the patient population due to discharge coding that took place after the MTM services. Pet-protocol analysis demonstrated no statistically significant difference in hospital readmissions between groups (OR: 1.04, 95% CI: 0.68-1.60). Pharmacists intervened on 189 medication-related problems via facsimile (35.7% of charts), contacted prescribers via phone for 23 medication- or health-related problems, and identified 823 medication list discrepancies (78.34% of charts).

CONCLUSIONS: Pharmacist-facilitated telephonic MTM services did not demonstrate a relationship between exposure and reduced readmission rate. Pharmacists did, however, demonstrate the ability to identify medication-related problems and medication list discrepancies.

SPONSORSHIP: None.

**U68 A Review of the Safety, Risks, and Discontinuation Strategies of Zohydro ER and Hysingla ER**

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BACKGROUND: In the U.S., chronic pain costs approximately $635 billion annually in medical costs and productivity loss. Over the last 10 years, opioid prescriptions have increased 222%. Opioids can cause overdose and death if they are not used correctly.

OBJECTIVE: The aim of this study was to provide an overview of the published peer-reviewed literature related to patient safety, risks, and discontinuation strategies associated with the use of two single entity, long acting hydrocodone derivatives, Zohydro ER and Hysingla ER.

METHODS: Electronic databases, PubMed, Medline, FDA, IDIS, Ovid, and DailyMed were searched from January 2004 to 2014. Key search terms were “Zohydro ER,” “Hysingla ER,” “hydrocodone extended release,” “safety,” “risk mitigation,” “chronic pain,” “opioids,” “tapering,” and “pain management.” Articles included clinical guidelines, systematic reviews, and randomized trials. Exclusion criteria consisted of non-human, non-English and studies addressing use of opioids for cancer pain, post-operative pain, and labor and delivery pain. Results were summarized in a table according to year published, author, title, study design, findings, and source.

RESULTS: A total of 5 articles (randomized controlled trials and observational studies) were retrieved. Other guidelines and reports were used to derive information on discontinuation strategies. Findings revealed that Zohydro ER and Hysingla ER have been shown to be safe and effective for the management of severe pain that requires daily, chronic opioid treatment, but use of these therapies can cause detrimental consequences when used improperly or for recreational purposes. Specifically, life-threatening, or fatal respiratory depression can result following dose increases. Additionally, the risks associated with the use of these drugs reveal a direct relationship between the consumption levels of the drugs and related morbidity and mortality. Adverse effect profiles were consistent with other opioids with the most common adverse effects being constipation, nausea, dizziness, somnolence and vomiting. Evidence suggests that discontinuation strategies related to Zohydro ER and Hysingla ER are limited. Although there is no standard discontinuation strategy, an example taper table is provided based on one randomized controlled trial.

CONCLUSIONS: There is no standard discontinuation guideline or clinical study on the long term use of Zohydro ER and Hysingla ER beyond 12 weeks. Safety associated with use needs to be monitored closely for pain management. More studies regarding discontinuation and long term use need to be conducted.

SPONSORSHIP: None.

**U69 Comparison of Generic Doxycycline and Minocycline Pricing and Utilization Trends Using a Co-Insurance Benefit Design**

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BACKGROUND: Doxycycline incurred a large price increase in the first quarter of 2013, which was among similar trends occurring with
generic drugs. Generic drugs are traditionally managed using either a flat copayment or a co-insurance benefit structure with additional strategies including age restrictions, gender restrictions, quantity limits, etc. Some plans have taken a more active management approach by implementing a multi-generic tier benefit structure to help differentiate between products that are similar in class and efficacy but differ significantly in price. As generic price increases have concerned the payer community, there has risen a need to identify other strategies to appropriately address this issue.

**OBJECTIVE:** To compare price and utilization trends of generic doxycycline and minocycline, and evaluate the role of benefit design in managing generic price increases.

**METHODS:** Pharmacy administrative claims data were compiled from July 2011 to July 2014 to observe cost and utilization trends of a regional health plan of approximately 250,000 lives that utilizes co-insurance for generic drugs. In order to accurately compare pricing trends, a cost per unit (CPU) was calculated using the total claim cost, which included both plan and member paid, divided by the dispensed quantity. The mean CPU per quarter was evaluated over the 12 quarters analyzed. Annual utilization trends in the 6 quarters prior to the doxycycline hyclate (DOX-HYC) price increase (Q2 2011 to Q4 2012) were used to estimate savings experienced as a result of a co-insurance benefit design in the 6 quarters after the price increase (Q1 2013 to Q2 2014).

**RESULTS:** The mean CPU of DOX-HYC (50 mg, 100 mg capsules; 100 mg tablets) increased from $0.15, $0.18 and $0.13 in Q3 2011 to $3.02, $1.47 (increase of 1,936%, 1,613% and 1,014%, respectively) by the end of Q2 2014. Mean units filled per quarter (UPQ) of DOX-HYC decreased 41.5% over the 6 quarters (Q1 2013 to Q2 2014) after the DOXY-HYC price increase. Conversely, minocycline and other doxycycline generic products that did not experience a price increase saw a 45.5% increase in UPQ over the same time periods analyzed. Estimated savings experienced as a result of the shift in utilization totaled approximately $261,808 ($43,635 per quarter).

**CONCLUSIONS:** Study results may suggest that co-insurance benefit design can be an effective cost management tool for driving members to lower cost alternatives. With minimal to no added administrative burden or education to patients or providers, there was a significant shift from high cost DOXY-HYC products to lower cost alternatives.

**SPONSORSHIP:** There was no external funding provided for this research.

**U70** Determining the Cost of Adverse Drug Reactions: Implications for Outcomes Research and Formulary Decisions

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**BACKGROUND:** In homogenous pre-approval clinical trials, observed adverse drug reactions (ADRs) frequently do not correlate with real-world ADRs in heterogeneous populations. Therefore, a drug’s true safety profile is not known until its’ marketing phase. FDA maintains a large collection of post-marketing ADR reports known as the Adverse Event Reporting database (FAERS). Approximately 1,000,000 ADR reports are currently submitted to FDA each year, and the database has over 5,000,000 reports. Substantial costs are associated with these ADRs. Healthcare organizations need improved methods to lower downstream costs associated with ADRs.

**OBJECTIVE:** To estimate ADR costs for individual drugs by combining (1) ADR-specific costs, (2) post-marketing ADR data from FAERS, and (3) drug usage information.

**METHODS:** The FAERS database was used to collect ADR data. Evaluate Pharma (evaluategroup.com) provided drug usage data. Hospitalization costs, coded to ICD-9-CM, were obtained from AHRQ’s Healthcare Cost and Utilization Project and assigned to individual ADRs. ICD-9 codes were mapped to MedDRA Preferred Terms (PT) by the use of BioPortal and ICD9Data.com. We limited our focus to (1) ADR terms included in the EudraVigilance Important Medical Event Terms list, and (2) PTs that had at least 1,000 cases in FAERS. For each drug we selected the 20 most frequently reported “primary suspect” ADRs from January 2011 through December 2013. We divided the number of each of these by the amount of prescriptions dispensed over the same time period to obtain 20 separate ADR-specific costs per drug. All costs were summed into a single total cost amount for each drug. 6 diabetes medications (3 dipeptidyl peptide 4 inhibitors [DPP-4] and 3 glucagon-like peptide-1 [GLP-1] agonists) were analyzed in detail.

**RESULTS:** 570 MedDRA PTs fit our inclusion criteria and cost figures were obtained for 556 of them (97.5%). From lowest to highest the total ADR costs associated with each DPP-4 drug over the 3-year period were: Janumet ($6,946,006 = $5.43 per script); Januvia ($22,873,953 = $6.89); and Onglyza ($4,393,671 = $7.06). For the GLP-1s the costs were: Victoza ($18,571,446 = $16.57); Bydureon $3,119,208 = $28.88); and Byetta ($20,935,840 = $57.94). Under-reporting of ADRs may result in an underestimation of the ADR costs above by as much as 90%.

**CONCLUSIONS:** ADRs are responsible for a huge financial burden for the healthcare industry, but techniques to analyze specific costs are lacking. This new method to estimate ADR costs illustrates how post-marketing data can be used for comparative safety research, outcomes analysis, and formulary decisions.

**SPONSORSHIP:** This research was funded by AdverseEvents.

**U71** Leveraging Real-World Evidence in Disease Management Decision Making with a Total Cost of Care Tool

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**BACKGROUND:** Health management is becoming more complex given a range of care options and the need to balance costs and quality. Healthcare payers and providers can use real-world evidence (RWE) to explore the value of disease management interventions and optimize decision making.

**OBJECTIVE:** To develop a RWE-based tool to examine the potential cost impact of disease management interventions in non-valvular atrial fibrillation (NVAF), pneumonia and rheumatoid arthritis (RA).

**METHODS:** Data was collected from a RWE dataset that uses the IMS National Prescription Audit (NPA) and PharMetrics Plus databases. For each disease, pharmacy and medical claims for patients meeting inclusion/exclusion criteria were combined in longitudinal cohorts with a 180-day pre-index and 360-day follow-up period. A Total Cost of Care (TCoC) tool was developed in MS Excel to explore the impact of mutually exclusive disease management trends, or “levers.” The tool compares current costs of disease to projected costs by applying the impact of levers. Levers include literature-based concepts and prevalence data impacting costs along the disease continuum for diagnosed group of patients. The tool supports investigations across geographic regions, patient age, cost types and settings of care over one year.

**RESULTS:** The base-case examines national benchmark data for a hypothetical plan of 1,000,000 covered lives. In this scenario the annual total direct medical costs (allowable and patient out-of-pocket) of managing diagnosed patients are estimated at $123,380,766 for
R.A. ($27,227/patient; 4,532 patients), $191,619,458 for pneumonia ($24,227/patient; 7,909 patients), and $176,115,289 for NVAF ($24,519/patient; 7,183 patients). The tool examines the potential impact of cost shifts to provide care in a more efficient manner. It can be used to shift cost trends in management (e.g., early treatment with disease-modifying antirheumatic drugs, adherence), NVAF (e.g., reducing risk of strokes and bleeding events, readmissions), and pneumonia (e.g., vaccination efficacy and coverage, length of stay care practices).

CONCLUSIONS: The TCoC tool supports population health management by providing national data on disease burden and quantifying potential shifts in cost trends based on disease management levers.

SPONSORSHIP: Pfizer.

U72 Prescriber-Oriented Comprehensive Medication Therapy Management Outreach in a Medicaid Managed Care Organization Population

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PROBLEM DESCRIPTION: Medicaid managed care organizations (MCOs) pose advantages over fee-for-service plans by offering larger provider networks, disease management programs, and care coordination. A typical MCO member population consists of patients with complex disease states requiring multiple providers and medications who generally cannot attend medication therapy management (MTM) appointments due to transportation difficulties. The number of patients in these populations who can benefit from MTM services exceeds the number of qualified clinical pharmacists available to provide this clinical service in person. Another hurdle MCOs face is a lack of awareness among providers regarding clinically appropriate brand and generic alternatives.

GOAL: To improve health and economic outcomes by optimizing MTM via targeted prescriber outreach utilizing pharmacy claims data and clinical information obtained via prior authorization, if available.

PROGRAM DESCRIPTION: Utilizing a risk-stratification tool, patients were identified from Q3, 2014 claims data based on a variety of parameters including: the condition being treated, the number of prescriptions and maintenance medications used to treat the condition, and the overall cost of care. Primary care providers were sent detailed information, including: cover letter, prescriber feedback survey and medication adherence report. Clinical and economic recommendations were provided by qualified clinical pharmacists based on medication fill history, inferred disease state(s), and, if available, clinical information obtained through prior authorization.

OBSERVATIONS: Of 370 completed reports, 2,029 clinical recommendations were made, including the identification of 343 duplication of therapy (DOT) and 311 drug-drug interactions (DDIs). A total of 581 economic recommendations were received with the top medication drug classes being combination inhalers (35%), anti-infective agents (76%), SNRIs (60), COPD inhalers (61), and rapid-acting insulin (58%).

FINDINGS/RECOMMENDATIONS: DDIs and DOTs comprised 33% of the clinical recommendations and is a strategic target in this patient population, as they facilitate decreased adverse drug events and medication waste. If prescribers acknowledge the top economic recommendation drug classes, plan savings would be over $47,000. Prescribers value the report, as it provides unbiased information regarding patients’ compliance with therapy and lists other providers involved in their care.

SPONSORSHIP: WellDyneRx.

U74 Review of Disease Burden and Gaps in Current Research in Peripheral Artery Disease

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PROBLEM DESCRIPTION: Peripheral artery disease (PAD) is progressive atherosclerotic narrowing of peripheral arteries, most often in the lower extremities. PAD can be symptomatic or asymptomatic, and leads to increased risk of cardiovascular (CV) mortality and morbidity.

GOAL: We conducted a comprehensive literature review to summarize existing evidence around disease burden and identify gaps for future research.

PROGRAM DESCRIPTION: PubMed and Embase/MEDLINE were searched for publications within the last 10 years using the search terms: (peripheral artery disease OR peripheral arterial disease) AND (incidence OR prevalence), (myocardial infarction); (cardiovascular event OR mortality); (quality of life OR qol); (cost OR burden OR economic); and (hospitalization). We summarized existing evidence that assessed prevalence, economic and humanistic burden to highlight research gaps for PAD disease burden.

OBSERVATIONS: In 2000 an estimated 164 million people lived with PAD (ABI ≤ 0.9) worldwide. The prevalence of PAD increased by 23.5% globally from 2000 to 2010, resulting in an estimated 202 million people living with PAD worldwide. The upsweep was driven by longer life expectancy and the increased incidence in developing countries. PAD patients have the highest risk of CV death, MI, stroke, or CV rehospitalization (24.3% to 27.9% 2-year cumulative absolute risk) compared to patients with any coronary artery disease (CAD), ~18%-21% 2-year cumulative absolute risk) or any CVD (~16%-21% 2-year cumulative absolute risk). In the U.S., 1-year vascular-related hospitalization costs were higher for PAD patients ($3,911) vs. CAD ($2,999) and CVD ($2,010) patients. In Europe, 2-year cumulative hospitalization costs for PAD patients were between €2,724 and €3,182 vs. other CV diseases (between €1,492 and €1,784). PAD patients have significantly lower Health State Utilities (SF-6D) scores vs. non-PAD patients (U.S.: 0.62 vs. 0.75; EU 0.63 vs. 0.73; P < 0.05). However, limited information is available in PAD patients with additional comorbid CV conditions (e.g., diabetes, MI).

FINDINGS/RECOMMENDATIONS: PAD confers a significant social, humanistic, and economic burden to society. Further unmet medical need research is needed in PAD patients with additional CV risk conditions.

SPONSORSHIP: This study was funded by Merck & Co., Kenilworth, NJ.
PROGRaM DESCR iPtiON: The newly implemented interactive voice response (IVR) discharge phone call program included patients from 3 services: general medicine, cardiology, and orthopedics. Patients 18 years and older discharged home after hospitalization were contacted within 48 hours of discharge by an automated phone call. Nurses contacted patients who indicated via the IVR system that they had a medication-related issue or additional questions, and calls were escalated to pharmacists if the issue was beyond the nurse’s scope of practice. Medication-related issues were classified into the following categories: insurance, access, prescription problems, side effects, directions, and miscellaneous issues.

OBSERVATIONS: 3,582 patients who received an IVR call were included in the study over a 20-week period. Among 1,247 patients who required a callback from a nurse, 322 patients (26% of total callbacks) had a medication issue. Insurance issues (23% of medication-related callbacks) were the most common reason patients did not start their medications. Over 75% of insurance issues were due to prior authorization requirements or plan exclusions. Issues related to directions (16%) and side effects (16%) also prevented patients from taking their medications. Overall, 18% of 322 callbacks were escalated to the pharmacist.

FiNDiNGS/RECOMMEND atiONS: Approximately one quarter of patients requiring callbacks in our study experienced medication-related issues immediately after hospital discharge. This resulted in delays in continuity of care and medication non-adherence. These findings may be used to develop programs to prevent medication-related issues prior to discharge and inform the skills and expertise needed of a healthcare team to resolve these issues.

SPONSORSHIP: None.

U77 Specialty (Nononcology) Drug Launch Pricing Analogues: Tremors of a Coming Tidal Wave?
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GfK Market Access

PROGRaM DESCR iPtiON: We analysed more than 17 criterias to identify potential rela -

As such, this analysis explores the potential price anchors and impact of these potentially valuable treatment options. Manufacturers also must consider the various features in defining the value of new therapies that may be paradigm changing, or economic tidal waves within the managed care community.

SPONSORSHIP: GfK Custom Research USA.

U78 Medication Adherence Using Informatics Reminders
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PROGRaM DESCR iPtiON: Maintaining adequate medication adherence to warfarin is critical, yet low warfarin medication adherence is often reported.

GOAL: Short Message Service (SMS) was implemented to evaluate the feasibility of using text-messaging reminders to increase warfarin medication adherence.

PROGRaM DESCR iPtiON: A pilot study was conducted at five ambulatory care clinics to evaluate the effectiveness of SMS medication reminders for increasing medication adherence. All study patients were >21 years of age. Patients (n = 46) received daily text-messaging reminders and answered questions regarding their warfarin use during the 4-week intervention period. The primary outcome, medication adherence, was assessed prior to the intervention and again at the completion of the 4-week period. Medication adherence was assessed using the eight-item Morisky Medication Adherence (MMAS-8) tool and text message responses. The pre and post adherence data were compared and analyzed using logistic regression to control for competing variables. Secondary outcomes were therapeutic outcomes and satisfaction of using SMS.

OBSERVATIONS: A total of 46 warfarin patients participated in the study. Their average age was 52.7; 44.1% was female. The results of the medication adherence level showed that participants had a higher average of Morisky score and more participants shifted from low to medium adherence level after intervention. Participants had 6.2% of missed doses based on SMS responses. Responses to SMS reminders were associated with a decreased number of missed doses. Logistic regression was used to compare pre and post scores from MMAS-8 and give results of which factors, such as gender, age, insurance type, race, and ethnicity might be associated with a difference in medication adherence between pre and post intervention, but none of the factors had association in increasing medication adherence. Overall, more than 50% of participants reported satisfaction in using SMS.

FiNDiNGS/RECOMMEND atiONS: The use of daily text messages by patients taking warfarin seemed feasible based on their self-reported satisfaction and usability. However, the project faced several challenges, including loss of data and study limitations. Possible effectiveness of text message reminders in increasing medication adherence was inconclusive.
Patients’ Perceptions of and Beliefs About Medication Therapy Management (MTM) Services

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EmblemHealth

PROBLEM DESCRIPTION: Do you ever wonder why your patients are opting out of MTM services? Have you considered ways to improve patient participation in MTM? Have you explored other ways to make MTM more appealing and valuable to patients? Research shows that medication therapy management (MTM) services are effective in decreasing medication problems and hospital readmission rates. Yet, patients are still largely unaware of the available services and beneficial effects; and in one study, 86% of those surveyed had never received a medication action plan. Interestingly, almost three-quarters of patients felt they did not need MTM services. Many patients could benefit from more appropriate medication education via MTM services. However, communicating health-related information presents challenges for both patients and health care providers. Many factors influence effective communication exchange. Typically, medical information is complex and wrought with jargon and unfamiliar terms, (e.g., MTM), making it difficult for most people to understand. Add the stress of dealing with a new diagnosis or chronic condition, and this further complicates the matter.

GOAL: To design an MTM model that can overcome these common barriers and allow for rapid expansion.

SPONSORSHIP: University of Arizona College of Pharmacy, Center for Health Outcomes and PharmacoEconomic Research (HOPE Center).

Expansion and Role-Based Processes Within a Telephonic MTM Program

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1The Ohio State University Medication Management Program; 2The Ohio State University Institute of Therapeutic Innovations and Outcomes;

PROBLEM DESCRIPTION: Numerous studies have reported that pharmacist-provided medication therapy management (MTM) services can improve health outcomes and reduce cost. However, inadequate reimbursement for MTM services and insufficient pharmacist time are significant barriers to their expansion. Innovative models are needed to address these concerns.

GOAL: To inform development of strategies to increase knowledge, awareness and potential use of MTM services by at-risk populations.

SPONSORSHIP: UCSD Clinical and Translational Research Institute (CTRI) TL1 program and partially supported by the NIH, Grant TL1TR00098.
Lack of adherence to prescribed medication is a significant problem contributing to sub-optimal outcomes for patients with type 2 diabetes. This problem is significant enough that diabetes adherence is now part of the Medicare’s Star rating system for health plans. By implementing role-based processes, ITIO-MMP was able to rapidly expand patient care services and create an efficient MTM model. The innovative model creates a unique teaching environment that exposes student pharmacists to real-life patient interventions and clinical decision making. Further research will measure patient outcomes, as well as student learning within this environment as compared to other practice settings.

BACKGROUND: Poor compliance causes 33% to 69% of medication-related hospitalizations and accounts for $100 billion in annual health care costs. A number of studies have shown that improving adherence is associated with reducing health care costs and improving quality of life. Due to the convenient features of information technology (IT), several studies have focused on IT for improving managed care.

OBJECTIVE: The aim of this study was to review the literature with regard to existing mobile applications to improve adherence and quality of life, to discuss currently marketed health-related mobile applications with pros and cons, and to review privacy concerns associated with applications.

METHODS: Articles published between January 2004 and December 2014 were searched through electronic databases: PubMed, Google Scholar, and Web of Science. Key terms were “adherence,” “compliance,” “prescriptions,” “medication,” “smartphone,” “application,” “security,” “privacy,” and “HIPAA.” Current medication-related applications in the Android Play Store and Apple App Store were also reviewed. Articles were summarized in a table that included the title, year published, author, and major findings.

RESULTS: Results revealed a total of 14 articles and 4 application reports. Based on review, hundreds of medication-related applications are currently available. Various applications are helpful to facilitate adherence, yet the majority have similar functions. These functions consist of a manual reminder alert and access to sources for drug information. Limited studies were found related to quality of life. However, a number of studies with specific disease states concluded that the patient’s medication adherence and quality of life were positively correlated with utilization of mobile applications. Target populations for mobile applications may include caregivers, the elderly, low literacy patients, and low income individuals. Multiple studies have shown concern regarding privacy. A 2007 study suggested not to store any patient, login or password data on devices to minimize security risk. Other studies also showed concern with meeting HIPAA regulations and suggested building a privacy framework.

CONCLUSIONS: This study provides beneficial information for clinical pharmacists, other health care professionals and patients. Future research will include the development of applications that focus on Patient Health Information security with unique code and passcode as well as automatic linking of prescriptions, administration alarms and contraindication pop-ups.

SPONSORSHIP: None.

**Z3 Mobile Applications in Advanced Managed Care: Medication Adherence, Quality of Life, Existing Health Care Apps, and Privacy**

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Mercer University College of Pharmacy

BACKGROUND: Lack of adherence to prescribed medication is a factor contributing to sub-optimal outcomes for patients with type 2 diabetes. This problem is significant enough that diabetes adherence measures are now part of the Medicare’s Star rating system for health plans.

OBJECTIVE: To examine whether an intervention program, targeted at patients who have exhibited poor adherence to oral diabetes medications, would be able to increase adherence.

METHODS: This study was performed using de-identified data from Pleio, Inc. and examined the PDC (proportion of days covered) for the 200 days prior to intervention. If the patient showed poor adherence to their existing medications, they were selected for the study. Poor adherence was defined as having a PDC of less than 60% for one or more prescriptions for oral diabetes medications. Roughly half of this selected population received the Pleio GoodStart intervention protocols, the other half received no intervention. The PDC of these patients for the next 200 days was measured to see if there was an improvement. The triggering event for the intervention was the introduction of a new diabetes medication by their physician. PDC was calculated using the PQPA 2015 methodology and drug list. The standard GoodStart intervention consists of a series of three phone calls from non-clinicians plus the optional use of daily medication tips delivered through either text, voice or e-mail. If the patient requests it, additional information, such as printed brochures or website referrals, is supplied.

RESULTS: 642 patients were selected who had a PDC of .6 or lower in the six months prior to the intervention. Of these, 288 were assigned to the control group and received no intervention and 354 received the intervention. 49% of the intervention group raised their PDC to over .8 (the current Start rating measurement threshold) while only 39% of the control group achieved this level, a 25% improvement.

CONCLUSIONS: Interventions targeted at diabetic patients with poor adherence can significantly improve their adherence to their prescribed medications.

SPONSORSHIP: This study was supported by Pleio.

**Z2 Impact of Targeted Adherence Interventions in Diabetic Population**

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Pleio

BACKGROUND: Lack of adherence to prescribed medication is a factor contributing to sub-optimal outcomes for patients with type 2 diabetes. This problem is significant enough that diabetes adherence measures are now part of the Medicare’s Star rating system for health plans.

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SPONSORSHIP: This study was supported by Pleio.

**Z00-Z99 Factors Influencing Health Status and Contact with Health Services (i.e., Adherence, Oral Contraceptives)**
Impact of Community Pharmacist-Provided Medication Adherence Strategies on Clinical and Economic Health Outcomes in the North Dakota MediQHome Project

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North Dakota State University

BACKGROUND: While medical research has produced effective treatments for many disorders, unfortunately, low adherence can undermine the effectiveness of care at many steps of the process. Medication adherence is a major public health problem in the United States with only an estimated 50% of patients with chronic conditions that are adherent to their medication regimens. Adherence rates vary considerably and taking at least 80% of all scheduled dosages is often considered the threshold for good medication adherence.

OBJECTIVE: To evaluate the impact of community pharmacist-provided medication management strategies (adherence) on clinical and economic outcomes associated with a medical home population.

METHODS: The North Dakota State University has partnered with insurer Blue Cross and Blue Shield of North Dakota, and the statewide MediQHome network (medical home), Outcomes MTM, and Thrifty White Pharmacy. Community pharmacists as part of the team may provide superior treatment of chronic conditions that includes medication therapy management, medication synchronization and counseling. This report assesses the relationship between medication adherence and the cost of health services in patients with one or more of six chronic conditions: asthma, congestive heart failure, depression, diabetes, dyslipidemia, and hypertension.

RESULTS: Our findings indicate that incorporating pharmacists into the medical home leads to higher rates of adherence to medication therapy, as measured by the proportion of days covered (PDC). Moreover, greater adherence to medication therapy results in lower inpatient and outpatient expenditures. This suggests that greater adherence to drug regimens may lead to increased overall medication expenditures, but these increased medication costs are more than offset by the medical savings realized leading to lower overall total health care costs. However, the magnitude of the savings varies by the type and number of chronic diseases for which a patient is receiving medications.

CONCLUSIONS: Incorporating community pharmacists into a medical home leads to improved clinical and economic patient outcomes. Strategies which utilize community pharmacists within a medical home, from the perspectives of patients, providers (especially integrated providers such as a medical home) and society as a whole, may be a financially viable and clinically appropriate means of providing cost-effective patient care.

SPONSORSHIP: This research was funded by a grant from the National Association of Chain Drug Stores Foundation.

Z6 Inspire: Improving Access to Counseling Tools and Increasing Competence, Confidence, and Frequency of Smoking Cessation Interventions Among Retail Clinicians

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PROBLEM DESCRIPTION: Retail clinicians need evidence-based training on conducting brief interventions and counseling resources for supporting patients to quit tobacco.

GOAL: Inspire’s goal is to increase smoking cessation interventions in retail-based clinics by providing attending clinicians with evidence-based training and counseling resources.

PROGRAM DESCRIPTION: The Foundation for Health Smart Consumers and Convenient Care Association initiated the Inspire Smoking Cessation Training Program in 2013. Inspire aims to promote tobacco use cessation among those utilizing retail-based healthcare services. This presentation will share Inspire findings, program expansion through partnership with Centers for Disease Control and Prevention, Office on Smoking and Health (CDC OSH), and discuss intervention training. Inspire’s evaluation focuses on reach, changes among trainees (in the areas of knowledge, confidence, buy-in and behavior) and trainee feedback.

OBSERVATIONS: Trainings at 2013 & 2014 Retail Clinicians Education Congresses and online trainings garnered 375 trainees across 33 states, primarily nurse practitioners. 99% of trainees describe the training as...
useful and 96% intend to refer patients post-training. Prior to training, 54% of trainees report being familiar with at least 5 tobacco cessation support options or pharmacotherapies; following trainings 99% of trainees report being more comfortable discussing cessation aids with patients. In comparing paired pre/post data, Inspire trainees report significant increases in confidence regarding their ability to refer to quit using tobacco and in confidence helping patients quit using tobacco (P < 0.01, 99% CI). Inspire trainees report high feasibility for them to consistently use brief intervention in the future (mean = 8.83, mode = 10 on 1-10 scale). 3-month follow-up data indicate increases in consistency of Ask, Advise, Refer use, with reduced drop off between Ask and Refer. The CDC OSH evaluated the Inspire training results and determined it to be an effective training methodology. CDC OSH now disseminates Inspire training to national healthcare provider organizations, including pharmacists. CDC’s Tips from Former Smokers program has been integrated into the Inspire program’s counseling toolkit.

FINDINGS/RECOMMENDATIONS: Retail-based clinic care expands care access and is a benefit covered by many health plans. Retail clinicians often work directly with pharmacists to coordinate cessation interventions and referrals. Tailored trainings and access to an online counseling toolkit has the potential to increase patient counseling with greater confidence among clinicians.

SPONSORSHIP: Grant provided by the Pfizer Independent Grants for Learning & Change and the support of the Smoking Cessation Leadership Center at the University of California at San Francisco. The Centers for Disease Control and Prevention, Office on Smoking and Health, provided a stipend to include the Tips from Former Smokers program has been integrated into the Inspire program’s counseling toolkit.

Decomposing the Impact of Clinical, Demographic, Socioeconomic, and Community Resource Availability Factors on Performance Measure Rates for Dual Eligible and Non-Dual Eligible Medicare Advantage Beneficiaries

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Inovalon

BACKGROUND: In 2014, the National Quality Forum released recommendations pointing to the need for risk adjustment of quality measures to account for socioeconomic factors (SES) to make fair inferences about quality. Lack of data on SES has limited the ability to scientifically test the validity and feasibility as risk adjustors.

OBJECTIVE: This study investigates the degree to which SES are linked to worse outcomes in dual eligible members served by Medicare Advantage (MA) plans. Two Part D measures used in the CMS Five Star Rating system will be discussed, including Adherence to Hypertensive Medications (MA-H) and Rheumatoid Arthritis Management (ART).

METHODS: The study used 2,207,940 MA members from the MORE2 Registry in 2013, a nationally representative, statistically de-identified database, supplemented by new sources of SES and community resource data (e.g., living in a physician shortage area). Measure rates were analyzed using Blinder-Oaxaca decomposition technique, which sorts differences in rates into: (1) “explained”—quantifies the impact of differences in prevalence of characteristics contributing to higher risk—and (2) “unexplained”—quantifies the differential impact of the factor on outcomes.

RESULTS: The ART rate was 5.8% lower in duals (73.5% vs. 78.0%). Decomposition found 82.7% of the gap explained, 26.0% by differences in prevalence of clinical conditions (e.g., alcohol/drug abuse, anxiety, dementia) and 56.7% by SES factors (e.g., median household income < $15,000, neighborhood with low home ownership, Census region). Some factors reduced the gap—duals are younger and more female, and older members and males are less likely to receive ART. Thus, 83% of the gap would be mitigated if members had similar characteristics, or if the measure was risk adjusted to control for differences. The MA-H rate was 4.0% lower in duals (72.2% vs. 75.2%). Differences in characteristics explained 135.8% of the gap, which indicates that if prevalence of characteristics were similar, measure scores would actually be higher in duals (and in plans serving duals)—MA plans are doing a better job with duals compared to non-duals with similar characteristics. Top factors were race/ethnicity, age, neighborhood with high proportion of population never married or with high poverty rate, and original reason for entitlement disability or ESRD.

CONCLUSIONS: These findings support calls to explore risk adjustment of quality measures and will inform the recent debate regarding accuracy and reliability of measures used to evaluate care for MA beneficiaries.

SPONSORSHIP: This study was conducted by the Inovalon research division in collaboration with multiple industry partners that participated in the project advisory panel and provided funding, including Cigna-HealthSpring, Wellcare, HealthFirst, Gateway Health, Blue Cross Blue Shield Minnesota, and Blue Plus, Health Care Services Corporation. The study advisory panel also included representatives from the Special Needs Plan (SNP) Alliance and Medicaid Health Plans of America (MHPA), and study methodology and findings were regularly reviewed by stakeholders including the Pharmacy Quality Alliance (PQA), Centers for Medicare and Medicaid Services (CMS), and the National Quality Forum (NQF).
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