AMCP Abstracts Program

The AMCP Abstracts program provides a forum through which authors can share their insights and outcomes of advanced managed care practice through publication in AMCP's Journal of Managed Care & Specialty Pharmacy (JMCP). Most of the reviewed and unreviewed abstracts are presented as posters so that interested AMCP meeting attendees can review findings and query authors. The Student/Resident/ Fellow poster presentation (unreviewed) is Wednesday, April 20, 2016, and the Professional poster presentation (reviewed) is Thursday, April 21. The Professional posters will also be displayed on Friday, April 22. The reviewed abstracts are published in the JMCP Meeting Abstracts supplement.

The AMCP Managed Care & Specialty Pharmacy Annual Meeting 2016 in San Francisco, 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.

**Abstract Review Process**

Thirty-six reviewers and 4 JMCP editorial reviewers were involved in the abstract review process for the 2016 AMCP Managed Care & Specialty Pharmacy Annual Meeting. Each abstract (with author name and affiliation blinded) was reviewed by reviewers and scored using a 1-5 scale on the following 5 criteria (15 rating scores per abstract) used by JMCP to evaluate manuscripts for publication:

- Relevance
- Originality
- Quality
- Bias
- Clarity

Each of the reviewers also made an independent accept/reject recommendation. The 15 rating scores and 3 accept/reject recommendations for each abstract were reviewed by a JMCP editorial reviewer, who made an accept/reject decision. These decisions were further reviewed by the JMCP editor-in-chief to ensure consistency in decision making. The mean rating scores were used to award Gold, Silver, and Bronze medals for the best abstracts submitted. The reviewers and JMCP editorial reviewers of the abstracts for the 2016 Annual Meeting were as follows:

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*AMCP Managed Care & Specialty Pharmacy*

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E63 PCSK9i Utilization, Cost, Utilization Management Impact, and Discontinuation Rate Among 13 Million Commercially Insured Americans

E64 Healthcare Resource Utilization (HCRU) and Clinical Characteristics of Medicaid Patients with Cystic Fibrosis (CF)

E65 Treatment Patterns Among Patients with Cystic Fibrosis Using Twice Daily Dorzolame Alla Regimen

E66 Frequency and Costs of Pulmonary Exacerbations and Association with Percent Predicted FEV1 (ppFEV1) in Patients with Cystic Fibrosis (CF)

E67 Correction of the Underestimation of Statin Utilization Metrics in a Typical Administrative Claims Dataset Through Augmentation with the IMS Retail Prescription Point of Sale Database

E68 Follow-up Care After Psychiatric Hospital Admission for Medicaid and Commercially Insured Patients with Schizophrenia or Bipolar Disorder

E69 Controlled Substances Triple Threat Overlapping Days: Relationship with Healthcare Utilization and Costs

E70 Subdermal Buprenorphine Implants Improve Societal Outcomes and Patient Morbidity and Mortality Relative to Sublingual Buprenorphine: Results of a Markov Model

E71 Healthcare Cost Burden of Opioid Abuse Among Employees with Injury-Related Workers Compensation or Short-Term Disability Events: A Retrospective, Observational Cohort Study

E72 Drivers of Excess Costs Associated with Opioid Abuse Among Commercially Insured Patients

E73 Understanding Drivers of Excess Costs Among Continuous Users of Extended-Release/Long-Acting Opioids Diagnosed with Opioid Abuse, Dependence, or Poisoning

E74 Impact of a Concurrent Drug Utilization Review Edit Designed to Curb Opioid Misuse

E75 Real-World Dosing Patterns Among Patients Receiving Buprenorphine for Opioid Dependence in the United States

E76 A Comparison of Characteristics, Health Resource Utilization, and Costs of Dual Medicare-Medicaid and Medicare-Only Eligible Patients with Schizophrenia

E77 Medication Adherence as a Predictor of Switching Oral Antipsychotic Users to Long-term Injectables

E78 Evaluation of Long-Acting Injectable (LAI) Antipsychotic Medications in Medicare Beneficiaries: A Utilization Review and Cost Analysis


E80 Regional Differences in HEDIS Measure Results for Schizophrenia Treatment Adherence in State Medicaid Programs

E81 Estimating the Value of New Technologies that Provide More Accurate Drug Adherence Information to Physicians for Their Patients with Schizophrenia

E82 Description of Health Care Utilization and Costs Among Young, Recently Diagnosed Schizophrenia Patients One Year Prior to Treatment with Paliperidone Palmitate Once Monthly Injectable

E83 Analysis of Medical Resource Utilization Secondary to Automated Prior-Authorization Criteria for the Oral Atypical Antipsychotics in a Medicaid Population
Comparing Fall Risk Among Antidepressant Classes in the Elderly: A Nested, Case-Control Study of a Medicare Database

G02 Budget Impact Analysis of Botulinum Toxin A Therapy for Adult Upper Limb Spasticity (AULS) in the United States

G03 Healthcare Resource Utilization Among Commercially Insured Clobazam-Treated Patients with Lennox-Gastaut Syndrome

G04 Specialty Drug Coupons Are Frequently Used and Significantly Reduce Out-of-Pocket Costs

G05 Adherence to Disease-Modifying Therapies Among Patients with Multiple Sclerosis

G07 Cost-Utility Analysis of Botulinum Toxin Type A Products for the Treatment of Cervical Dystonia

G11 Impact of Natalizumab on Multiple Sclerosis Relapse-Related Costs in a Real-World Setting

G13 Healthcare Utilization in a Contemporary Cohort of Primary Progressive Multiple Sclerosis NARCOMS Registry Participants

G14 Differences in Preferences for Disease-Modifying Treatments Across Subgroups of U.S. Patients with Relapsing Multiple Sclerosis

G15 Healthcare Utilization and Comorbidities in Working Age Persons with Different Types of Multiple Sclerosis

G16 The Impact of Multiple Sclerosis Treatment Persistence and Adherence on Emergency Room Visits and Inpatient Hospital Stays

G17 Evaluation of First-Switch Disease-Modifying Therapies in a Market with Many Multiple Sclerosis Treatment Options

G18 Real-World Comparison of Relapse Rates in Multiple Sclerosis Patients Treated with Disease-Modifying Therapies

G19 Comparison of Costs and Health Resource Utilization in Multiple Sclerosis Patients Treated with Disease-Modifying Therapies

G20 Patients with Active RRMS and an Inadequate Response to Prior Therapy Demonstrate Persistent Improvements in Relapse and Disability Following Treatment with Alemtuzumab: 5-Year Follow-up of the CARE-MS II Study

G21 A Randomized, Double-Blind, Parallel Group Study to Compare the Safety and Efficacy of Arbaclofen Extended Release Tablets to Placebo and Baclofen for the Treatment of Spasticity in Patients with Multiple Sclerosis

G22 Payer Insight-Mining for Multiple Sclerosis Disease Management: Clinical and HEOR Decision Making

G23 Efficacy and Safety of Treatments for Acute Relapses of Multiple Sclerosis: Results of a Systematic Literature Review

G24 Retrospective Medical and Pharmacy Claims Analysis to Assess Medication Adherence in Commercially Insured and Medicare-Enrolled Patients with Multiple Sclerosis

G25 Twelve-Month MS-Related Direct Cost Analysis of Relapse Outcomes with Alemtuzumab Versus IFNB-1a in Active Relapsing-Remitting MS (CARE-MS II)

G26 Resource Use Associated with Outpatient Management of Multiple Sclerosis: Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs

G27 Validation of a Novel Measure of Multiple Sclerosis Disease Severity Using Real-World Data

G28 Real-World Assessment of Cost Among Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs

G29 Real-World Relapse Rates Among Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs

G30 Potential Cost Savings Due to Alemtuzumab Persistent Reduction in Disease Endpoints Through 5 Years Without Retreatment for Majority of Patients

G34 Literature Review of Studies Assessing Direct Costs Associated with Migraine

G35 Off-Label Prescribing for Children with Migraines in U.S. Ambulatory Care Settings

G36 Impact of a Clinical Outreach Program on the Utilization of High-Risk Medications for CMS STAR Ratings

G37 Characteristics and Resource Utilization of U.S. Emergency Department Visits (2008-2011) for Patients with Epilepsy and Convulsions

G39 Uncontrolled Epilepsy in the U.S.: A Major Clinical and Economic Problem

G40 Uncontrolled Epilepsy Hospitalizations in the U.S.: A Dramatic Increase in Costs over Last 15 Years

G41 Cost-Effectiveness of Eslicarbazepine Acetate Monotherapy in Partial-Onset Epilepsy

G42 Rapid Relief of Pain in Episodic Migraine Is Associated with Lower Self-Reported Disability and Lower Rates of Migraine Associated Symptoms: A Secondary Analysis of the COMPASS Trial

G43 Healthcare Resource Utilization and Costs of Chronic and Episodic Migraine

G44 Faster Migraine Relief Using AVP-825 Compared with Sumatriptan Tablet: Using a Latent Variable Perspective

G45 Cost-Effectiveness of OnabotulinumtoxinA for Chronic Migraine Prophylaxis in Adults in the United States

G46 A Comparative Assessment of Intravenous Immunoglobulin (IVIG) Therapy in the Treatment of Chronic Inflammatory Demyelinating Polynuropathy (CIDP)

G48 Health Care Resource Utilization and Costs Among Patients Diagnosed with Sporadic Inclusion Body Myositis in the U.S. Medicare Population

G49 Association of Rescue Medication Use with Clinical Outcomes and Health Care Costs in Patients with Seizure Clusters

G50 Impact of a Prior Authorization Program on an Extended Release Opioid Market Share and Pharmacy Costs: A Comparison Among Two National Commercial Payers

H01 Satisfaction and Adherence with Current Treatment Options for Dry Eye Disease: Analysis of Data from the United States National Health and Wellness Survey

H02 Impact of Ophthalmalic Antihistamines Formulary Coverage in a Medicaid Pediatric Accountable Care Organization (ACO)

H03 Real-World Treatment Patterns and Costs of Ranibizumab and Aflibercept for Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema in the United States

H04 Health Care Resource Utilization Associated with Tympanostomy Tube Placement in Pediatric Populations

I05 Drivers of Statin Intolerance in Claims Data as Defined by a Regional Managed Care and Clinical Expert Panel

I06 Reevaluating the Value of Ezetimibe in the U.S. for Patients with History of CVD Based on the IMPROVE-IT Results
Trends in Palivizumab Utilization Within Medicaid and
Cost of First-Line Treatment of Pulmonary Arterial Hypertension
Modeling Health Outcomes Associated with Add-on Vorapaxar
Treatment to Standard Care Antiplatelet Therapy for Prevention of
Atherothrombotic Events in Patients with a Recent MI or PAD
Impact of Warfarin Adherence Status on Healthcare Costs
Among Patients with Nonvalvular Atrial Fibrillation
A Significant Economic Opportunity Using Unique Prescriptive
Analytics to Improve Medication Adherence
The Impact of a Pharmacy Pay-for-Performance Program on
Medication Adherence in a Medicare Population
Improving Part D Stars Scores with a High-Touch, Patient-
Centric Model Using Intensive Care-Coordination in a Medicare
Dual-Special Needs Population with Low Health Literacy
Pulmonary Arterial Hypertension (PAH) Episodes of Care: Survival Analysis of PAH Patients Based on World Health Organization (WHO) Functional Class (FC)
Cost of First-Line Treatment of Pulmonary Arterial Hypertension
with Ambrisentan Plus Tadalafil
Predictors of All-Cause Healthcare Costs Among Patients with Newly Diagnosed Non-valvular Atrial Fibrillation Initiated on Dabigatran Versus Warfarin
Predictors of Admission and Mortality among Patients with Heart Failure
Identifying Atrial Fibrillation Patients at Increased Risk for Developing Stroke: A Systematic Review of Risk Factors
A U.S. Budget Impact Analysis of ENTRESTOTM (Sacubitril/ Valsartan) Versus Renin-Angiotensin-Aldosterone System Inhibition Only, for Heart Failure Patients with Reduced Ejection Fraction
LDL-C Goal Achievement After Adding or Switching to Ezetimibe in Patients with Clinical Atherosclerotic Cardiovascular Disease or Probable HeFH
Cost Per Point Reduction in LDL-C for Patients Treated with Evolocumab 140 mg or Alirocumab 75/150 mg Within Employer-Sponsored Insurance Plans
Cost Per Effectively Treated Patient with Evolocumab 140 mg and Alirocumab 75/150 mg
Adherence to Treatment in Hemophilia: A Comparison of Conventional and Prolonged Half-Life Therapies
Analysis of Treatment Patterns in High Utilizers of Conventional FVIII Therapy
Cost of Care Among Pediatric Hemophilia Patients with and without Central Venous Access Devices Treated in U.S. Hospitals
A Systematic Review on the Health and Safety of Electronic Cigarettes
Impact of AATD Patient Management Program on Health Outcomes and Medical Costs
Predictors of Readmission Rates After COPD-Related Hospital or Emergency Department Visits
The Relative Burden of Community-Acquired Pneumonia Hospitalizations Compared to Other Serious Conditions in the Older Population
Trends in Palivizumab Utilization Within Medicaid and Commercial Populations
Initial Diagnosis and Treatment Patterns by Healthcare Setting Among Chronic Obstructive Pulmonary Disease (COPD) Patients in the United States
Incidence and Predictors of Hospital Readmission Among Patients with Chronic Obstructive Pulmonary Disease in the Department of Veterans Affairs
Severity and Acute Inhaler Use in Chronic Obstructive Pulmonary Disease
Numbers Needed to Treat with Omalizumab to Prevent an Asthma Exacerbation, Emergency Room Visit, or Hospitalization in Patients with Severe Uncontrolled Asthma
Associations Between Asthma Control and Economic Outcomes Among Patients with Allergic Asthma Treated with Inhaled Corticosteroids and Long-Acting Beta Agonists Combination Therapy
Factors Affecting Prescription Drug Coverage Gap Among COPD Patients: Analysis of Time to Coverage Gap
Impact of Non-adherence to Inhaled Corticosteroid/Long-Acting β2-Agonist (ICS/LABA) Therapy on Health Care Costs in Patients with Chronic Obstructive Pulmonary Disease (COPD)
Chronic Obstructive Pulmonary Disease Medication Adherence and Hospital Use
Costs and Length of Stay in Hospitalized Patients with Idiopathic Pulmonary Fibrosis: Analysis of the National Inpatient Sample
Ulcerative Colitis Treatment Patterns and Cost of Care
Impact of Site of Care on the Drug and Administration Costs of Cetorizumab Pegol Versus Infliximab in Crohn's Disease
Healthcare Resource Utilization and Direct Medical Costs Among Patients with Irritable Bowel Syndrome with Diarrhea
Factors Influencing Treatment Choice Among Patients with Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C): Results from the CONTOR Study
Long-term Safety of Obeticholic Acid in Patients with Primary Biliary Cirrhosis
Physician Versus Patient Perceptions of Medical Care Quality in Primary Biliary Cirrhosis
The Need for Improved Liver Literacy in the U.S. Population
The Classification and Regression Tree Approach to Predicting Patient-Specific Factors Associated with Discussing Biologic Treatment with a Health Care Provider in Crohn's Disease Patients
Differences Between Patient and Physician Perspectives Toward Starting Biologics: Stratification by Patients Who Had a Discussion About Biologics with Their Physician Versus Those Who Did Not
Estimation of Annual Indirect Costs Associated with Moderate-to-Severe Plaque Psoriasis in the United States
Number Needed to Treat and Cost Per Responder to Achieve PASI-90 for the Novel Treatments of Moderate-to-Severe Psoriasis in the United States
Cost-Effectiveness of Adding Clostridial Collagenase Ointment to Standard of Care in Individuals with Stage IV Pressure Ulcers
The Comparative Effectiveness of Adding Clostridial Collagenase Ointment to Standard of Care in Individuals with Stage IV Pressure Ulcers
Long-term Safety of Crisaborole Topical Ointment 2% in Children and Adults with Mild-to-Moderate Atopic Dermatitis
Economic Impact of Above-Label Dosing with Etanercept,

Medication Utilization Patterns of Apremilast Among Patients with Psoriatic Arthritis

Healthcare Costs in Psoriasis Patients Newly Initiated on Apremilast Among Patients with Psoriatic Arthritis

Healthcare Costs in Psoriasis Patients Newly Initiated on Apremilast or Biologic Therapies

Comparison of Persistence Between Adults with Psoriasis Initiating Apremilast or Biologics

Prevalence and Systemic Treatment of Psoriasis and Psoriatic Arthritis Among Differently Insured Populations

Economic Impact of Above-Label Dosing with Etanercept, Adalimumab, or Ustekinumab in Patients with Moderate-to-Severe Psoriasis

Oral Isotretinoin Prescribing, Utilization, and Costs in a Managed Care Plan

The Multi-biomarker Disease Activity Score in Methotrexate Incomplete Responders Predicts Clinical Responses to Nonbiological Versus Biological Therapy in Early RA


Gout-Related Ambulatory Care Utilization and Patient Characteristics Predictive of Resource Use

Real-World Experience with Tofacitinib Versus Certolizumab Pegol for the Treatment of Rheumatoid Arthritis in Biologic-Naïve Patients and After First Biologic Experience

An Economic Evaluation of Tofacitinib (Xeljanz) Treatment After One or Two TNF Inhibitors in Rheumatoid Arthritis from the United States Perspective

Healthcare Resource Utilization and Costs Between Psoriatic Arthritis Patients with Moderate-to-Severe Psoriasis and Those with Minimal Skin Psoriasis in the U.S.

Impact of Site of Care on the Drug and Administration Costs of Certolizumab Pegol Versus Infliximab in Rheumatoid Arthritis

Increased Out-of-Pocket Costs and Limited Access to Specialists Are Associated with Lower Quality of Care for Patients with Rheumatoid Arthritis

Real-World Treatment Patterns and Demographic, Clinical, and Economic Characteristics of Systemic Lupus Erythematosus (SLE) Patients Initiating Repository Corticosteroid Injection Therapy

Clinical Characteristics and Disease Activity in Psoriatic Arthritis Patients with Dactylitis or Enthesitis in a Real-World Setting Results from Corrona Registry

Identifying Psoriatic Arthritis and Ankylosing Spondylitis Patients Responsible for the Highest Costs of Care in the Real World: Data from a Large U.S. Cohort

Real-World Clinical Characteristics and Disease Outcomes in Psoriatic Arthritis Patients by Extent of Body Surface Area Affected by Psoriasis: Results from Corrona Registry

Misalignment Between Physician and Patient Satisfaction with Current Psoriatic Arthritis Treatment

Satisfaction in Psoriatic Arthritis Patients Despite Active Joint Disease

Medicaid Osteoporosis Drugs Utilization and Expenditures: The Effect of Generic Drugs Market Entry

Adherence and Persistence with Oral Bisphosphonate Therapy Within an Integrated Healthcare Delivery System

Prevalence and Direct Costs of Patients at Risk for Opioid Abuse and Risk Model in Medicare Beneficiaries

Contemporary Anemia Management in U.S. Hemodialysis Patients

Patiromer Lowers Serum K+ and Prevents Recurrent Hyperkalemia in CKD Patients ≥65 Years of Age on RAAS Inhibitors

Trends in the Use of IV Iron and ESAs Under the Prospective Payment System: ESRD Commercial and Medicare Populations

Chronic Diuretic Therapy Does Not Impair the Effectiveness of Patiromer in Hyperkalemic Patients with CKD

Medicare Beneficiaries Initiating Mirabegron Versus Anti-muscarinic Treatment for Overactive Bladder: Patient-Reported Adherence and Claims-Based Adherence Rates

A Prospective Study of Medicare Beneficiaries Initiating Mirabegron Versus Anti-muscarinic Treatment: Patient-Reported Outcomes from the Overactive Bladder Satisfaction Scales (OAB-S)

Network Meta-Analysis of OnabotulinumtoxinA Compared to Mirabegron and Anticholinergics for Overactive Bladder

Increasing Management of Orphan Drugs

Burden of Illness in Adult Patients with Nocturia

Primary Nonadherence to Overactive Bladder Medications in an Integrated Managed Care Healthcare System

Healthcare Costs Associated with Nausea and Vomiting in Patients Receiving Oral Immediate-Release Opioids for the Management of Acute Pain in the Outpatient Setting

Appraising the Value of Digital Health Technologies from the Managed Care Perspective: Insights for Evidence Assessment and Reimbursement in the U.S.

Predicting FDA Alerts: A Pharmacovigilance Signaling System Based on Past Regulatory Action

A Randomized, Placebo- and Active-Controlled Phase 2b Study Investigating Oliceridine (TRV130), a Novel µ Receptor G Protein Pathway Selective (µ-GPS) Modulator

EPIPEN4SCHOOLS Survey Combined Analysis: Staff Training and Use of Epinephrine Auto-Injectors

Do Low-Cost Physicians Refer to Low-Cost Specialists? Considerations for the Development of Accountable Care Organization Networks

The U.S. Payor Landscape for Specialty Pharmacy: Results from a Survey of Medical and Pharmacy Directors

Factors Associated with Time to Complete a Comprehensive Medication Review for Medicare Part D MTM-Eligible Beneficiaries
Exhibit Hall Map: Professional Poster Presenters (continued)

Z20 Is Real-World Evidence Cited in P&T Monographs and Therapeutic Class Reviews?
Z21 Plan Sponsor Perceptions on the Influence of Quality Metrics on Formulary Coverage Decisions
Z22 The Impact of Pharmaceutical Manufacturer Copay Cards on Patient Access to Biologics
Z23 Impact of a Patient Support Program on Abandonment of Adalimumab Treatment Initiation
Z24 Specialty Medication Capture Rates Through Electronic Prescription Order Data Within a Health System
Z25 The Prevalence and Predictors of Low-Cost Generic Program Use in the Pediatric Population
Z28 Cost Savings from the Implementation of a Compound Drug Management Program
Z29 A Unique Method for Identifying Coordination of Benefit Recovery Opportunities in a Pediatric Medicaid Accountable Care Organization Claims Database
Z30 Virtual Academic Detailing: A Cost-Effective Approach to Align Payers and Physicians?
Z31 Continuation of Long-Acting Reversible Contraception at Two Years in a University Healthcare Setting: A Retrospective Review
Z40 INSPIRE: Increasing Competence, Confidence, and Frequency of Smoking Cessation Interventions Among Retail Clinicians and Access to Counseling Resources
Z41 Medication Therapy Management Comprehensive Medication Reviews for Residents in Long-Term Care Facilities: 2015 Results
Z42 Examination of Physician Preference Regarding Mode of E-Newsletter Communication: A Sub-analysis of a Physician Survey Within a Medicare Advantage Plan Regarding PCP E-Newsletters
Z45 Clinical Pharmacy Medication Therapy Management and Patient Follow-up to Improve Real-World Adherence to Novel Oral Anticoagulants: A Single-Center Prospective Study

U26 Effect of Pharmacist-Supported Transition-of-Care Program on 30-Day Readmission Rates: A Systematic Review and Meta-Analysis
U27 The Influence of a Community Pharmacy Automatic Prescription Refill Program on CMS Adherence Metrics
U28 Impact of Mailed Letters on Medication Adherence in a Medicare Advantage Plan
U30 Pharmacist- and Nurse-Managed, Interprofessional, Post-hospital Discharge Transition of Care Program
U32 Impact of Managed Care Restrictions on Medication Adherence, Clinical and Economic Outcomes, Healthcare Resource Utilization, and Treatment Satisfaction: A Systematic Literature Review
U33 Primary Care Physician Perception of an E-Newsletter Within a Medicare Advantage Plan
U35 Variability in State Medicaid Medication Therapy Management (MTM) Initiatives
U36 State Variation in the Use of Mail Order Pharmacy in the U.S.: Findings from the 2015 National Consumer Survey on the Medication Experience
U37 Pharmacists’ Perceptions of Biosimilars’ Impact on the Cost of Biologics and Patient Out-of-Pocket Spending
Z01 Rates of Hospitalization and Repeat Procedures in Patients Receiving Sodium Picosulfate/Magnesium Citrate Bowel Preparation Prior to Colonoscopy
Z16 Drug Pricing in the United States: Payers Evaluate Strategies Proposed by Presidential Candidates to Lower Drug Costs
Z17 Financial Impact of a Medicare Part D Assistance Program in a High-Risk Patient Population
Z18 Results of the Implementation of Pharmacy Network Continuing Participation Verification Program for a Large Managed Care Organization
Z19 Onsite Health Clinics: Do They Lower Healthcare Cost and Resource Use?
Medal Winning Abstracts

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

**Cynthia L. Gong:** [J02] Use of Behavioral Economics and Social Psychology to Improve Treatment of Acute Respiratory Infections (BEARI): A Discrete Choice Experiment

**Michael Pillinger, MD:** [M06] Factors Associated with Urate-Lowering Therapy and Reaching Gout Treatment Goals in Patients with Cardiovascular Disease

**Bijal M. Shah, PhD:** [I23] Patient and Care Characteristics that Heighten Risk for 30-Day Readmission in Patients with Congestive Heart Failure

**Christie Teigland, PhD, MA:** [Z27] Association of Socioeconomic and Clinical Factors with Rates of High-Risk Medication Use in Medicare Advantage Plans

**Maher Abdel-Sattar, PharmD:** [Z16] Drug Pricing in the United States: Payers Evaluate Strategies Proposed by Presidential Candidates to Lower Drug Costs


**Michael Campos:** [J05] Impact of AATD Patient Management Program on Health Outcomes and Medical Costs

**Alexandra Cruz:** [I12] The Impact of a Pharmacy Pay-for-Performance Program on Medication Adherence in a Medicare Population

**Channel De Leon, PharmD:** [Z17] Financial Impact of a Medicare Part D Assistance Program in a High-Risk Patient Population

**Jacqueline Erdo, MPH:** [E61] Impact of Cost Sharing on Access to Care for Patients with Cystic Fibrosis

**Steven R. Feldman, MD, PhD:** [L14] Economic Impact of Above-Label Dosing with Etanercept, Adalimumab, or Ustekinumab in Patients with Moderate-to-Severe Psoriasis

**Arijit Ganguli, MBA, PhD:** [M13] Increased Out-of-Pocket Costs and Limited Access to Specialists Are Associated with Lower Quality of Care for Patients with Rheumatoid Arthritis

**Rita L. Hui, PharmD, MS:** [M24] Adherence and Persistence with Oral Bisphosphonate Therapy Within an Integrated Healthcare Delivery System

**Peter Hur, PharmD, MBA:** [J16] Severity and Acute Inhaler Use in Chronic Obstructive Pulmonary Disease

**Philip Mease:** [M18] Clinical Characteristics and Disease Activity in Psoriatic Arthritis Patients with Dactylitis or Enthesitis in a Real-World Setting: Results from Corrona Registry

**Manish Mittal:** [Z22] The Impact of Pharmaceutical Manufacturer Copay Cards on Patient Access to Biologics

**Melissa Pavilack, PharmD:** [J10] Trends in Palivizumab Utilization Within Medicaid and Commercial Populations

**Carl L. Roland, PharmD, MS:** [M25] Prevalence and Direct Costs of Patients at Risk for Opioid Abuse and Risk Model in Medicare Beneficiaries

**Jessica Sanders:** [Z31] Continuation of Long-Acting Reversible Contraception at Two Years in a University Healthcare Setting: A Retrospective Review

**Sujit S. Sansgiry, PhD:** [J19] Factors Affecting Prescription Drug Coverage Gap Among COPD Patients: Analysis of Time to Coverage Gap


**Douglas Taylor, MBA:** [K05] Factors Influencing Treatment Choice Among Patients with Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C): Results from the CONTOR Study

**Rolin L. Wade, RPh, MS:** [E71] Correction of the Underestimation of Statin Utilization Metrics in a Typical Administrative Claims Dataset Through Augmentation with the IMS Retail Prescription Point of Sale Database

**Lihua Zhang, MD, PhD:** [L13] Prevalence and Systemic Treatment of Psoriasis and Psoriatic Arthritis Among Differently Insured Populations

**Suyuan Zhang, MS:** [J21] Chronic Obstructive Pulmonary Disease Medication Adherence and Hospital Use
Medal Winning Abstracts (continued)

Maher Abdel-Sattar, PharmD; [Z45] Clinical Pharmacy Medication Therapy Management and Patient Follow-up to Improve Real-World Adherence to Novel Oral Anticoagulants: A Single-Center Prospective Study

Joshua D. Brown; [J08] The Relative Burden of Community-Acquired Pneumonia Hospitalizations Compared to Other Serious Conditions in the Older Population

Brieana Buckley; [I31] Adherence to Treatment in Hemophilia: A Comparison of Conventional and Prolonged Half-Life Therapies

Brieana Buckley; [I33] Cost of Care Among Pediatric Hemophilia Patients with and without Central Venous Access Devices Treated in U.S. Hospitals

Suvapun Bunniran, PhD; [N06] A Prospective Study of Medicare Beneficiaries Initiating Mirabegron Versus Anti-Muscarinic Treatment: Patient-Reported Outcomes from the Overactive Bladder Satisfaction Scales (OAB-S)

Jessica L. Buono, MPH; [K04] Healthcare Resource Utilization and Direct Medical Costs Among Patients with Irritable Bowel Syndrome with Diarrhea

Jill Davis, MS; [J20] Impact of Non-Adherence to Inhaled Corticosteroid/Long-Acting & Beta2-Agonist (ICS/LABA) Therapy on Health Care Costs in Patients with Chronic Obstructive Pulmonary Disease (COPD)

Arijit Ganguli, MBA, PhD; [L10] Medication Utilization Patterns of Apremilast Among Patients with Psoriatic Arthritis

Matthew Gitlin, PharmD; [I28] Cost Per Point Reduction in LDL-C for Patients Treated with Evolocumab 140 mg or Alirocumab 75/150 mg Within Employer-Sponsored Insurance Plans

Matthew Gitlin, PharmD; [I29] Cost Per Effectively Treated Patient with Evolocumab 140 mg and Alirocumab 75/150 mg

Anna M. Hall, PharmD, BCACP; [U25] Factors Associated with Time to Complete a Comprehensive Medication Review for Medicare Part D MTM Eligible Beneficiaries

Mariam Hassan, PhD, BPharm; [E64] Healthcare Resource Utilization (HCRU) and Clinical Characteristics of Medicaid Patients with Cystic Fibrosis (CF)

Stephen Johnston, MA; [F15] Healthcare Cost Burden of Opioid Abuse Among Employees with Injury-Related Workers Compensation or Short-Term Disability Events: A Retrospective, Observational Cohort Study

Noam Y. Kirson, PhD; [F16] Drivers of Excess Costs Associated with Opioid Abuse Among Commercially Insured Patients

Rosemarie Lajara, MD; [E39] Achievement of Individualized Glycemic Targets and Cost-Effectiveness: Comparison Between Two Insulin Delivery Methods in Patients with Diabetes

Corey Lester, MS, PharmD; [U27] The Influence of a Community Pharmacy Automatic Prescription Refill Program on CMS Adherence Metrics

Daniel C. Malone, PhD; [Z20] Is Real-World Evidence Cited in P&T Monographs and Therapeutic Class Reviews?

Philip Mease; [L08] Treatment Patterns, Healthcare Resource Utilization, and Costs Associated with Psoriatic Arthritis Among Humana Commercial and Medicare Member Populations

Philip Mease; [M20] Real-World Clinical Characteristics and Disease Outcomes in Psoriatic Arthritis Patients by Extent of Body Surface Area Affected by Psoriasis: Results from Corrona Registry

Jeetvan Patel, PhD; [I27] LDL-C Goal Achievement After Adding or Switching to Ezetimibe in Patients with Clinical Atherosclerotic Cardiovascular Disease or Probable HeFH

Nazia Rashid, PharmD, MS; [R03] Primary Nonadherence to Overactive Bladder Medications in an Integrated Managed Care Healthcare System

Craig G. Schilling; [L09] A Significant Economic Opportunity Using Unique Prescriptive Analytics to Improve Medication Adherence

Jeffrey R. Skaar, PhD; [B27] Opioid Analgesic Use and Polypharmacy Is Routine in the Treatment of Post-herpetic Neuralgia: A Potential Role for Managed Care Intervention?

Zhuliang Tao, MSPH, MD; [B03] Impact of Member Benefit and Out-of-Pocket Costs on Herpes Zoster Vaccine Uptake and Abandonment: An Observational Study in a Medicare Managed Care Population

Joseph Tkacz; [K03] Impact of Site of Care on the Drug and Administration Costs of Certolizumab Pegol Versus Infliximab in Crohn's Disease

Joseph Tkacz; [M12] Impact of Site of Care on the Drug and Administration Costs of Certolizumab Pegol Versus Infliximab in Rheumatoid Arthritis

Candace Zheng, PharmD; [H02] Impact of Ophthalmic Antihistamines Formulary Coverage in a Medicaid Pediatric Accountable Care Organization (ACO)
Medal Winning Abstracts (continued)

- **Osayi Akinbosoye, PhD, PAHM**: [E18] The Relationship Between Digital Health Program Activity Tracking and Medication Adherence Among Members Age 50+ Years
- **Brittany Berry**: [F24] Evaluation of Long-Acting Injectable (LAI) Antipsychotic Medications in Medicare Beneficiaries: A Utilization Review and Cost Analysis
- **Wendy S. Bibeau, PhD**: [E21] Impact of Out-of-Pocket Costs on Branded Medication Adherence and Outcomes Among Patients with Type 2 Diabetes
- **Kevin Bowen, MD, MBA**: [E23] Diabetes Mellitus (DM) Prevalence, Incidence, Drug Regimens, and Insulin Therapy Cost by Type Among 4 Million Commercially Insured Members Continuously Enrolled 4.5 Years
- **Diana I. Brixner, RPh, PhD, FAMCP**: [E60] Evaluation of a Linked Database for Cystic Fibrosis Research on Clinical, Demographic, and Resource Use Variables

**Michael S. Broder, MD, MSHE**: [E68] Treatment Patterns Among Patients with Cystic Fibrosis Using Twice Daily Dornase Alfa Regimen

**Emily Cole**: [R02] Burden of Illness in Adult Patients with Nocturia

**Kathleen M. Fox, PhD**: [J15] Incidence and Predictors of Hospital Readmission Among Patients with Chronic Obstructive Pulmonary Disease in the Department of Veterans Affairs


**Sabyasachi Ghosh**: [I20] Predictors of All-Cause Healthcare Costs Among Patients with Newly Diagnosed Non-valvular Atrial Fibrillation Initiated on Dabigatran Versus Warfarin


**Mindy Ho**: [B15] Discontinuation Rates Associated with Sofosbuvir-Based Hepatitis C Virus Treatment Regimens at an Academic Health System with an Integrated Specialty Pharmacy Service

**Keith D. Huff, PharmD, MS**: [C06] Budgetary Impact of Adding Ziv-aflibercept to a United States Health Plan Formulary as a Post-oxaliplatin Biologic Option for Patients with Metastatic Colorectal Cancer (mCRC)

**Bhakti Jadav**: [U33] Primary Care Physician Perception of an E-Newsletter Within a Medicare Advantage Plan

**Shellie Keast, PharmD, PhD**: [B16] Effect of a Novel Prior Authorization and Management Program on HCV Treatment Adherence and Cost

**Tiffany Kreys**: [F31] Comparing Fall Risk Among Antidepressant Classes in the Elderly: A Nested, Case-Control Study of a Medicare Database

**Pavel Lavitas, PharmD, BCPS**: [B12] Adherence to Sofosbuvir- and Simeprevir-Based Regimens to Treat Chronic Hepatitis C Virus in a State Medicaid Population

**Amanda Mann, PharmD**: [U28] Impact of Mailed Letters on Medication Adherence in a Medicare Advantage Plan

**Ruben A. Mesa, MD, FACP**: [D05] Real-World Treatment Persistence and Dose Adjustment in Myelofibrosis Patients Newly Initiated with Ruxolitinib

**Hiep Nguyen**: [E38] Is 80% Proportion of Days Covered a Meaningful Quality Measure Threshold for Glucagon-like Peptide-1 Receptor Agonist Therapy in U.S. Patients with Type 2 Diabetes? A Retrospective Cohort Study

**Mark Olsson, MD**: [F05] Follow-up Care After Psychiatric Hospital Admission for Medicaid and Commercially Insured Patients with Schizophrenia or Bipolar Disorder

**Busuyi Olotu, PhD**: [E40] Use of Statins and the Risk of Incident Diabetes: A Retrospective Cohort Study

**Catherine Starner, PharmD**: [E63] PCSK9i Utilization, Cost, Utilization Management Impact, and Discontinuation Rate Among 13 Million Commercially Insured Americans

**Jennifer L. Strohecker, PharmD**: [I13] Improving Part D Stars Scores with a High-Touch, Patient-Centric Model Using Intensive Care-Coordination in a Medicare Dual-Special Needs Population with Low Health Literacy

**Amanda M. Teeple, MPH**: [K13] The Classification and Regression Tree Approach to Predicting Patient-Specific Factors Associated with Discussing Biologic Treatment with a Health Care Provider in Crohn's Disease Patients


**Stuart Turner, MS**: [I25] A U.S. Budget Impact Analysis of ENTRESTOTM (sacubitril/valsartan) Versus Renin-Angiotensin-Aldosterone System Inhibition Only, for Heart Failure Patients with Reduced Ejection Fraction

**Jonathan M. Vecchiet, PharmD**: [E44] Impact of Prior Authorization Removal on Utilization and Cost of Insulin Pens and Vials for Type 1 Diabetic Patients in a Pediatric Accountable Care Organization

**Tina M. Willson, PhD**: [F20] Real-World Dosing Patterns Among Patients Receiving Buprenorphine for Opioid Dependence in the United States

**Xiaolan Ye**: [G05] Adherence to Disease-Modifying Therapies Among Patients with Multiple Sclerosis

**Lisa Young**: [Z01] Rates of Hospitalization and Repeat Procedures in Patients Receiving Sodium Picosulfate/Magnesium Citrate Bowel Preparation Prior to Colonoscopy

**Zoibar Younossi, MD**: [B10] Reduction in Clinical and Economic Burden by Treating All Medicaid Patients with Chronic Hepatitis C (CHC): A Decision-Analytic Model
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ABSTRACTS

Podium Abstracts
(Presentations: Thursday, April 21, 8:30 am-9:45 am)

I23 Patient and Care Characteristics that Heighten Risk for 30-Day Readmission in Patients with Congestive Heart Failure
Shah B1, Bradford C2, Wachi N1, Sabota K1, Shane P1. 101 Brigantine Rd, Vallejo, CA 94591; bijal.shah@tu.edu; 707.638.5991
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BACKGROUND: Within 30 days of hospital discharge, heart failure readmission rates nationally accumulate to more than 20%. Due to the high rate of unplanned re-hospitalization in patients with heart failure, predictive models are needed to identify patients who are at high risk for readmission.

OBJECTIVE: To evaluate the diagnosis and timing of 30-day readmissions and to identify patient and care characteristics associated with readmissions among patients with an index visit for congestive heart failure (CHF).

METHODS: A retrospective analysis was conducted utilizing electronic health records and claims data at an acute care medical center during the period October 2008 to November 2014. Patients with a primary discharge diagnosis consistent with CHF were included. Readmitted and non-readmitted cohorts were compared using descriptive statistics and logistic regression was used to develop a predictive model to assess characteristics associated with 30-day readmission. Sensitivity analysis was conducted to assess factors associated with readmission at 15 days and 45 days after an index visit for CHF.

RESULTS: Characteristics of the study cohort (n = 2,420) were: a mean age of 72 (range 20-103), predominantly male (55%), white (55%), currently not employed (91%), and utilizing Medicare as a payer (68%). Over the study period there were 394 (16.3%) all-cause 30 day readmissions after 2,420 hospitalizations for CHF. The three most common reasons for readmission were heart failure (36.0%), renal disorders (8.4%), and other cardiac diseases (6.9%). Retired patients (OR, 2.30; 95% CI, 1.14 to 5.37) were more likely to readmit within 30 days. Visiting the ED one or more times within the 90 days preceding the index visit (OR, 1.56; 95% CI, 1.13 to 2.15) increased the risk for readmission.

CONCLUSIONS: This study provides a deeper understanding of patient and care characteristics that are associated with 30-day readmission after an index CHF hospitalization. Evaluation of these characteristics strengthens strategies to target those at highest risk for readmission and provides an evidence basis for guiding clinical interventions and services for heart failure patients that can improve outcomes and reduce readmissions.

SPONSORSHIP: None.

J02 Use of Behavioral Economics and Social Psychology to Improve Treatment of Acute Respiratory Infections (BEARI): A Discrete Choice Experiment
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BACKGROUND: Antibiotics are often inappropriately prescribed for non-bacterial acute respiratory infections. A variety of interventions have been developed to improve prescribing practices, some of which include principles of behavioral economics. It is not uncommon to design interventions based on information gathered in discussion with clinicians. However, little research has been done to compare prescriber stated preferences with actual behavior in a healthcare setting.

OBJECTIVE: To identify prescribers’ stated preferences for behavioral economics interventions designed to reduce inappropriate antibiotic prescribing as compared to prescriber education and guideline review.

METHODS: A RCT evaluated three behavioral economic interventions designed to reduce inappropriate antibiotic prescribing. We evaluated prescribers’ stated preferences for the same interventions relative to monetary and time rewards for improved prescribing outcomes. The interventions included: Suggested Alternatives (SA), an alert that populated non-antibiotic treatment options if an inappropriate antibiotic was prescribed; Accountable Justifications (JA), which prompted the prescriber to enter a justification for an inappropriately prescribed antibiotic that would then be documented in the patient’s chart; and Peer Comparison (PC), in which an email was periodically sent to each prescriber comparing his/her antibiotic prescribing rate with those who had the lowest rates of inappropriate antibiotic prescribing. A discrete choice experiment (DCE) was administered to determine whether prescribers preferred SA, JA, PC, pay-for-performance, or additional clinic time as incentives to reduce inappropriate antibiotic prescribing. Mixed logit modeling was used to analyze the DCE responses, and willingness-to-pay (WTP) was calculated for each intervention.

RESULTS: Prescribers overwhelmingly preferred SA, with an odds-ratio ranging from 1.96-2.96 (P < 0.05) depending on treatment group, followed by PC and JA. Overall, WTP estimates for each intervention showed that each intervention would be significantly cheaper to implement than a pay-for-performance incentive of $200/month.

CONCLUSIONS: Prescribers generally felt that any behavioral economic intervention was likely to reduce their rate of inappropriate antibiotic prescribing compared to just education and guideline review, thus it is likely that these behavioral economic interventions would be accepted in the work place. WTP estimates suggest that implementing these interventions would cost less than a more traditional P4P incentive system.

SPONSORSHIP: Grant RC4 AG039115 from NIH and AHRQ.

M06 Factors Associated with Urate-Lowering Therapy and Reaching Gout Treatment Goals in Patients with Cardiovascular Disease
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BACKGROUND: While strong associations are seen between serum uric acid levels and gout and cardiovascular disease (CVD), few studies have assessed differences between gout patients (pts) with and without CVD.

OBJECTIVE: To compare disease and comorbidity characteristics among gout pts with and without CVD, identifying differences in treatment patterns and healthcare utilization in a real-world cohort.
METHODS: Data were assessed from a survey of U.S. physicians and in-depth patient chart audits. Severity of gout was measured by physician global assessment, flares, organ/joint damage, and tophi. Type/dose of xanthine oxidase inhibitor, length of current treatment, sociodemographic factors, and physician type were identified. Multivariate and descriptive statistics described differences among pts with and without CVD and assessed urate-lowering therapy (ULT) use and gout disease control.

RESULTS: 1159 patient charts were abstracted (738, CVD; 421, no CVD; 81% male; 38% ≥61 y; 71% white). Pts with CVD had longer duration of gout (52 vs. 34 mo, P<0.001) and were more likely to have clinician-reported tophi (28% vs. 15%; P<0.001), organ/joint damage (19% vs. 9%; P<0.001), severe gout (19% vs. 11%; P<0.001), and more flares in the past 12 mo. (2.1% vs. 1.8%; P<0.001). Time from gout diagnosis to start of ULT was delayed for those with CVD (24 vs. 16 mo; P=0.02), but these pts were more likely to be on ULT (83% vs. 59%; P<0.001). Gout pts with CVD were more likely to have obesity (28% vs. 18%; P<0.001), diabetes (26% vs. 12%; P<0.001), osteoarthritis (25% vs. 11%; P<0.001), chronic kidney disease (17% vs. 5%; P<0.001), and prostate disease (males, n=933; 10% vs. 2%; P<0.001). Gout pts with CVD were more likely to have an emergency department visit for gout in the past 12 mo. (12% vs. 7%; P=0.003). Overall, ULT use was associated with better gout control. In a backward, stepwise logistic model in pts with CVD, those more likely be treated with ULT had organ/joint damage (odds ratio [OR] = 13.3), severe gout (OR = 1.5), and prostate disease (OR = 4.2), but these were not significant predictors for pts without CVD.

CONCLUSIONS: In this study, pts treated with ULT were more likely to have better gout control. Gout pts with CVD were more likely to be on ULT, despite delayed initiation of therapy. Given that gout pts with CVD were more likely to have additional comorbidities and more severe gout, the delay in treatment may be associated with the severity of disease in these pts. These data suggest that gout pts with CVD constitute a less healthy group in need of earlier, more aggressive therapy.

SPONSORSHIP: AstraZeneca.

BACKGROUND: High Risk Medications (HRM) will be removed from the Star Ratings in 2017 due to: (1) Specification changes resulting from 2015 Beers Criteria update; (2) CMS direction that the measure be reviewed to better understand the association between dual eligible status and HRM use found in their analysis to assess impact of socioeconomic status (SES) on Star Ratings.

OBJECTIVE: To investigate clinical and SES factors associated with HRM use in dual vs. non-dual eligible Medicare Advantage (MA) plan members.

METHODS: We used medical/pharmacy claims for 2.2 million MA members from the 2013 MORE Registry supplemented by SES data. Mixed effects logistic regression was used to estimate the effect of dual status on HRM use after controlling for percent duals (contextual effect) and quality differences between 364 plans in 80 contracts. Further analysis decomposed the disparity in HRM rates using Blinder-Oaxaca technique.

RESULTS: There is a 16% disparity in HRM rates between duals and non-duals (11.6% vs. 10.0%). Consistent with CMS findings, there was a negative effect of dual status on HRM use (OR=0.76; 95%-CI: 0.73-0.77) after controlling for differences across plans. HRM rates were not statistically associated with the percent duals in the plan (i.e., contextual effect was not significant). Decomposition analysis found differences in dual vs. non-dual characteristics explained 71.1% of the performance gap. Disability/ESRD as original reason for Medicare entitlement is more prevalent in duals (19.7% vs. 10.3%) and explained 25.8% of the disparity. Higher prevalence of Diabetes explained 35%; bipolar/major depression 19.5%; schizophrenia 9.1%; COPD 8.8%; anxiety 7.1%; alcohol/substance abuse 5%. HRM use was not influenced by SES factors (e.g., income/education) but there were significant regional differences. Members living in physician or mental health professional shortage areas were less likely to use HRMs.

CONCLUSIONS: Higher prevalence of clinical risk factors in duals explains most of the disparity in HRM rates but are not used for adjustment or exclusion criteria since the measure is calculated with pharmacy data only. Measure developers should investigate whether this association is penalizing plans serving disabled members. Not all factors are appropriate for adjustment, but are important to understand for targeted quality improvement. Others warrant evaluation for adjustment or exclusion to assure the measure provides a fair comparison of plan performance.

SPONSORSHIP: Inovalon conducted this study with support from Cigna-HealthSpring, Wellcare, HealthFirst, Gateway Health, BCBS-MN and HCSC.
**A01 Clinical and Economic Outcomes for Hepatitis C and AIDS/HIV Coinfection Within Inpatient Settings**

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**BACKGROUND:** Approximately 25% of patients with human immunodeficiency virus (HIV) are coinfected with Hepatitis C virus (HCV) in the U.S. Coinfection is associated with higher risk of severe morbidity, mortality, and health care utilization. Few studies have examined the burden of coinfection, particularly in acute care centers.

**OBJECTIVE:** To assess clinical and economic outcomes for hospital discharges involving HIV/HCV coinfection in the U.S. from 2003-2012 based upon demographic, hospital, and clinical characteristics.

**METHODS:** Using discharge data from the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project, adult hospital cases involving HIV/AIDS diagnoses and HCV coinfection were identified using ICD-9-CM codes spanning from 2003-2012. Four diagnosis-related strata were analyzed: (1) active AIDS monoinfection; (2) active AIDS with HCV coinfection; (3) asymptomatic HIV monoinfection; and (4) HIV with HCV coinfection.

**RESULTS:** HCV coinfection comprised 17.9% of HIV/AIDS cases (n=416,891 of 2,334,682). Coinfected cases averaged 47.4 ± 8.9 years and 68.0% were male, with charges and LoS of $43,490 ± 71,627 and 6.5 ± 8.4 days, respectively. Among those with advanced AIDS and HCV sequelae, mortality was 21.4%, charges were $90,832 ± 66,982, and LoS was 11.5 ± 6.3 days. Multivariable analyses suggested that the odds of mortality for active AIDS/HCV coinfection cases decreased by 13% from 2003-2007 (OR = 0.87, 95% CI: 0.82-0.91) and 16% from 2008-2012 (OR = 0.84, 95% CI: 0.79-0.90) (P < 0.05), though not for asymptomatic HIV/HCV cases (P > 0.05). No annual differences in either charges or LoS were observed. Rural residence was also associated with higher odds of mortality in asymptomatic HIV/HCV coinfection cases from 2003-2007 (OR = 2.32, 95% CI: 1.29-4.20) and 2008-2012 (OR = 3.01, 95% CI: 1.31-6.95) (P < 0.05).

**CONCLUSIONS:** HIV/HCV coinfection in hospital settings is common and imparts a large burden of illness. Given that the odds of inpatient death among AIDS/HCV coinfections decreased over time versus asymptomatic HIV/HCV coinfected cases, more aggressive screening and clinical intervention may be warranted in those with asymptomatic HIV, particularly in rural locations.

**SPONSORSHIP:** None.

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**A02 Academic Detailing Has a Positive Effect on Appropriate Antibiotic Prescribing and Drug Costs to a Health Plan**

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**PROBLEM DESCRIPTION:** Academic detailing is the practice of specially trained pharmacists with detailed medication knowledge meeting with prescribers to share best practice prescribing. Cefixime, which is a third line antibiotic for the most common infections in children, was more commonly prescribed than expected in a Medicaid Health Plan in Texas.

**GOAL:** To evaluate the impact of academic detailing on appropriate antibiotic prescribing and its impact on prescription drug costs to a health plan.

**PROGRAM DESCRIPTION:** A prospective intervention study was carried out that evaluated the prescribing practices and prescription drug costs of appropriate antibiotic prescribing. Eleven prescribers in the state of Texas were detailed by one pharmacist between August 2014 and March 2015. The physicians prescribing habits and prescription costs were compared before and after detailing to evaluate the effectiveness of the intervention. Data was collected for approximately 5 months before and after the intervention. Each prescriber served as his or her own control.

**OBSERVATIONS:** There was a 36.35% decrease in the number of cefixime prescriptions of written and a 21% decrease in the amount of money spent on cefixime compared to the previous year following the intervention.

**FINDINGS/RECOMMENDATIONS:** Academic detailing provided a positive impact in both prescribing and prescription drug costs to the health plan.

**SPONSORSHIP:** Texas Southern University Seed Grant.

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**B02 Treatment Patterns and Medication Use in Patients with Postherpetic Neuralgia**

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**BACKGROUND:** Postherpetic neuralgia (PHN) is a frequent complication of herpes zoster (HZ) infection characterized by chronic neuropathic pain. Evidence-based guidelines for 1st line PHN treatment (tx)—including American Academy of Neurology, European Federation of Neurological Societies, & Special Interest Group on Neuropathic Pain—recommend lidocaine patches (LIDO), gabapentin (GBP), pregabalin (PGB), or tricyclic antidepressants (TCA). Opioids & capsaicin are sometimes recommended as 2nd or 3rd line tx. Nonsteroidal anti-inflammatory drugs (NSAIDs) are not recommended.

**OBJECTIVE:** To explore treatment patterns & healthcare utilization associated with PHN diagnosis (dx) & treatment (tx).

**METHODS:** We examined medical and pharmacy claims from 2010-2015 in Truven Health Analytics MarketScan Commercial and Medicare Supplemental databases (n=232 million) to compare tx patterns and healthcare utilization in adults with PHN. Patients (pts)
were identified by a dx of HZ and met PHN dx criteria reported by Klompas (2011) or received newly prescribed LIDO tx within 60 days of HZ dx. Tx patterns are reported for pts <65 (n = 42,465) & ≥65 years (n = 20,806) based on tx newly initiated after dx.

RESULTS: Of the 0.4% of pts <65 and 1.3% ≥65 years diagnosed with HZ, 14% and 34% of pts, respectively, were subsequently diagnosed with PHN and patterns of initial analgesic use were observed. 29% of pts were started on a tx recommended as 1st line tx in PHN tx guidelines (LIDO 8% of pts, GBP 13%, PGB 3%, or TCA 2%). 22% of pts were started on opioids and 9% started on NSAIDs, which are not recommended in guidelines. Opioids (22% of pts) and GBP (15% of pts) were the most common initial tx in both age groups. In younger pts, NSAIDs were used prior to 1st or 2nd line tx more frequently (11% of pts <65 versus 6% of pts ≥65, P < 0.001).

CONCLUSIONS: Recommended 1st line txs are underutilized in PHN pts. Despite evidence of ineffectiveness for neuropathic pain, NSAIDs are frequently prescribed for PHN pts and likely to be even more frequently used in these pts when over-the-counter use is considered. These analyses indicate substantial opportunity for provider and payer education related to benefits of improved adherence to guidelines for 1st line PHN tx. The elderly population more commonly affected by PHN are at increased risk for tx AE. Our data indicate that more than 1 in 5 pts with PHN is started on opioids as 1st line tx. Choosing the right analgesic for an older adult can be challenging for a number of reasons, including comorbidities, polypharmacy, physiological changes, and cognitive challenges.

SPONSORSHIP: This study was supported by funding from SCILEX Pharmaceuticals.

B10 Reduction in Clinical and Economic Burden by Treating All Medicaid Patients with Chronic Hepatitis C (CHC):
A Decision-Analytic Model
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BACKGROUND: Prevalence of CHC in Medicaid is 7.5 fold higher than commercially-insured patients. Despite this and the tremendous efficacy (>95% cure) of new all-oral antivirals, significant restrictions exist to treat Medicaid CHC patients. A large proportion of untreated CHC patients are expected to enter Medicare with more advanced liver disease, contributing to higher costs and negatively impacting antiviral efficacy.

OBJECTIVE: To evaluate the clinical and economic impact of lifting current Medicaid restrictions in treating CHC.

METHODS: We constructed a decision-analytic Markov model which followed a cohort of treatment-naive, genotype 1 (GT1) Medicaid CHC patients over a lifetime horizon. Medicaid patients entered the model with a mean age of 43 years and were treated with an approved all oral regimen [LDV/SOF 8 weeks (W) or 12W depending on cirrhotic status and viral load]. Two scenarios were compared: (1) Treatment under state-specific restrictions by Metavir stage and (2) Treatment without restrictions. Untreated patients were assumed to age into Medicare at age 65, where they were treated without restriction. Transition probabilities, population inputs, and utilities were sourced from the literature and hepatologist consensus.

RESULTS: 120,982 Medicaid CHC patients were included. Under current restrictions, 4.2%, 49.6% and 6.8% of patients can access LDV/SOF regardless of fibrotic stage is projected to result in 38,670 fewer cases of cirrhosis, 1,847 fewer liver transplants (LT), 8,686 fewer cases of HCC, 17,234 fewer HCV-related deaths, 2.15 additional per-patient life years and 2.31 additional per-patient quality-adjusted life years. Under current restrictions, treating all eligible Medicaid patients with LDV/SOF 8W are projected to age into Medicare as compensated cirrhotics and become more difficult to treat. A further 27,844 patients are projected to age into Medicare with decompensated cirrhosis, hepatocellular carcinoma, or LT patients (or die due to liver-related mortality) and become ineligible for antivirals. The strategy to treat all patients with OOP of $80-$90 were 21% more likely (OR = 1.21, 1.16-1.27 95% CI) and those with OOP >$90 were 90% more likely (OR = 1.9, 1.85-1.96 95% CI) to abandon HZV than those with OOP <$80. Cox models suggested that disparities exist; Blacks and Hispanics were 48% and 32%, respectively less likely than Whites to get HZV, high income members were 10% (HR = 0.9, P < 0.0001) and 22% (HR = 0.78, P < 0.0001) more likely than middle and low income members to use HZV. Those with OOP between $80 and $90 were 20% less likely (HR = 0.79, P < 0.0001), and those with OOP > $90 were 33% less likely (HR = 0.67, P < 0.0001) to take HZV than members with OOP <$80.

CONCLUSIONS: OOP cost is a key factor influencing HZV abandonment and uptake in Medicare patients. Higher OOP is associated with increased risk of abandonment and a lower likelihood of taking the HZV. Different benefit design strategies may be needed to increase uptake, reduce abandonment, and minimize disparities.

SPONSORSHIP: Merck & Co. and CORE.

B03 Impact of Member Benefit and Out-of-Pocket Costs on Herpes Zoster Vaccine Uptake and Abandonment: An Observational Study in a Medicare Managed Care Population
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BACKGROUND: Herpes zoster (HZ) vaccination (HZV) is approved for adults 50+ for prevention of HZ, but is underutilized. Reasons for suboptimal uptake of HZV include lack of awareness, lack of routine stocking, non-compliant patient behavior, and financial barriers.

OBJECTIVE: To evaluate the association between patient out-of-pocket cost (OOP) and HZV utilization and abandonment, given that low HZV use undermines public health efforts aimed at reducing the burden of HZ.

METHODS: Medicare Advantage (MAPD) and Part D only (PDP) patients eligible for HZV and enrolled for at least 12 months following eligibility from 1/1/2007 to 6/30/2014 were selected from Humana’s research data warehouse. HZV uptake was defined as a claim for HZV within 60 days of an HZ dx with no evidence of abandonment for at least 90 days. Abandonment was defined as a reversed claim for HZV with no other claim within 90 days. OOP was determined by actual patient out-of-pocket amounts associated with the HZV claim or from the pharmacy benefit and formulary status of HZV at eligibility and annually. Descriptive statistics were run on OOP, abandonment and uptake rates were calculated and compared by year and line of business. Cox and logistic models were used to estimate uptake and abandonment probabilities across ordinal OOP categories.

RESULTS: 6,295,970 patients met eligibility criteria, 40.5% MAPD and 59.5% PDP. Overall HZV abandonment was 7.3%. Mean OOP was higher for abonnders versus non-abandoners ($89 ± $55) vs. $79 ± $49). Both mean OOP and HZV abandonment rates showed an increasing trend over the study period. Logistic regression indicated that
was most cost-effective (dominant). Furthermore, treating all Medicaid CHC led to savings of $14,118/SVR and to a total of $6.4 billion in savings over the model time horizon.

CONCLUSIONS: Medicaid CHC restrictions significantly compromise patient outcomes and will lead to a substantial economic burden when patients age into the Medicare program.

SPONSORSHIP: Gilead Sciences.

B11 Payer Perceptions on the Value of Cost-Per-Outcome Data in Select Disease States

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Xcenda

BACKGROUND: Centers for Medicare & Medicaid Services set a goal to tie quality or value to 90% of Medicare fee-for-service payments by 2018. Pharmaceutical manufacturers may be able to assist with the delivery of value-based care by providing payers with data on the cost to achieve disease-specific health outcomes with a given treatment. However, when considering costs per outcome, there is little information on the disease states and outcomes for which payers perceive this data to be most compelling.

OBJECTIVE: To better understand which disease states and outcomes payers perceive cost-per-outcome data to be the most compelling for formulary decision-making.

METHODS: An electronic survey of medical and pharmacy directors from national and regional health plans was conducted via Xcenda’s December 2015 PayerPulse Survey with payers from Xcenda’s Managed Care Network. Respondents were asked to rank 7 disease states according to how compelling cost-per-outcome data would be for formulary decision-making. For each of these disease states, respondents were then asked which health outcomes were perceived as most compelling. Descriptive statistics and analyses were used to characterize differences in payer perceptions by organization geography, type, and role of survey respondent.

RESULTS: 53 payer representatives completed the survey. Survey results showed that of the 7 disease states presented, hepatitis C (HCV), type 2 diabetes (T2DM), and multiple sclerosis (MS) are the disease states in which information on cost-per-outcome data is most compelling for formulary decision-making (mean ranking of 2.17, 2.87, and 4.06, respectively). Sustained virologic response (SVR) was selected as the most compelling outcome by the majority (54.7%) of respondents for HCV. For T2DM, 66.0% selected Hba1c at goal, and for MS, 52.8% selected relapse as the most compelling outcome. In all 7 disease states, quality-adjusted-life year was not ranked among the top 3 compelling outcomes by payers for cost-per-outcome data.

CONCLUSIONS: Payers identified HCV, T2DM, and MS as the disease states for which information on cost-per-outcome is most compelling for formulary decision-making. Among these disease states, there was a moderately high level of agreement in the most compelling disease-specific outcome. This consensus in disease states and outcomes of importance creates confidence in potential opportunities for manufacturers to meet the needs of payers.

SPONSORSHIP: This research was conducted by Xcenda without external funding.

B12 Adherence to Sofosbuvir- and Simeprevir-Based Regimens to Treat Chronic Hepatitis C Virus in a State Medicaid Population

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BACKGROUND: Strict adherence to regimens for chronic hepatitis C virus (HCV) is necessary to achieve a sustained virological response. Challenges to adherence include regimen complexity, pill burden, and medication toxicities. Massachusetts Medicaid (MassHealth) members receiving sofosbuvir- or simeprevir-based regimens within a primary care clinician (PCC) plan receive outreach to the prescribing clinician to support adherence.

OBJECTIVE: To evaluate adherence to sofosbuvir or simeprevir-based regimens among MassHealth PCC members, assess correlates of adherence, and describe reasons for treatment discontinuation.

METHODS: This retrospective cohort study used enrollment, eligibility, and medical claims data from MassHealth PCC members from December 6, 2012-July 31, 2014. The sample included members with one or more claims with an ICD-9-CM code for HCV during this time and who were continuously enrolled from December 6, 2013 (date of FDA approval for sofosbuvir) through July 31, 2014. Pharmacists called the prescribing clinician if there was no claim for a new fill within two days of the end of the days’ supply of the previous fill. We calculated the proportion of days (PDC) covered by all medications in the HCV regimen for all 12-week regimens; patients were classified as adherent if they had 90% or higher PDC. Logistic regressions estimated regimen for all 12-week regimens; patients were classified as adherent if they had 90% or higher PDC. Logistic regressions estimated correlates of adherence, and describe reasons for treatment discontinuation.

RESULTS: Overall, 215 PCC members initiated a 12-week regimen containing simeprevir or sofosbuvir. One hundred and eighty-eight (87.4%) had a PDC of 90% or higher. In multivariable analysis, white- non-Hispanic members were less likely to be adherent than members of other race/ethnicities (OR = 0.22, 95% CI 0.07-0.72). Adherence decreased with increasing comorbidity, but was not associated with regimen, diagnosis of substance use, mental illness, or pharmacy type. Eighteen members discontinued treatment prior to 12 weeks, nine from adverse events, five for other reasons, one for virological breakthrough, and three were lost to follow-up.

CONCLUSIONS: In a state Medicaid program that provides outreach to support adherence, the majority of patients maintain a high level of adherence to sofosbuvir/simeprevir regimens.

SPONSORSHIP: This work was funded by the Massachusetts Executive Office of Health and Human Services.

B13 Implementing a Proactive Clinical Evaluation to Enhance Hepatitis C Treatment Outcomes

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Fairview Specialty Services Pharmacy

PROBLEM DESCRIPTION: At Fairview Specialty Services Pharmacy (FSSP) a centralized process for dispensing Hepatitis C (HCV) antivirals was implemented which includes a proactive clinical evaluation of the prescribed treatment regimen for appropriateness based on the
METHODS: This was a retrospective chart review of SOF-containing HCV regimens from 12/15/13 to 12/15/14. Patients included were those receiving care at UI Health, > 18 years old, and started SOF in combination with peg-interferon/RBV, simprevir or ledipasvir. Patients excluded did not have medical chart data, did not start treatment during the study or received their regimen from an external pharmacy. The DCR was determined based on the total number of patients who started a SOF-containing HCV regimen compared to those who had documented early discontinuation according to refill history and clinical records. The discontinuation reasons were identified by chart review.

RESULTS: 298 records were identified for possible inclusion. 100 were excluded (33 didn’t start treatment during the study, 65 were managed by external pharmacy). 198 patient records were evaluated for the study objectives. Overall DCR was 6.1% (n = 12). Reasons for discontinuation included adverse event (AE) event (n = 6, 3.0% which included abnormal lab (n = 1, 0.5%), death (n = 1, 0.5%), prolonged hospitalization (n = 2, 1%), adverse drug reaction (n = 2, 1%), insurance loss (n = 1, 0.5%), or documented non-adherence (n = 5, 2.5%).

CONCLUSIONS: The DCR in this study was slightly higher than those reported during clinical trials but much lower than published real world estimates. Similar to clinical trials, the most common reason for early discontinuation was AE related with rates similar to clinical trials. Non-adherence was identified as a factor occurring in practice but not recognized with substantial frequency in trials.

SPONSORSHIP: None.

B16 Effect of a Novel Prior Authorization and Management Program on HCV Treatment Adherence and Cost
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BACKGROUND: Recently-approved direct-acting antivirals (DAAs) for hepatitis C (HCV) offer new curative approaches, though with a potential to markedly increase short-term medical or pharmacy budgets.

OBJECTIVE: To compare adherence and cost between HCV patients included in a novel prior authorization (PA) and management program versus no intervention in Medicaid members undergoing treatment.

METHODS: This retrospective cross-sectional time-series analysis of Medicaid members ≥ 18 years with diagnosed HCV undergoing treatment used administrative claims data from the Oklahoma Health Care Authority from 01/2014-11/2015. Multivariable generalized estimating equations (GEE) were employed to assess outcomes of cost from the perspective of the payer and medication possession ratio (MPR) after controlling for sex, age, Deyo-Charlson Comorbidity index, metropolitan/rural patient residence, medication regimen, and implementation of the Medicaid PA program which began in 07/2014. This PA and management program included patient and pharmacy agreements, prescriber verification of appropriate treatment, detailed counseling, frequent follow-up, and ongoing PAs at each refill with required pill counts.

RESULTS: Overall, 384 enrollees met inclusion criteria, averaging 52.5 ± 9.9 years of age and 52.9% being female. Before the prior authorization program, the average unadjusted MPRs and costs were 55.7 ± 31.2% and $29,109 ± 1,614, respectively. After the PA program began, the average unadjusted MPRs and costs were 80.7 ± 26.9% and $31,424 ± 2,631. After controlling for numerous patient and clinical factors including medication regimens, the multivariable GEE analysis indicated that a +33.7% increase in MPR was observed with the Medicaid PA program (exp(b) = 1.337, P < 0.001, 95th CI: 1.226, 1.457) with no change in total average costs (exp(b) = 0.997, P = 0.171, 95th CI: 0.904, 1.001).

SPONSORSHIP: None.
CONCLUSIONS: This evaluation of a novel Medicaid PA and management program for HCV patients undergoing treatment indicated large and significant increases in medication adherence without higher overall costs. While longer-term studies are required to assess the relationship between increased adherence, improved outcomes, and cost changes, these findings suggest that intensive programs for Medicaid beneficiaries provide benefit in a condition where treatment adherence is crucial to achieving a cure.

SPONSORSHIP: Gilead Sciences.

B18 Evaluating Outcomes of Commercially Insured Hepatitis C Patients Co-infected with Human Immunodeficiency Virus Treated with 56 Days of Ledipasvir and Sofosbuvir

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Aetna Pharmacy Management

BACKGROUND: The efficacy of Harvoni for the treatment of the Hepatitis C virus (HCV) has been demonstrated in clinical trials. Real world sustained viral response results are just emerging. The American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) collaborated on HCV treatment guidance that included a recommendation to use the same approach when treating patients co-infected with human immunodeficiency virus (HIV) as with those patients with monoinfection.

OBJECTIVE: To evaluate the sustained viral response (SVR) rates among HCV co-infected patients with HIV treated with 56 days (8 weeks) of ledipasvir and sofosbuvir (Harvoni).

METHODS: A retrospective analysis was conducted using pharmacy claims data, medical data, laboratory data, and clinical data from provider medical records. Patients were identified through medical claims having a diagnosis of both HCV and HIV. Patients who had paid pharmacy claims for Harvoni for a total duration of 56 days, and received treatment between November 2014 and September 2015 were included.

RESULTS: In the interim analysis, 33 commercially insured patients were identified as having HCV and being co-infected with HIV and were treated with 8 weeks of Harvoni. SVR results are available for 10 patients. 100% achieved a successful SVR (defined as aviremia 12 weeks after completion of antiviral therapy for chronic HCV infection: SVR results are pending regarding the remaining 23 patients.

CONCLUSIONS: Harvoni proved to be effective in treating 100% (10/10) of commercially insured HCV patients co-infected with HIV in just 8 weeks. Aetna continues analysis on the remaining 23 patients, and the results will be updated prior to poster submission.

SPONSORSHIP: Funding for this study was provided by Aetna.

B19 Switch Rates, Retreatment, and Persistence to Chronic Hepatitis C Treatment Regimens

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BACKGROUND: Chronic Hepatitis C (CHC) affects an estimated 2.7 to 3.9 million people in the U.S. and can lead to liver cancer or liver transplant. The treatment landscape for CHC has rapidly changed as newer therapies have been introduced to the market. Results from clinical trials suggest high persistence to these newer CHC therapies, but results from the real-world setting are limited.

OBJECTIVE: To describe real-world rates of switching, retreatment, and persistence to CHC medications in a large, insured U.S. population.

METHODS: This was a retrospective cohort analysis using data from OptumRx, a large, national pharmacy benefits manager. Members were identified if they filled at least one pharmacy claim for sofosbuvir (SOF), simprevir (SIM), ledipasvir-sofosbuvir (LED-SOF), or ombitasvir/paritaprevir/ritonavir/dasabuvir (VIE) between 11/1/2013 and 12/31/2014. The first fill during this period was defined as the index date. Continuous pharmacy eligibility was required during the 90-day pre-index period and 180-day treatment period following the index date. Switchers were identified as members who switched from...
one regimen to another during the treatment period with a gap of <12 weeks between regimens. Retreatment was identified if the member was retreated with a subsequent regimen after a 12-week gap following the end of the initial regimen. Treatment length was calculated as the cumulative sum of days supply during the treatment period. Members with gaps in therapy for >15 days were identified as non-persistent.

All study outcomes were compared between members who filled the majority of their CHC medications at OptumRx specialty or mail order pharmacies compared to those who did not.

RESULTS: A total of 12,228 members were evaluated. Switch rates were low for all regimens (0.6% to 3.6%). Retreatment rates were lowest for LED-SOF (0.5%) and highest for the SOF/IFN/ribavirin (RBV) regimen (8.9%). About 1.6% of LED-SOF members and 8.5% of SOF/IFN/RBV members did not complete a minimum of 8 and 12 weeks of therapy, respectively. Between 6.3% (for LED-SOF) and 9.5% (for SOF/RBV) of members had treatment gaps. Members who mostly filled at OptumRx pharmacies had lower rates of non-persistence (6.6%) compared to those who mostly filled at non-OptumRx pharmacies (8.2%) or a mix (13.1%) [P<0.01].

CONCLUSIONS: LED-SOF was associated with lower switch and retreatment rates, and better persistence than other SOF-based regimens used in combination with IFN, IFN, and/or RBV. Better persistence was also seen among members who filled at OptumRx pharmacies.

SPONSORSHIP: No outside funding supported this study.


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BACKGROUND: Highly effective antiretroviral (ARV) therapies have transformed treatment of HIV patients from acute to chronic-care. HIV patients are living longer and treated earlier. With increasing age, comorbidities such as chronic kidney disease (CKD), cardiovascular disease (CVD) and fractures are increasing. E/C/F/TAF, a novel ARV approved by the U.S. FDA and included in the DHHS list of recommended regimens, has demonstrated robust clinical efficacy with superior renal and bone and improved CVD safety profiles compared to recommended and alternative regimens.

OBJECTIVE: To estimate the projected budget impact of introducing E/C/F/TAF in treatment-naive and virally suppressed treatment-experienced HIV patients compared to current formularies using DHHS recommended and alternative regimens.

METHODS: A budget impact model (BIM) generated from cost-consequence analyses (CCA) was developed using an event simulation framework; the simulation framework considers patients’ conditions and the events impacting these conditions. Inputs were drawn from published randomized controlled trials, reviews of the peer-reviewed literature, and real-world database analyses. Model structure, assumptions, and inputs were validated by a panel of experts in HIV, nephrology, CVD, endocrinology and skeletal abnormalities. Comparative regimens included E/C/F/TDF, elavirenz/F/TDF, dolutegravir/abacavir/lamivudine, and F/TDF+dolutegravir. ART prices were based on 2015 wholesale acquisition costs. The model assessed time horizons of 1-5 years, and simulated Commercial, Medicaid, and Medicare plans of $1,000,000, 100,000, and 100,000 members respectively.

RESULTS: In years 1 and 2, E/C/F/TAF had a negligible pharmacy and total budget impact of $0.04 and $0.01 per member per month (PMPM) in a simulated Commercial health plan. In years 3 to 5, E/C/F/TAF produced pharmacy budget savings of $0.13 to $0.49 PMPM and overall budget savings of $0.14 to $0.51, driven by costs associated with switching due to virologic failure, CKD, CVD, and/or fracture events. This reduction in CKD (26-34%), CVD (19%), and virologic failure events (62-79%) produced medical cost offsets in years 1 to 5. Over 5 years, the model estimates that the addition of E/C/F/TAF will reduce total budget (pharmacy plus medical) by $0.92 PMPM. Results were similar in Commercial, Medicaid, and Medicare.
payer populations and were robust against comprehensive sensitivity analyses of model assumptions.

**CONCLUSIONS:** According to this analysis, E/C/F/TAF will reduce comorbid events and switch thus improving health outcomes, and generate savings at 5 years.

**SPONSORSHIP:** Gilead Sciences.

**B24 Economic Outcomes of Stable Switching Among Patients with HIV**

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**BACKGROUND:** Treatment changes among HIV patients who are well-maintained on antiretroviral therapy (ART) may result in development of new side effects, virologic failure, or increased costs.

**OBJECTIVE:** To examine the impact of switching therapies on subsequent healthcare utilization and cost among stable HIV patients.

**METHODS:** The study population comprised patients with HIV from a large U.S. administrative claims database initiating common ART regimens (≥0.5% prevalence) from 2007-2013, with ≥6 months pre-treatment continuous enrollment and maintained for ≥6 months on their 1st-line regimen (i.e. considered stable). Patients with pregnancy or HIV-2 were excluded. A switch was defined as any discontinuation and/or add-on to the 1st-line regimen (switch date = index date). For each switcher, up to 20 gender- and treatment duration-matched comparators were selected randomly with replacement and weighted accordingly. Patient characteristics and post-index healthcare utilization and costs were assessed descriptively, and with multivariable-adjusted models. Subgroup analyses were conducted among patients with observed viral suppression during 90 days pre-index and with no identifiable reason to switch based on detailed claims review.

**RESULTS:** Analyses included 927 switchers and 18,511 (unweighted) comparators; 168 switchers had observed viral suppression, and 55 had no identifiable clinical reason to switch. Overall, 89% of patients were male with mean ± standard deviation pre-index treatment duration of 1.8 ± 1.2 years. Age in years at treatment initiation was 42.0 ± 9.5 for switchers and 41.6 ± 9.9 for comparators. Mean follow-up in years was 1.5 ± 1.3 for switchers; 1.6 ± 1.4 for comparators. Annualized follow-up healthcare utilization for switchers vs. comparators, respectively, were inpatient: 0.11 ± 0.61 vs. 0.07 ± 0.58, P = 0.12, emergency: 0.85 ± 3.42 vs. 0.61 ± 3.32, P = 0.03; and ambulatory: 14.7 ± 15.6 vs. 11.6 ± 13.6, P < 0.01. Annualized healthcare costs averaged 37,641 ± 35,226 for switchers vs. 31,355 ± 33,470 for comparators, P < 0.01. After adjustment for demographics, comorbidities, and baseline cost, follow-up costs were 10.9% higher among switchers vs. comparators, P < 0.01. Results were similar in subsets with viral suppression and no identified reason to switch.

**CONCLUSIONS:** In this large real-world population, patients with HIV who were stable and changed ART had significantly more healthcare utilization and cost relative to comparators. Further study is needed to determine if these differences are driven by clinical consequences of switching.

**SPONSORSHIP:** Bristol-Myers Squibb.

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**B25 Comparison of Healthcare Costs Between First-Line Antiretroviral Therapy Regimens in Commercially and Medicaid-Insured Patients with Human Immunodeficiency Virus**

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**SPONSORSHIP:** Bristol-Myers Squibb

**BACKGROUND:** For the treatment naive patient with human immunodeficiency virus (HIV), there are numerous potential antiretroviral therapy (ART) regimens that may be used as first-line treatment.

**OBJECTIVE:** To compare healthcare costs between first-line ART regimens used in commercially- and Medicaid-insured patients with HIV.

**METHODS:** This retrospective, observational cohort study using U.S. health insurance claims included patients aged ≥18 years who initiated one of 10 first-line ART regimens—chosen on the basis of May 2014 U.S. Department of Health and Human Services recommendations—between 1/1/2006 and 10/1/2013 (initiation date = index). Patients were required to have continuous enrollment for at least 6 months before and 14 days after index, to have a medical claim with an HIV diagnosis during that time, and to have no evidence of HIV-related ART prescriptions any time prior to index. Follow-up extended from index to a ≥30-day gap in any agent within the initiated regimen, disenrollment, or study end date (12/31/2013). The study outcome was per-patient per-month (PPPM) total healthcare costs incurred during follow-up. Multivariable log-ordinary least squares regressions adjusting for patient characteristics were used to compare PPPM total healthcare costs across the ART regimens.

**RESULTS:** The study included 16,286 commercially-insured patients and 4,998 Medicaid-insured patients. The most commonly-used ART regimen was EFV/TDF/FTC (N = 10,590 Commercial; N = 2,611 Medicaid); DTG + ABC/3TC and DTG + TDF/FTC had too few patients to analyze. Mean follow-up ranged from 192-460 days in Commercial and 142-300 days in Medicaid. Adjusted predicted PPPM healthcare costs varied across the regimens; in Commercial with EFV/TDF/FTC as reference ($3,632), costs of patients treated with other regimens were: ATV/r + TDF/FTC = $4,685, P < 0.01, DRV/r + TDF/FTC = $4,954, P < 0.01, EVG/Cobi/TDF/FTC = $4,316, P < 0.01, RAL + TDF/FTC = $4,436, P < 0.01, EFV + ABC/3TC = $3,279, P = 0.30, RPV/TDF/FTC = $3,541, P = 0.33, and ATV/r + ABC/3TC = $4,625, P < 0.01. In Medicaid, with EFV/TDF/FTC as reference ($5,044), costs of patients treated with other regimens were: ATV/r + TDF/FTC = $6,340, P < 0.01, DRV/r + TDF/FTC = $6,899, P < 0.01, EVG/Cobi/TDF/FTC = $5,676, P = 0.03, RAL + TDF/FTC = $3,988, P < 0.01, EFV + ABC/3TC = $5,048, P = 0.09, RPV/TDF/FTC = $4,899, P = 0.69, and ATV/r + ABC/3TC = $5,859, P = 0.13.

**CONCLUSIONS:** In this study of commercially-insured and Medicaid patients with HIV initiating first-line ART, those prescribed EFV/TDF/FTC had significantly lower total healthcare costs compared with most other groups of patients prescribed other first-line ART regimens.

**SPONSORSHIP:** Bristol-Myers Squibb.

**B27 Opioid Analgesic Use and Polypharmacy Is Routine in the Treatment of Post-herpetic Neuralgia: A Potential Role for Managed Care Intervention?**

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**BACKGROUND:** Post Herpetic Neuralgia (PHN) is a painful neuropathic condition that can last for months or years. PHN guidelines recognize NSAIDs as ineffective and support the use of topical lidocaine,
tricyclic antidepressants, and anticonvulsants as first-line therapy. Opioid analgesics are considered second- or third-line treatment.

**OBJECTIVE:** To investigate PHN treatment patterns and adherence to evidence-based guidelines.

**METHODS:** A retrospective analysis was performed using a large, de-identified U.S. electronic health record database (HealthFacts, Cerner Corp., Kansas City, MO, USA). A univariate description of the population was generated to determine the treatment landscape for PHN. Quantitative outcomes assessments of patients receiving different analgesia regimens were performed using propensity-score matched populations.

**RESULTS:** Of 5,033 PHN patients, 35% received opioid analgesics, and when prescribed, opioids were most often used (85%) as first-line therapy. In contrast, tricyclic antidepressants and topical lidocaine were prescribed for 3.8% and 21.7% of patients, respectively. Despite a lack of systemic adverse events, topical lidocaine was first-line therapy in only 33.7% of patients. NSAIDs were prescribed to 8.5% of PHN patients. A high degree of analgesic polypharmacy (≥4 medications) was observed.

**CONCLUSIONS:** Appropriate pharmacological management should be based not only on efficacy, but safety and tolerability. Our data show that opioid use is prevalent in PHN treatment despite well-documented safety issues. Evidence-based guidelines recommend opioids as second- and third-line agents, but they are often prescribed first-line, instead of topical lidocaine, tricyclic antidepressants, and anticonvulsants. In addition, our data revealed a high degree of analgesic polypharmacy which potentially contributes to adverse effects. Clinician adherence to evidence-based treatment guidelines appears suboptimal. Managed care organizations and pharmacists have an opportunity to assist in applying evidence-based guidelines and raise awareness regarding the potential risks associated with frequent prescribing of opioid analgesics and CNS depressants to this sensitive, mostly elderly, population of patients affected by PHN.

**SPONSORSHIP:** This research was funded by Scilex Pharmaceuticals, Malvern, PA.

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**B30 The Social Value of Childhood Vaccination in the United States**

Philipson T1, Snider J2, Chit A3, Green S2, Hosbach P4, Schwartz T2, Wu Y2, Aubry W5. 555 12th St, Oakland, CA 94607; values sourced from clinical and observational data, as well as the literature. The model quantified the health effects of routine vaccination for 14 diseases in terms of quality-adjusted life years (QALYs) saved. The health effects were then valued by applying an economic value of a QALY. Producers' and consumers' shares of this social value were computed. Sensitivity analyses were conducted to determine how results depended on the value of a QALY, the discount rate, manufacturers' profit margins, and the underlying health effects of vaccines.

**RESULTS:** Our estimates indicated that vaccination of this cohort will save 1.2 million QALYs, relative to no vaccination. Of those health gains, 87% stemmed from reduced mortality and 13% from reduced morbidity. We estimated a social value from these gains of $189.0 billion, of which $34 billion accrues to manufacturers as profits, while $155.7 billion accrues to the rest of society. In sensitivity analysis, the total social value ranged from $65 billion to $344 billion, or $13,756 to $83,280 per child in the cohort.

**CONCLUSIONS:** Childhood vaccination greatly reduces morbidity and mortality due to vaccine-preventable disease. When the economic value of these health effects is compared to the cost of the vaccines, it is clear that vaccines provide a large value for society. Policymakers should account for this social value when considering policies affecting incentives to develop new vaccines.

**SPONSORSHIP:** Sanofi-Pasteur.

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**C01 Adoption of Rolapitant, a Novel NK-1 Receptor Antagonist for Chemotherapy-Induced Nausea and Vomiting (CINV), Has a Negligible Budget Impact for a Typical U.S. Health Plan**

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1TESARO; 2Trinity Partners

**BACKGROUND:** Prevention of chemotherapy-induced nausea and vomiting (CINV) is a key component of supportive care in patients receiving emetogenic chemotherapy, as nausea and vomiting can have a significant negative impact on the health and quality of life of these patients. As defined in the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) and Multinational Association of Supportive Care in Cancer (MASCC)/European Society for Medical Oncology (ESMO) guidelines, optimal protection from CINV induced by highly emetogenic (HEC) and moderately emetogenic chemotherapy (MEC) can be achieved with a triple therapy of dexamethasone with a serotonin-3 receptor antagonist (5-HT3 RA) and a neurokinin 1 receptor antagonist (NK-1 RA). Rolapitant is a newly approved NK-1 RA indicated for the prevention of delayed CINV.

**OBJECTIVE:** To develop a budget impact model (BIM) to estimate the impact of oral rolapitant on the management of delayed CINV associated with initial and 5 repeat courses of emetogenic chemotherapy.

**METHODS:** The model aimed to reflect the perspective of a U.S. third-party payer, with a focus on pharmacy costs and a time horizon of 3 years (baseline 2015 up to 2018). Cost inputs included drug cost for NK-1 RA and 5-HT3 RA, and administration costs. Cost for 5-HT3 RA reflected treatment guidelines (NK-1 RA is usually given with a 5-HT3 RA) and allowed comparison with NEPA (NK-1 RA/5-HT3 RA combination). Inputs and assumptions for the default model were based on literature sources and market research studies done by the sponsor.

**RESULTS:** Assuming a hypothetical commercial plan population of 1,000,000 (1M) members, the model estimated 3,000 patients on chemotherapy, with 1,050 receiving HEC or MEC, 160 of which receiving NK-1 RAs. The model assumed a 9% yearly growth in NK-1 RA treatment rates overall and 18% market share for oral rolapitant by 2018. Rolapitant’s maximal cost was estimated at $7,178 per cycle, or $46,246 per year (assuming 6 chemotherapy cycles per patient per
A Conceptual Framework for Value-Based Oncology Treatment: A Societal Perspective

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SPONSORSHIP: TESARO.

PROBLEM DESCRIPTION: Cancer is the leading cause of death in developed nations and additionally imposes a substantial economic burden on society. Oncology was the leading therapeutic class among global pharmaceutical sales in 2014 with an estimated spend of $79.2 billion. With the growing cost of pharmaceuticals, a number of initiatives have been proposed to assess the true "value" of oncology treatment.

GOAL: To conceptualize a framework that captures the overall value of pharmaceutical treatment for cancer from a societal perspective, thereby appealing to a diverse set of healthcare stakeholders. The study will utilize work productivity outcomes as an example to demonstrate one aspect of potential value for oncology treatments for patients and caregivers.

PROGRAM DESCRIPTION: The study was conducted in two phases: (1) a comprehensive review of the literature was conducted to identify different value-based models of oncology treatments, based on which a new model from a societal perspective is being proposed; and (2) using work productivity as an example, existing evidence and gaps in knowledge of the impact of oncology treatment on patient and caregiver work productivity was categorized.

OBSERVATIONS: A systematic literature evaluation of all relevant English-language publications till December 2015 was conducted using MEDLINE, CINAHL, Scopus and Cochrane databases. Search terms focused on work productivity and caregiver burden.

FINDINGS/RECOMMENDATIONS: Value models previously developed include (1) the American Society for Clinical Oncology (ASCO) model based on clinical benefit, toxicity, and treatment acquisition cost; (2) Memorial Sloan Kettering Cancer Center's model which evaluates the therapeutic impact, toxicity and cost of 54 cancer drugs; and (3) the National Comprehensive Cancer Network (NCCN) model which focuses on efficacy, safety, and quality of evidence. Our proposed model takes a societal perspective and evaluates the value of oncology treatment based on all outcomes of interest—clinical (RCTs, observational studies, patient registry, systematic reviews, meta-analyses); economic (budget impact, incremental cost-effectiveness ratios, work productivity), patient and caregiver-related (quality of life, preference, treatment satisfaction), and equity considerations. Our preliminary literature search on work productivity yielded over 20 articles which will be of interest to patients, payers and employers in decision making. Data from this review are being used to identify evidence gaps in demonstrating the full value of cancer treatment, and suggests a number of areas for future research.

SPONSORSHIP: Novartis Pharmaceuticals.
commercially available CDT's and compare it to payer expectations to identify gaps.

METHODS: Five oncology biomarkers were included in the scope of this study: ALK, BRAF V600E, EGFR, HER2, and KRAS. Each drug and CDT manufacturer was called via telephone from the perspective of a clinical pharmacist requesting CDT information to assist in formulary decision making about the corresponding drug. Specifically, information about the test's analytical validity, clinical validity, and clinical utility (ACCE framework) was requested. Additionally, a Pharmacy & Therapeutics (P&T) committee at a major medical institution was surveyed to assess current information provision expectations.

RESULTS: A total of 21 calls were made to manufacturers utilizing a standardized script of questions. Of the requests, 40% to CDT manufacturers resulted in referral to their website, while 60% resulted in an email with the test's package insert and a reference to the manufacturer's online website. While all drug manufacturers provided a written response, only 23% of medical letters were informative. Additionally, 54% resulted in referral to the CDT manufacturer, and 23% in referral to the FDA's website. Survey results showed 57% of P&T members believe both drug and CDT manufacturers should provide analytical validity, clinical validity, clinical utility, and cost information about CDT's, and all preferred a response with primary literature.

CONCLUSIONS: This study suggests that gaps exist in obtaining CDT information. In total, 60% of CDT manufacturers and 23% of drug manufacturers provided package inserts and medical letters respectively with variable amounts of desired information. On the other hand, P&T committee members surveyed expect both drug and CDT manufacturers to provide medical information based on primary literature when requested. This limitation may impede payers from acquiring information necessary to evaluate drugs, used in conjunction with CDT's, for formulary decisions. It remains to be seen how CDT and drug manufacturers respond to information requests given the CDT Addendum in The AMCP Format.

SPONSORSHIP: Eli Lilly and Company.

C06 Budgetary Impact of Adding Ziv-aflibercept to a United States Health Plan Formulary as a Post-oxaliplatin Biologic Option for Patients with Metastatic Colorectal Cancer (mCRC)

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BACKGROUND: As the number of treatment options for mCRC increases, the economic impact of these therapeutic advances becomes increasingly important.

OBJECTIVE: To assess the economic impact of the availability of ziv-aflibercept for patients with mCRC following disease progression after oxaliplatin, a user-adaptable budget impact model was developed for payers, based on use of 5-fluorouracil, leucovorin and irinotecan (FOLFIRI) chemotherapy alone or combined with a biologic agent, including ziv-aflibercept.

METHODS: A Markov-like model simulated transition from progression-free survival (PFS) to progressive disease (PD) and death, to identify the number of patients most likely to receive biologic therapy. Over the model time frame of 1 year, each 90-day cycle adjusted for the probability of patients experiencing PFS, PD or death. Treatment options were FOLFIRI alone or combined with a biologic agent: ziv-aflibercept, bevacizumab, cetuximab or panitumumab. April 2013 United States utilization rates were used as baseline values. The January 2015 Medicare Part B Drug Average Sales Prices provided the biologic agent drug costs. PFS and overall survival were derived from pivotal trial data for each of the biologic agents combined with chemotherapy. Adverse event cost calculations used documented incidence rates and published cost sources. Other costs included biomarker testing, drug administration/monitoring and death/terminal care.

RESULTS: The estimated number of patients receiving FOLFIRI alone or with a biologic agent for mCRC, post-oxaliplatin was 58 in a one million-member hypothetical health plan population. Using baseline utilization rates for FOLFIRI with or without biologics, estimated treatment costs were $6,180,066, a per-member-per-month (PMPM) cost of $0.5150. Changes in the utilization rates of biologic agents including, for example, a hypothetical increase in ziv-aflibercept
The Cost-Effectiveness of Alectinib in Anaplastic Lymphoma Kinase-Positive (ALK+) Advanced NSCLC Previously Treated with Crizotinib

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BACKGROUND: Two recent phase II studies (NP28761 & NP28673) demonstrated the efficacy and safety of alectinib in patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) who have progressed on crizotinib.

OBJECTIVE: To estimate the cost-utility of treatment with alectinib vs. ceritinib from the U.S. payer perspective.

METHODS: We developed a cost-utility model with three health states: progression-free (PF), post-progression (PP), and death. Patients were assumed to received treatment until progression or death. Data for alectinib and ceritinib progression free survival (PFS) and overall survival (OS) were derived from the key clinical trials for these drugs in this setting (alectinib: NP28761 & NP28673, ceritinib: ASCEND I and II). Time in each health state was estimated using partition survival methods (i.e. area under the survival curves). We used the Kaplan Meyer (KM) curves until the end of the study and extrapolated beyond the end of study using a Weibull parametric function (best fit to the KM data). Costs included drug therapy, adverse events and supportive care. Utilities in the PF state (alectinib: 0.79; ceritinib: 0.73) and the PP state (0.46) were based on clinical trial data and the literature, respectively. One way and probabilistic sensitivity analyses (PSA) were performed to assess parameter uncertainty. We applied a discount rate of 3%.

RESULTS: Treatment with alectinib vs. ceritinib resulted in an increase of 2.55 months in the PF state, and an increase of 22,400 adjusted life-years (QALYS) and an increase of $22,400. This yielded a mean cost per QALY of $50,300. The PSA demonstrated that alectinib has an 88% probability of being cost-effective at a willingness to pay of $100,000/QALY. The main model drivers were drug costs and utilities in the PF health state.

CONCLUSIONS: Treatment with alectinib in ALK+ crizotinib-treated NSCLC patients increased time in the PF health state and increased QALYs vs. ceritinib. The marginal increase in costs was driven by longer treatment durations with alectinib. Additional scenario analyses are underway including patient subgroup analyses in patients with prior chemotherapy. This model demonstrates that alectinib may be considered a cost-effective treatment after patients have progressed on crizotinib according to commonly used thresholds in the U.S. (i.e. < $100 to $150,000/QALY).

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BACKGROUND: Afatinib is one of three tyrosine kinase inhibitors (TKI) approved in the U.S. for the first-line treatment of patients with metastatic non-small cell lung cancer (mNSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions (Del19) or exon 21 (L858R) substitution mutations. However, afatinib is the only TKI to have demonstrated significant improvement in both progression-free survival and overall survival in the EGFR Del19 mutation subgroup versus chemotherapy.

OBJECTIVE: To estimate the budget impact of adding afatinib to a U.S. health plan formulary for the first-line treatment of mNSCLC patients with EGFR Del19 mutations.

METHODS: A decision-analytic model was developed to evaluate the budget impact of adding afatinib to the current mix of therapies for the first-line treatment of mNSCLC patients with EGFR Del19 mutations, over a 3-year time horizon. The model compared the total annual costs (i.e. therapy-related and disease management costs) with and without afatinib on a formulary of a health plan with 1 million covered lives. The number of patients eligible for treatment was estimated using published incidence data. Therapies included in the model were afatinib, erlotinib, gefitinib, and chemotherapy doublets (paclitaxel/cisplatin). Market share of afatinib was assumed to increase 3% each year. The mean time spent by patients in progression-free and progressive disease states were based on survival data from clinical trials and a network meta-analysis. Therapy-related costs included monthly drug acquisition and administration costs and adverse reaction management costs. Disease management costs were also assessed in the model. A one-way sensitivity analysis was performed by changing key input parameter values.

RESULTS: Assuming afatinib uptake of 5% annually, the estimated total annual costs to the health plan decreased by 79% in year 1, and increased by $2,554 and $14,494 in years 2 and 3. Per member per month (PMPM) budget changes were $0.0000, $0.0002, $0.0012 in years 1, 2, and 3. Increases in budget were due in part to the increase in mean survival time of patients as a result of adding afatinib. Sensitivity analyses showed that results were most sensitive to afatinib acquisition costs and the mean survival times for afatinib patients.

CONCLUSIONS: Under current model assumptions, adding afatinib for the first-line treatment of mNSCLC patients with EGFR Del19 mutations would result in minimal budget impact to a U.S. health plan.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals.

Real-World Treatment Patterns and Brain Metastasis Development in ALK-Positive Non-Small Cell Lung Cancer

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BACKGROUND: The anaplastic lymphoma kinase (ALK) gene rearrangement on chromosome 2 has been found in approximately 2 to 8% of patients with non-small cell lung cancer (NSCLC). Crizotinib was the first targeted ALK inhibitor approved by the FDA to treat ALK+NSCLC patients.
OBJECTIVE: To describe the treatment patterns of ALK+ NSCLC, including testing for an ALK rearrangement, discontinuation of crizotinib, and development of brain metastases.

METHODS: This retrospective study combined data from two large administrative claims databases from 01/2008-03/2014. As crizotinib was the only approved treatment for ALK + NSCLC during this timeframe, a prescription fill of crizotinib on or after the lung cancer diagnosis date served as a proxy to identify patients with ALK + NSCLC. Discontinuation of crizotinib was defined as the first gap of at least 30 days in crizotinib prescription fill. Tests for an ALK rearrangement were identified via CPT codes, and brain metastasis were identified via ICD-9 codes. Kaplan-Meier analyses were conducted to evaluate the time to discontinuation.

RESULTS: A total of 168 ALK + NSCLC patients were included in the analysis. The average age was 57 years and 45% of patients were male. The majority of the patients (73%) had metastatic disease at initiation of crizotinib and 24% had brain metastasis. All patients received chemotherapy, 33% received radiotherapy and 17% received other targeted therapy before crizotinib. 79% of patients were identified to have had a test for an ALK rearrangement, among which 96% were tested prior to crizotinib initiation and 4% were tested after. The median time to discontinuation of crizotinib was 388 days. Rates of discontinuation were 29% by six months and 44% by one year. Among the 127 patients without brain metastasis prior to crizotinib initiation, 33% developed brain metastases while on crizotinib treatment within one year.

CONCLUSIONS: In this real-world analysis, additional treatment options are needed for patients with ALK + NSCLC as 44% patients had a test for an ALK rearrangement, among which 96% were tested prior to crizotinib initiation and 4% were tested after. The median time to discontinuation of crizotinib was 388 days. Rates of discontinuation were 29% by six months and 44% by one year. Among the 127 patients without brain metastasis prior to crizotinib initiation, 33% developed brain metastases while on crizotinib treatment within one year.

SPONSORSHIP: Genentech.

OBJECTIVE: To compare progression-free survival (PFS) between EVE and FUL in a real-world setting.

METHODS: This retrospective chart review examined postmenopausal women with HR+/HER2- metastatic breast cancer (mBC) who received EVE vs. FUL using Kaplan-Meier (KM) analyses with log-rank tests and multivariable Cox models adjusting for the line of therapy and differences in patient characteristics (e.g., age, insurance type, de novo vs. non–de novo mBC, prior use of CT for mBC, sites of metastases [bone, brain, visceral], Charlson comorbidity index).

RESULTS: Across the first four lines of therapies for mBC, a total of 940 EVE, 953 FUL, and 721 CAP regimens were included. Based on the different lines of therapies, the KM estimators of median TOT ranged from 5.5 to 7.2 months for EVE, 4.9 to 8.4 months for FUL, respectively. Patients receiving EVE were less likely to have bone metastases, more likely to have visceral metastases or to have received prior chemotherapy, and had a shorter duration from initiation of last adjuvant endocrine therapy to mBC diagnosis. No significant PFS difference was observed between groups in the unadjusted analysis. After adjusting for baseline characteristics, patients receiving EVE significantly longer PFS compared with patients receiving FUL (HR = 0.71, 95% confidence interval [CI] 0.51-0.99). When stratified by treatment line, the EVE group had significantly longer PFS in second and later lines (second-line: HR = 0.52, 95% CI 0.29-0.91; third or later lines: HR = 0.48, 95% CI 0.24-0.93) than patients receiving FUL in the same treatment line.

CONCLUSIONS: In this real-world analysis of postmenopausal women with HR+/HER2- mBC who progressed on NSAI, the use of EVE was associated with better PFS, particularly on second, third, and later lines of treatment.

SPONSORSHIP: This study was supported by Novartis Pharmaceuticals.
and 3.5 to 6.0 months for CAP. Pooling all lines of therapies, EVE was associated with significantly longer TOT compared with FUL (multivariable-adjusted hazard ratio [HR] = 0.87, 95% confidence interval [CI] 0.76-0.99) or CAP (multivariable-adjusted HR = 0.73, 95% CI 0.64-0.83). Similar results were observed in each line of therapy.

CONCLUSIONS: This real-world U.S. claims study of postmenopausal women with HR+/HER2− mBC showed that patients receiving EVE experienced significantly longer TOT than those receiving mono-therapy with FUL or CAP, suggesting a comparative advantage of EVE in extending the duration of ET.

SPONSORSHIP: This study was supported by Novartis Pharmaceuticals.

C14 Comparative Effectiveness of Everolimus Versus Chemotherapy for HR+/HER2− Metastatic Breast Cancer: A Retrospective Chart Review of Community Oncology Practices in the U.S.

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BACKGROUND: Everolimus-based therapies (EVE) and chemotherapies (CT) are commonly used to treat postmenopausal women with hormone receptor-positive/human epidermal growth factor receptor 2 negative (HR+/HER2−) metastatic breast cancer (mBC).

OBJECTIVE: To compare key effectiveness outcomes between EVE-based therapies and CT in a real-world setting.

METHODS: This retrospective chart review examined a nationwide sample of postmenopausal women with HR+/HER2− mBC in community-based oncology practices. Patients were required to have received EVE or CT (index therapy) for mBC between July 1, 2012 and April 15, 2013, after disease recurrence or progression on a nonsteroidal aromatase inhibitor. Stratified sampling was used to ensure sufficient sample size in each treatment group and by line of therapy (first-, second-, third-line, and later). Overall survival (OS), progression-free survival (PFS), and time on treatment (TOT) were compared between treatment groups using Kaplan-Meier analysis and Cox proportional hazards model adjusting for baseline characteristics.

RESULTS: A total of 234 and 137 patients received EVE and CT, respectively. Compared with CT-treated patients, EVE-treated patients were older, more likely to be white, and had lower proportion of liver, lung, and visceral metastases, fewer metastatic sites, and lower tumor volume. Multivariate-adjusted Cox model results showed that EVE was associated with significantly longer OS (hazard ratio [HR] = 0.37, 95% confidence interval [CI] 0.22-0.63), PFS (HR = 0.70, 95% CI: 0.50-0.97), and TOT (HR = 0.34, 95% CI: 0.25-0.45) than CT. When further adjusted by interaction between line of therapy and treatment arms, patients receiving EVE had longer PFS in third/later lines (P = 0.059), significantly longer OS in first and third/later lines (P ≤ 0.011), and TOT in all lines (P ≤ 0.004) compared with CT.

CONCLUSIONS: This study showed that treatment with EVE was associated with significantly longer OS, PFS, and TOT compared with CT, largely across all lines of therapy, in postmenopausal women with HR+/HER2− mBC in the real-world setting.

SPONSORSHIP: This study was supported by Novartis Pharmaceuticals.

C15 Comparison of Medical Costs and Healthcare Resource Utilization of Postmenopausal Women with HR+/HER2− mBC Receiving Everolimus-Based Therapy or Chemotherapy: A U.S. Claims Study

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BACKGROUND: Treatment guidelines recommend the use of endocrine therapy as first-line therapy for postmenopausal women with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2−) metastatic breast cancer (mBC). For patients who fail these therapies, everolimus-based therapy (EVE) and chemotherapy (CT) are commonly used. There are limited studies reporting real-world health economic outcomes on EVE.

OBJECTIVE: To compare all-cause, breast cancer (BC)-related, and adverse event (AE)-related medical costs and all-cause healthcare resource utilization (HRU) among patients with HR+/HER2− mBC who received EVE-based therapy or CT.

METHODS: The MarketScan Commercial and Medicare Supplemental and PharMetrics claims databases were used to identify postmenopausal women with HR+/HER2− mBC who failed a nonsteroidal aromatase inhibitor and later initiated a new line of therapy for mBC (index therapy/index date between 7/20/2012 and 4/30/2014). Patients’ drug regimens were classified into mutually exclusive index treatment groups (i.e., EVE and CT) and followed until index treatment dis-continuation, end of insurance eligibility, or data cutoff (6/30/2014). All-cause, BC-related, and AE-related medical costs and all-cause HRU including inpatient (IP), outpatient (OP), emergency room, and other medical services per patient per month were assessed. Adjusted differences in costs and HRU between the EVE and CT treatment groups were estimated pooling all lines and using multivariable generalized linear models, accounting for differences in patient characteristics.

RESULTS: A total of 3,298 patients who received EVE (n = 902) or CT (n = 2,396) in the first four lines of treatment for mBC were included. Compared with CT, EVE was associated with significantly lower all-cause (adjusted mean difference = $3,455, P < 0.01) and BC-related ($2,310, P < 0.01) total medical costs. Cost differences were driven by lower IP ($1,897, P < 0.01) and OP ($1,395, P < 0.01) service costs. EVE was also associated with significantly lower AE-related ($1,730, P < 0.01) medical costs, as well as significantly lower HRU (IP incidence rate ratio [IRR] = 0.74; IP days IRR = 0.65; OP IRR = 0.71; visits to oncologist IRR = 0.66; all P < 0.01), compared with CT.

CONCLUSIONS: This retrospective claims database analysis of patients with HR+/HER2− mBC showed that EVE was associated with substantial all-cause, BC-related, and AE-related medical cost savings and less HRU relative to CT.

SPONSORSHIP: This study was supported by Novartis Pharmaceuticals.

C16 Number Needed to Treat and Associated Incremental Costs to Achieve One Additional Patient Free of Event: Indirect Comparison of Enzalutamide and Abiraterone Plus Prednisone in Chemotherapy-Naïve Metastatic Castration-Resistant Prostate Cancer

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BACKGROUND: Enzalutamide (ENZ) and abiraterone acetate plus prednisone (ABI) are approved second-generation hormone therapies for the treatment of patients with chemotherapy-naïve, metastatic
castration-resistant prostate cancer (mCRPC). The lack of head-to-head studies comparing ENZ with ABI necessitates an indirect comparison study to evaluate the relative efficacy and cost-effectiveness between the two drugs. Number needed to treat (NNT) and incremental costs per additional outcome are established and easily interpretable measures for relative efficacy and cost-effectiveness of alternative treatments. Furthermore, this methodology has been widely used for treatment evaluations over short time horizons from a payer perspective.

**OBJECTIVE:** To compare ENZ with ABI with respect to NNT and associated incremental costs to achieve one additional chemotherapy-naive mCRPC patient free of radiographic progression (including death) or chemotherapy over a 1-year time horizon.

**METHODS:** The 1-year outcomes were obtained from the PREVAIL trial (ENZ) and the COU-AA-302 trial (ABI), and included radiographic progression-free survival (rPFS) and time to initiation of chemotherapy. The NNT was calculated as 1/(ENZ event rate – ABI event rate); a lower NNT represents a more favorable outcome. The incremental costs to achieve one additional outcome were calculated as the difference in cost per treated patient (ENZ vs. ABI) multiplied by the NNT. Furthermore, per treated patient costs were considered from the U.S. payer perspective and included costs of medications, monitoring, adverse events, post-progression treatments, and end-of-life care.

**RESULTS:** With respect to rPFS, the NNT to achieve one additional patient free of chemotherapy was 26 and the associated cost was $57,467. The NNT to achieve one additional patient free of chemotherapy was 14; thus, treating 14 patients with ENZ resulted in one additional patient with rPFS over 1 year. The incremental cost to achieve this additional rPFS event was $31,196. The NNT to achieve one additional chemotherapy-naive mCRPC patient free of chemotherapy was 26 and the associated cost was $57,467.

**CONCLUSIONS:** The results of the present study suggest that treating chemotherapy-naive mCRPC patients with ENZ (vs. ABI) led to more patients having rPFS and avoiding chemotherapy at 1 year, with additional cost. Future research is warranted to further evaluate the benefit and risk associated with ENZ vs. ABI.

**SPONSORSHIP:** Astellas Pharma and Medivation.

C18 Real-World Effectiveness of Everolimus and Axitinib in 2nd Targeted Therapy of Advanced Renal Cell Carcinoma (aRCC) in the U.S.: A Retrospective Chart Review

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**BACKGROUND:** Everolimus and axitinib are approved as 2nd targeted therapies (TTs) for aRCC. Patients treated with everolimus and axitinib following 1st tyrosine kinase inhibitor (TKI). The extent to which duration of 1st TKI treatment modifies comparative effectiveness of 2nd TT is also assessed.

**OBJECTIVE:** To compare real-world OS and PFS among aRCC patients treated with everolimus and axitinib following 1st tyrosine kinase inhibitor (TKI). The target duration of 1st TKI treatment modifies comparative effectiveness of 2nd TT is also assessed.

**METHODS:** Retrospective reviews of medical records were conducted by medical oncologists or hematologists/oncologists recruited from a nationwide panel. Patient eligibility criteria included: (1) aged ≥18 years; (2) initiated and continued 1st TKI (sunitinib, sorafenib, or pazopanib) for medical reasons; (3) initiated 2nd TT between 2/2012 and 1/2013. OS was defined as time from initiation of 2nd TT to death. PFS was defined as time from initiation of 2nd TT to physician-assessed progression or death, whichever occurred first. Multivariable Cox proportional hazards models were used to estimate the comparative hazard ratios (HRs) and 95% confidence interval (CIs) for OS and PFS between everolimus and axitinib, adjusting for age, gender, type and duration of 1st TKI, response to 1st TKI, duration of mRCC at 2nd TT, metastatic disease at initial diagnosis, clear cell RCC, prior nephrectomy, performance status, metastatic sites, comorbidity, and years of physician practice. Comparative effectiveness was also analyzed by type and duration (<6, 6-12, ≥12 months) of 1st TKI.
RESULTS: A total of 325 and 127 patients received 2nd TT with everolimus and axitinib. After adjusting for baseline characteristics, there was no statistically significant difference between everolimus and axitinib for OS [HR (95% CI): 1.16 (0.73-1.82)] or PFS [HR (95% CI): 1.16 (0.85-1.59)]. When stratified by type and duration of 1st TKI, there was no statistically significant difference in OS between everolimus and axitinib. After adjusting for baseline characteristics, there was no statistically significant difference between everolimus and axitinib. No statistically significant difference in PFS was observed in any subgroup.

CONCLUSIONS: In this large, retrospective chart review, there was no significant difference in OS or PFS between everolimus and axitinib in the overall population. Longer durations of 1st TKI were not associated with better comparative effectiveness for subsequent treatment with axitinib vs. everolimus.

SPONSORSHIP: This study was funded by Novartis Pharmaceuticals.

C19 Real-World Effectiveness of Everolimus Subsequent to Different First Targeted Therapies for the Treatment of Advanced Renal Cell Carcinoma (aRCC): Synthesis of Three Retrospective Chart Reviews

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BACKGROUND: Sequential use of targeted therapies (TTs) has become the mainstay of treatment for aRCC.

OBJECTIVE: To inform such sequencing, this study assessed the real-world associations between use of different first TTs and outcomes with everolimus used as second TT

METHODS: Patients who received pazopanib, sunitinib, or sorafenib as 1st TT and everolimus as second TT were included from three retrospective U.S. chart review studies conducted in 2011, 2012, and 2014 among medical oncologists and hematologists/oncologists from academic centers and community practices. Patients were classified into two groups: those who received pazopanib versus those who received sunitinib or sorafenib as 1st TT. Overall survival (OS), time to treatment failure (TTF), and time to treatment discontinuation (TTD) were studied following everolimus initiation. Follow-up for patients without events was censored at their last visit. Multivariable-adjusted Cox proportional hazards models comparing the two groups were used to estimate hazard ratios (HRs) for OS, TTF, and TTD for each chart review study. The Cox models adjusted for age, gender, duration of first TT, RCC subtype, and metastatic sites and ECOG performance status at everolimus initiation. Results were synthesized across studies using random-effects meta-analyses.

RESULTS: There were 233, 138, and 325 eligible patients from the 2011, 2012, and 2014 studies, respectively. There were no significant differences in OS, TTF, or TTD following initiation of everolimus between patients who received pazopanib vs. sunitinib/sorafenib as 1st TT. Across the three studies, adjusted HRs ranged from 0.71 to 0.81 for OS (pooled HR = 0.79, 95% confidence interval (CI): 0.49-1.26), 0.17 to 1.02 for TTF (pooled HR = 0.87, 95% CI: 0.53-1.44), and 0.20 to 1.15 for TTD (pooled HR = 0.89, 95% CI: 0.50-1.58). No significant heterogeneity in HRs was observed across the three studies.

CONCLUSIONS: Based on a meta-analysis of three retrospective chart reviews in the U.S., clinical outcomes with everolimus as second TT were not significantly different between patients who received pazopanib or sunitinib/sorafenib as first TT.

SPONSORSHIP: This study was funded by Novartis Pharmaceuticals.

C20 Economic Burden of Glioblastoma Among Adults in the United States (U.S.)

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BACKGROUND: Glioblastoma (GBM) is an aggressive high-grade brain tumor associated with a significant clinical burden. Few estimates exist of the U.S. economic impact of GBM in the U.S.

OBJECTIVE: To assess the resource utilization patterns and total direct medical costs associated with the management of GBM in a commercially-insured U.S. population.

METHODS: Adult patients with ≥1 malignant brain cancer diagnosis (ICD9-CM, 191.XX), who underwent brain-related surgery ≤90 days prior to temozolomide (TMZ) initiation (index date) and were continuously enrolled for a 12-month pre-index and a 1-month post-index period, were identified in the IMS Pharmscistics Lifelink Plus claims database from 01/2009 to 03/2014. Per-patient-per-month (PPPM) total costs (total allowed charges for all claims including GBM- and non-GBM related diagnoses) and cumulative total costs over time (from 12 months prior to the index date to a maximum 5 years post-index date) were calculated after adjusting for length of follow up.

RESULTS: Inclusion criteria were met by 2,729 patients. The age distribution was slightly left-skewed with a median (Q1-Q3) of 56 (48-62) and mean (SD) of 54 (11) years. The majority of patients were male (60%), had radiation therapy (82%), and were commercially insured (97%). The average mean (SD) PPPM total costs were $759 ($447) between 12 and 3 months pre-TMZ initiation. The average PPPM costs increased to $24,295 ($20,830) in the 3 months immediately prior to TMZ initiation and remained high for about approximately the first 3 months post-TMZ initiation ($22,821 [$14,811]). The cumulative per-patient costs from 12 months pre-TMZ initiation to the maximum 5-year post-index follow-up were $292,329. Corresponding cumulative post-index costs up to 6 months were $182,248, 12 months $225,483, and 24 months $263,337. Total estimated costs during the 3 months immediately preceding TMZ initiation were increased by $107,080; inpatient costs ($58,780) accounted for 55% of the total costs during this period. During the year following TMZ initiation, cumulative per-patient costs increased by $107,052. The corresponding amount at 24 months was $145,007.

CONCLUSIONS: The cumulative costs to a U.S. commercial payer for treating GBM patients with surgery followed by TMZ (with or without radiation) approached $300,000 per patient between 12 months pre-TMZ initiation up to 5-years post-TMZ initiation; 77% of these costs ($225,483) were incurred between the 12 months preceding and the 12 months following TMZ initiation.

SPONSORSHIP: This research was funded by Celldex Therapeutics, Hampton, NJ.

C23 Economic Benefits Associated with Resolution of Cardiac Syndrome Symptoms Following Treatment with Above-Standard Dose of Octreotide LAR in Patients with Neuroendocrine Tumors: Data from a Multicenter Chart Review Study

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BACKGROUND: Cardiac syndrome X (CSX) and noncardiac chest pain (NCCP) are common in patients with neuroendocrine tumors (NETs) and are associated with significant clinical and economic burden. New guidelines recommend the use of octreotide LAR for the treatment of NETs at doses above the standard dose.

OBJECTIVE: To evaluate the economic benefits associated with resolution of CSX and NCCP following treatment with higher doses of octreotide LAR comparing the costs of medical care during the year prior to initiation of octreotide LAR to the costs during the year following initiation.

METHODS: The study included patients with NETs and CSX treated with ≥3x the standard dose of octreotide LAR who had 1 year of claims data before and 1 year of claims data after octreotide LAR initiation. Medical care costs were calculated using the resource utilization tool developed by Pharmerit International. Costs were calculated at the payer level for all medical care costs.

RESULTS: The study included 291 patients with NETs and CSX who were treated with ≥3x the standard dose of octreotide LAR. The results showed a significant reduction in the cost of medical care following treatment with higher doses of octreotide LAR. The average total medical care cost was $75,000 lower during the year following octreotide LAR initiation compared to the year prior to initiation. The reduction was due to a decrease in costs for medical care related to cardiac symptoms.

CONCLUSIONS: Treatment with higher doses of octreotide LAR was associated with significant economic benefits for patients with NETs and CSX. The results provide evidence for the cost-effectiveness of higher doses of octreotide LAR in the management of CSX and NCCP.

SPONSORSHIP: This study was funded by Novartis Pharmaceuticals.
BACKGROUND: In patients with neuroendocrine tumors (NET), major symptoms of carcinoid syndrome (CS) are diarrhea and flushing. A retrospective chart review of 239 NET patients from 3 U.S. tertiary oncology centers (NET 3-Center) from 2000-2012 demonstrated that above-standard dosing of octreotide LAR resolved/improved CS symptoms in most patients within 1 year. The economic benefits of CS symptom resolution/improvement (res/imp) associated with above-standard octreotide LAR doses have not been quantified.

OBJECTIVE: To evaluate potential cost savings associated with CS symptom res/imp in the NET 3-Center study.

METHODS: NET 3-Center study data were used, along with healthcare resource utilization/cost inputs, for patients from the Truven Health Analytics MarketScan healthcare claims database (2003-2012) to estimate incremental costs for patients with and without CS symptoms. Total healthcare costs (HC), including inpatient, outpatient, emergency department, and pharmacy services, were adjusted using multivariate OLS regression for age, gender, region, chronic conditions, and Charlson comorbidity index. For each NET 3-Center patient, the period after initiation of above-standard dosing of octreotide LAR (index date) was divided into days with and without CS symptoms; costs were calculated for each period. Annual total HC of patients with CS symptom res/imp over the 12-month period post-index date were compared to annual total HC of patients with CS symptoms.

RESULTS: 136 patients had diarrhea or flushing within 3 months prior to the index date; 108 (79%) patients experienced CS symptom res/imp within 1 year. Patients with CS symptom res/imp had significantly lower mean annual total HC/patient (by $14,766; P = 0.03) vs. those with CS symptoms. Cost savings were driven by res/imp of diarrhea. Among 107 patients with diarrhea within 3 months prior to the index date, 85 (79%) patients experienced res/imp. Patients with res/imp of diarrhea had significantly lower mean annual total HC/patient (by $18,740, P = 0.01) than patients with diarrhea, with outpatient costs accounting for most of the difference (mean difference: $10,467, P = 0.02).

CONCLUSIONS: This economic model showed statistically significant mean annual total HC savings in patients with CS symptom res/imp after receiving above-standard doses of octreotide LAR. These economic benefits are in addition to any possible improvements in quality of life and functional status associated with CS symptom control. This model uses assumptions that need to be further validated in future studies and using alternative data sources.

SPONSORSHIP: Novartis Pharmaceuticals.

C26 Cost-Effectiveness of Treatments for Peripheral T-Cell Lymphoma

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BACKGROUND: Peripheral T-Cell Lymphoma (PTCL) is a rare yet aggressive form of non-Hodgkin Lymphoma. Initial treatment typically consists of chemotherapy regimens; however, patients often fail to respond or quickly relapse. Targeted therapies for relapsed/refractory patients have shown promise in clinical trials, but there is a lack of economic evaluations comparing currently available options.

OBJECTIVE: To develop a model to evaluate the cost-effectiveness of pralatrexate, romidepsin, and belinostat for relapsed/refractory PTCL patients.

METHODS: The deterministic cohort model programmed in TreeAge modeling software used data from Phase II clinical trials to assess the average duration of response, both among those responding as well as for all patients treated, and adverse event rates for each treatment. Costs, including product acquisition, product administration, and adverse event treatment, were considered from the payer perspective and based on pricing databases and published literature. Patients were included in the model until discontinuing therapy, and results were calculated as incremental cost-effectiveness ratios (ICERs) in terms of 2015 $US per additional month of response. The influence of model parameters was assessed in one-way sensitivity analyses in which all parameters were varied individually ± 20% of their base case values.

RESULTS: In the base case, the model predicted that patients treated with romidepsin have lower per-patient costs ($144,937) compared to patients treated with belinostat ($204,809) or pralatrexate ($243,452). Patients receiving romidepsin also have the highest duration of response among responders (28.0 months vs. 13.6 and 10.1 months) and among all treated patients (7.1 months vs. 3.5 and 2.9 months). Given these results, romidepsin was dominant (i.e., provided greater clinical benefit at a lower cost) over both other treatments. In sensitivity analyses, product costs and duration of response for each
therapy were the most influential parameters, although the finding of romidepsin’s dominance did not change.

**CONCLUSIONS:** Results of this analysis suggest that treating PTCL patients with romidepsin may enhance clinical benefit while providing cost savings. Data limitations prevented consideration of a longer time-horizon, inclusion of subsequent lines of therapy, or comparison of survival. Future analyses should take into account real-world efficacy and costs. However, clinicians, payers, and policy makers may consider this finding of reduced costs and greater clinical benefit as one aspect in making healthcare resource allocation decisions.

**SPONSORSHIP:** This study was sponsored by Celgene.

### C28 Nilotinib Versus Dasatinib as Second-Line Therapy in Patients with Chronic Myeloid Leukemia in Chronic Phase (CML-CP) with Imatinib Resistance Or Intolerance: A Cost-Effectiveness Analysis (CEA) Based on Real-World Data

**OBJECTIVE:** To evaluate the cost-effectiveness of second-line nilotinib (NIL) vs. dasatinib (DAS) for Philadelphia-positive CML-CP using real-world comparative survival endpoints data from a third-party payer perspective in the U.S.

**METHODS:** A lifetime partitioned survival model was developed to compare healthcare costs, life years (LYs) and quality-adjusted life years (QALYs) associated with second-line NIL vs. DAS therapy in imatinib-resistant or intolerant CML-CP pts. The model included four health states: CP on second-line therapy, CP post-discontinuation of second-line therapy, accelerated phase or blast crisis, and death. Patients can only transition into a subsequent health state but not in the other direction; pts in the first three health states can all transition to death. Time on treatment (TOT), progression-free survival (PFS), and overall survival (OS) were estimated using data from a real-world comparative effectiveness study (Griffin CMRO 2013, 29(6):623-31).

Parametric survival models were used to extrapolate outcomes beyond the study period. Costs, LYs, and QALYs were discounted at 3% per annum. Incremental cost-effectiveness ratios (ICERs) included incremental cost per LY gained and incremental cost per QALY gained.

**RESULTS:** Over life time, initiating second-line treatment with nilotinib was associated with 11.69 LYs, 9.13 QALYs, and total costs of $1,406,265; initiating second-line with DAS was associated with 9.51 LYs, 7.30 QALYs, and total costs of $1,418,235. Second-line NIL was associated with better health outcomes (difference in LY = 2.18 years, difference in QALY = 1.84 years) and lower costs (difference in total cost = $11,970) relative to DAS. Deterministic sensitivity analysis (DSA) results similarly showed better outcomes and lower costs for NIL vs. DAS based on variations of sex-ratio, progressive disease treatment costs, medical costs for all health states, adverse event costs, and utility for CP post-discontinuation; DSA results also showed better outcomes but higher costs for NIL vs. DAS based on variations of starting age, adherence to second-line therapies, and CP post-discontinuation treatment cost with ICERs of $10,738/QALY, $2,648/QALY, and $2,318/QALY, respectively.

**CONCLUSIONS:** CEA based on real-world comparative evidence suggests that second-line NIL is associated with better life expectancy, quality of life, and lower cost when compared with DAS.

**SPONSORSHIP:** Novartis Pharmaceuticals.

### C27 New and Emerging Novel Therapy Combinations for Relapsed and Refractory Multiple Myeloma (RRMM)

**OBJECTIVE:** To review recent U.S. Food and Drug Administration (FDA) approvals and Phase III clinical trials of novel therapy combinations (incorporating at least 2 targeted therapies) in RRMM.

**METHODS:** A targeted literature review was performed to identify publications from 2014-2015 of Phase III clinical trials of novel therapy combinations in RRMM. PubMed and abstracts from the annual meetings of the American Society of Hematology (ASH) and American Society of Clinical Oncology (ASCO) were searched. The FDA website was reviewed to assess recent FDA approvals.

**RESULTS:** A total of 16 conference abstracts and 2 peer-reviewed publications describing 7 Phase III clinical trials were reviewed. Pomalidomide (POM), an immunomodulatory compound, is being evaluated in combination with BTZ and low-dose dexamethasone (LoDEX) in the MM-007 OPTIMISM trial. Second-line carfilzomib (CFZ) was approved in 7/2015 in a novel combination (CFZ/LEN/DEX) based on the ASPIRE trial. Panobinostat (PAN), a histone deacetylase (HDAC) inhibitor, was approved in 2/2015 in combination with BTZ/DEX based on results from the PANORAMA-1 trial. Ixazomib (IXA) from the PI class was approved in 11/2015 in combination with BTZ/DEX based on results from the TOURMALINE-MM1 trial. Another mAb, elotuzumab, was approved in 11/2015 in combination with LEN/DEX based on the ELOQUENT-2 trial.

**CONCLUSIONS:** This review found that a number of novel therapy combinations for RRMM have recently been approved by the FDA or are currently being investigated in Phase III trials. These novel combinations have the potential for enhanced clinical value to patients. Three out of the 4 recently approved novel therapy combinations incorporate LEN, suggesting the important role of the immunomodulatory compound as the backbone of therapy in MM.

**SPONSORSHIP:** Celgene.
OBJECTIVE: To comprehensively evaluate nationwide CML treatment practices over an extended period and across multiple lines of therapy that included imatinib, dasatinib, and nilotinib.

METHODS: This observational study utilized internal Veterans Health Administration (VHA) databases for the time period of 10/1/2000-9/20/2012. The study included VHA beneficiaries, age 18-89 years, with ≥ 1 encounter at any of the VHA institution with a diagnosis code for CML (ICD-9 205.1x). Patients had to have filled ≥ 1 prescription for imatinib, nilotinib, or dasatinib. Primary study endpoints included change in TKI treatment, gaps in TKI treatment, TKI treatment persistence, and patient survival. A Kaplan-Meier model was used to evaluate persistence and survival.

RESULTS: Of the 2,873 patients receiving first-line TKI treatment, 586 (20.4%) switched to a different TKI, constituting second-line treatment. Two-hundred forty-five patients (8.5%) were switched again to third-line treatment. Only 44% of patients receiving first-line treatment experienced a ≥ 60-day gap in therapy. First-line treatment persistence rates were 75%, 65%, and 55% for the first, second, and third years of treatment, respectively. Persistent rates for second and third line treatments were similar: 48 and 44% respectively at year one of treatment, and identical with 36 and 26% at year two and three of treatment. Persistence of first-line treatment was significantly longer for treatment initiated pre-approval of dasatinib relative to after its approval (P value < 0.001). By year six of treatment, the continuation rate was 39% for treatments initiated pre-dasatinib approval as compared to 23% post-dasatinib approval. Five-year survival was 62% with first-line, 52% for second-line, and 45% for third-line TKI treatment.

CONCLUSIONS: In this national cohort of VHA patients, one-year persistence to first-line TKI treatment was similar to prior studies. Five-year survival was comparable to other observational studies, but lower than prospective clinical trials. Persistence rates declined after the introduction of the new TKIs.

SPONSORSHIP: Bristol-Myers Squibb.

C32 Changes in the Economic Burden of Multiple Myeloma Among Patients in Successive Lines of Therapy in the United States

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BACKGROUND: For patients with multiple myeloma (MM), significant improvements in clinical outcomes conferred by proteasome inhibitors (PIs) and immunomodulatory drugs (IMiDs) increase the financial burden of treatment (Tx). Little is known about the cost attributable to treatment for newly diagnosed, first-relapsed, and second-relapsed MM.

OBJECTIVE: To characterize the costs of MM during first-line (1L), second-line (2L), and third-line (3L) Tx from the U.S. payer perspective.

METHODS: Patients with ≥ 2 outpatient or ≥ 1 inpatient claims with a primary diagnosis ICD-9 code for MM preceded by 6 months (baseline period) with no claims for MM or for anti-MM Tx were identified in Truven’s MarketScan Commercial and Medicare claims database from 7/1/2006-6/30/2013, and followed until last visit or 6/30/2014, whichever was first. The index date was the 1 inpatient or earlier of the 2 outpatient claims meeting these criteria, and the sample was restricted to patients with follow-up ≥ 12 months. Patients with stem cell transplant were excluded. All anti-MM Tx used following the 1st claim for an anti-MM prescription or administration were considered the start of that Tx line. The end of any given line of Tx was defined as the 1st day of any gap in Tx > 90 days. A standard cost per-patient per-month (PPPM) metric was used to calculate total all-cause and anti-MM pharmacy costs in 1L, 2L, and 3L Tx. Tx duration was estimated using descriptive analysis. All figures were inflated to 2015 USD.

RESULTS: 5,704 patients met the study eligibility criteria (median age 66 y, 50% male). Of these, 3,626 (64%) initiated 1L Tx (median age 66 y, 53% male), and 2,143 (39%) of treated patients in 1L received PI/IMiDs. Mean PPPM total all-cause and anti-MM pharmacy costs in 1L were $22,527 and $4,886, respectively. 1,797 (50%) patients proceeded to 2L Tx, of whom 1,024 (57%) used PI/IMiDs. Mean PPPM total and anti-MM pharmacy costs in 2L were $35,266 and $10,290, respectively. 817 (45%) of patients who received 2L progressed to 3L and 488 (27%) were transitioned to 1L. Total and anti-MM pharmacy costs in 3L were $39,181 and $12,577, respectively. For patients progressing from 1L to 2L, mean PPPM total all-cause and anti-MM costs were $11,755 and $3,421, respectively. For patients progressing from 2L to 3L, mean PPPM total all-cause and anti-MM costs were $12,294 and $3,878, respectively.

CONCLUSIONS: Given the high costs of MM, significant improvements in clinical outcomes conferred by PIs and IMiDs increase the financial burden of treatment, which is different from previous studies. Identifying gaps in Tx initiation and discontinuation may help to further reduce the financial burden of treatment.

SPONSORSHIP: Novartis Pharmaceuticals.
3L; 442 (54%) received PI/IMiDs in 3L. Mean PPPM total and anti-MM pharmacy costs in 3L were $47,417 and $13,583, respectively. The average Tx duration was 7 months in 1L, 6 months in 2L, and 5 months in 3L.

CONCLUSIONS: Compared with patients in 1L Tx, total all-cause costs were higher among MM patients in 2L or 3L, while anti-MM pharmacy costs on average represented less than a third of all-cause costs across 1L, 2L, and 3L Tx. In patients with MM, the use of PIs/IMiDs decreased slightly as disease progressed.

SPONSORSHIP: Bristol-Myers Squibb.

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C34 Indirect Comparison to Assess the Relative Efficacy of Carfilzomib + Lenalidomide + Dexamethasone Versus Bortezomib + Thalidomide + Dexamethasone: A Matching Adjusted Indirect Comparison

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BACKGROUND: Several novel treatments have recently been approved for the treatment of relapsed multiple myeloma (RMM). In the absence of randomized head-to-head studies between these treatments, clinicians and payers must rely on statistical indirect cross-trial comparisons. This was a comparative effectiveness analysis for carfilzomib + lenalidomide + dexamethasone (KRd) against bortezomib + thalidomide + dexamethasone (VTD) in patients with RMM who have been treated with an autologous stem cell transplant (ASCT).

OBJECTIVE: To conduct a matching-adjusted indirect comparison (MAIC) (Signorovitch, 2010) for progression-free survival (PFS) and overall survival (OS) between the KRd arm of the Phase III study ASPIRE (Stewart et al., 2015) versus the VTd arm of the Phase III study MMVAR (Garderet et al., 2012).

METHODS: The MAIC utilized patient level data from ASPIRE, and adjusted for reported patient population differences in age, gender, history of ASCT, disease duration, ISS stage, beta-2-microglobulin, and renal function. Cox proportional hazard models were fit to estimate hazard ratios (HRs) for PFS and OS using the MAIC-weighted KRd data and virtual patient level data for VTd. Weibull survival curves best fit the adjusted survival data and were used to estimate median survival times. A simulated treatment comparison (STC) was conducted as a cross validation.

RESULTS: The sample sizes in the trials were 396 (KRd) and 135 (VTd). After matching the KRd population had an effective sample size (ESS) of 56. HRs (95% CIs) from the Cox models for PFS and OS outcomes were 0.535 (0.346, 0.828) and 0.694 (0.38, 1.27), respectively. Corresponding HRs from the STC were similar and validate the MAIC results. Estimated median PFS and OS in months for KRd vs. VTd were 28.6 ± 18.0 and 57.9 ± 43.2, respectively.

CONCLUSIONS: This MAIC analysis suggests that KRd provides a consistent benefit relative to VTd in RMM patients who have been treated with an ASCT. The PFS benefit found was statistically significant. Patient characteristics not reported for MMVAR and thus not included in this analysis may potentially influence these outcomes. The small ESS is a potential limitation of this analysis.

SPONSORSHIP: This study was sponsored by Amgen.

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C35 Indirect Comparisons to Assess the Relative Efficacy of Carfilzomib + Revlimid + Dexamethasone Versus Panobinostat + Bortezomib + Dexamethasone and Bortezomib + Dexamethasone: A Matching Adjusted Indirect Comparison

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BACKGROUND: Several novel treatments have recently been approved for the treatment of relapsed multiple myeloma (RMM). In the absence of randomized head-to-head studies between these treatments, clinicians and payers must rely on statistical indirect cross-trial comparisons. This was a comparative effectiveness analysis for carfilzomib + lenalidomide + dexamethasone (KRd) against bortezomib + dexamethasone (Vd) and the recently approved combination of panobinostat + bortezomib + dexamethasone (Pvd) in patients with RMM.

SPONSORSHIP: Bristol-Myers Squibb.
OBJECTIVE: To conduct matching-adjusted indirect comparisons (MAIC) (Signorovitch, 2010) for progression-free survival (PFS) and overall survival (OS) between the KRd arm of the Phase III study ASPIRE (Stewart et al., 2015) versus the PVd and Vd arms of the Phase III study PANORAMA 1.

METHODS: The MAICs utilized patient level data from ASPIRE, and adjusted for reported patient population differences in age, gender, ECOG status, history of autologous stem cell transplant, disease duration, number of prior regimens, ISS stage, prior bortezomib use, and renal function. Cox proportional hazards models were fit to estimate hazard ratios (HRs) for PFS and OS using the MAIC-weighted KRd data and virtual patient level data for PVd and Vd. Weibull survival curves best fit the adjusted survival data and were used to estimate median survival times. A simulated treatment comparison (STC) was conducted as a cross validation.

RESULTS: The sample sizes in the trials were 396 (KRd), 387 (PVd), and 381 (Vd). After matching the KRd population had an effective sample size of 131 for the PVd comparison and 138 for Vd. HRs (95% CIs) from the Cox models for PFS and OS outcomes were 0.317 (0.228, 0.44) and 0.582 (0.394, 0.86) for KRd vs. PVd, respectively, and 0.208 (0.153, 0.283) and 0.472 (0.324, 0.688) for KRd vs. Vd, respectively. Corresponding HRs from the STC were similar and validate the MAIC results. Estimated median PFS and OS in months for KRd vs. PVd were 29.5 vs. 12.0 and 65.2 vs. 40.9, respectively. Corresponding estimates for KRd vs. Vd were 29.7 vs. 8.2 and 57.3 vs. 33.0.

CONCLUSIONS: This MAIC analysis suggests that KRd provides a consistent and statistically significant PFS and OS benefit relative to PVd and Vd in RMM patients. Patient characteristics not reported for PANORAMA 1 and thus not included in this analysis may potentially influence these outcomes. This analysis did not compare KRd to PVd in panomistat’s FDA-approved indication due to lack of published data on this patient subset in PANORAMA 1.

SPONSORSHIP: This study was sponsored by Amgen.

C38 The Budget Impact and Cost-Effectiveness of Defibrotide for Treatment of Veno-Occlusive Disease with Multi-organ Dysfunction (VOD with MOD) in Patients Post-hematopoietic Stem Cell Transplant (HSCT)

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BACKGROUND: A Phase 3 study of defibrotide compared with historical controls (HC) demonstrated a 23% improvement in survival at Day+100 using propensity adjusted analysis in patients with veno-occlusive disease with multi-organ dysfunction (VOD with MOD) post-hematopoietic stem cell transplantation (HSCT).

OBJECTIVE: To evaluate the budget impact of introducing defibrotide to a transplant center, and to assess its cost effectiveness.

METHODS: A budget impact model was developed from a bone marrow transplant center perspective. We estimated that 2.3% of adults and 4.2% of children would develop VOD with MOD based on a retrospective analysis of the Premier hospital database. The analysis accounted for the cost of treating VOD with MOD with defibrotide as well as associated hospitalization costs. We also developed a cost-utility analysis to capture the long-term cost-effectiveness of defibrotide. Projected life expectancies in the two groups were estimated based on trial data, transplant registry data, studies of long-term survival, and U.S. population life-tables. The patient population was assumed to be similar to the defibrotide trial population. Outputs included the incremental total direct costs, increase in life expectancy, incremental quality-adjusted life years (QALYs), and incremental cost-effectiveness ratio of treatment with defibrotide vs. standard care.

RESULTS: The additional cost of adopting defibrotide was approximately $330,706 per year for adult transplant centers and $106,385 for pediatric transplant centers assuming a 100 transplant per year center, which represents a 3% and <1% increase over the total transplantation costs, respectively, for centers of that size. The additional cost per HSCT patient was $1,438 and $253 for adult and pediatric patients, respectively. In the cost-utility analysis, the total increase in cost per patient with VOD with MOD treated was $106,929, the increase in life expectancy was 3.74 years, and the increase in QALYs was 2.24. The incremental cost-effectiveness ratio (ICER) was $47,736 per QALY.
DO1 Baratatumumab Monotherapy for Multiple Myeloma Patients Who Have Received at Least 3 Prior Lines of Therapy or Are Double Refractory: A Budget Impact Analysis from a U.S. Payer Perspective

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BACKGROUND: Daratumumab was recently approved by the FDA for the treatment of patients with multiple myeloma (MM) who have received at least 3 prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double refractory to a PI and immunomodulatory agent.

OBJECTIVE: To estimate the budget impact of adding daratumumab to U.S. Commercial and Medicare health plans.

METHODS: The prevalence of MM was derived from SEER and the proportion of treatment-eligible patients was based on an analysis of the IMS Oncology Electronic Medical Records Database (Usman 2015). Alternative therapies that are FDA approved, NCCN-recommended for treatment of previously treated MM and had ≥10% utilization in patients with at least 3 prior lines of therapy were included (i.e., bortezomib (bex), lenalidomide + dexamethasone (len + dex), bex + len + dex, carfilzomib, or pomalidomide + dext) based on analysis of the IntrinsiQ clinical database (data on file). Introduction of daratumumab was assumed to decrease market shares of all alternative therapies by 20%. Dosing, administration, comediations, monitoring requirements, and AE information were obtained from FDA labels and published data. Treatment duration for each therapy was assumed to be median PFS, since treatment duration is not consistently reported and treatment is typically until progression in this population. AE included in the analysis were grades ≥3 occurring in ≥5% of patients. Costs were based on WAC, CMS payment rates, and published literature. Separate analyses for Medicare and Commercial health plans were performed for a 1-year time horizon. Sensitivity analyses were conducted to determine the parameters most influential on results.

RESULTS: In hypothetical 1-million member Medicare health plan and 1-million member Commercial health plan, 180 patients and 25 patients, respectively, were estimated to be treatment-eligible. The incremental budget impact of adopting daratumumab was $0.06 PMPM and $344.52 PTMPM for the Medicare plan and $0.01 PMPM and $344.52 PTMPM for the Commercial plan. Sensitivity analyses indicated treatment duration, daratumumab market share, and the proportion of treated patients were the most influential parameters on the results.

CONCLUSIONS: This analysis suggests that adding daratumumab to U.S. health plan formularies may result in an incremental PMPM of $0.06 or less. These results are important for healthcare decision-making considering the efficacy and safety benefits for daratumumab in this patient population.

SPONSORSHIP: This project was funded by Janssen Scientific Affairs.

DO2 Patterns of Switching from Imatinib to Other BCR-ABL1 Tyrosine Kinase Inhibitors Among Chronic Myeloid Leukemia Patients in the U.S. Managed Care Setting

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BACKGROUND: BCR-ABL1 tyrosine kinase inhibitors (TKIs) are now standard treatment for chronic myeloid leukemia (CML), with imatinib (IM) being the most commonly used in 1st line treatment. Little is known about the rate and timing of switching from IM to other TKIs or the patient characteristics associated with switching.

OBJECTIVE: To evaluate the rate and timing of switching from IM to other TKIs among CML patients in a U.S. managed care setting and predictors associated with the switching.

METHODS: Patients ≥18 years of age who had ≥1 inpatient or ≥2 outpatient diagnoses for CML and initiated IM between Jan 2007 and Dec 2013 were identified from the MarketScan databases. Patients were grouped into 2 cohorts: those who switched from IM to other TKIs (switchers) and those who did not (non-switchers). Demographics and clinical characteristics were evaluated. Multivariable regression was used to evaluate potential predictors associated with switching as well as predictors associated with early (<1 year) vs. late (>1 year) switching.

RESULTS: 1,511 patients (mean age: 57 years; 56% male; mean Charlson Comorbidity index: 2.87) were identified. Among the study population, 31% (n = 474) switched from IM to another TKI in the ≥12-month follow-up period after IM initiation. Mean follow-up durations were 43 (median = 41) and 37 (median = 32) months for switchers and non-switchers, respectively. Among the switchers, 50% (n = 237) switched in the first year, of which 20% (n = 48) switched within 3 months. Mean time to switch was 17 months (median = 12). Predictors associated with switching included younger age (unit: per one year of younger age; OR: 1.008, P = 0.0276), U.S. region (West vs. South OR: 1.495, P = 0.0121), and baseline comorbidities of cardiomyopathy (OR: 3.776, P = 0.0008) and thrombophlebitis (OR: 4.881, P = 0.0008). Other characteristics evaluated in the regression analysis did not statistically predict switching. Among switchers, there were no statistically significant predictors associated with early vs. late switching. Reasons for TKI switching could not be evaluated from the database analysis.

CONCLUSIONS: This real-world study suggests that switching from IM to other TKIs in the U.S. managed care setting may be substantial, which may add an administrative burden to healthcare plans. The flexibility of open access to TKI medications may need to be considered when making decisions regarding CML treatments.

SPONSORSHIP: Bristol-Myers Squibb.

DO3 An Analysis on Utilization Trends and Potential Savings from Dose Optimization of Antihemophilic Factor Products Based on Ideal Body Weight

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BACKGROUND: Hemophilia is one of the most expensive chronic diseases in the United States. Prevalence of hemophilia remains low with approximately 130 patients per million commercial lives, but annual cost has increased from $9 million in 2007 to $12 million in 2012. This increase is likely attributed to high doses of factor products, presence of inhibitors, and hospitalizations due to bleeds. Dosing of factor products is often based on weight and population pharmacokinetics.

RESULTS: From 2007 to 2012, the average dose of clotting factor increased from 29.7 units/kg to 33.4 units/kg. The dose calculated on ideal body weight in clinical practice decreased from 35.5 units/kg in 2007 to 31.3 units/kg in 2012, with the largest decrease in 2010. The average cost of clotting factor per day increased from $973 in 2007 to $1,189 in 2012. The largest increase was in 2010, from $973 to $1,292. The largest savings were achieved in 2010, where the average cost per patient per year decreased from $7,531 to $5,995.

CONCLUSIONS: This analysis suggests that dose optimization of antihemophilic factor products based on ideal body weight can result in significant cost savings for healthcare payers.

SPONSORSHIP: This project was funded by Magellan Rx Management.
In recent years, a growing number of literature has supported dose optimization in adult hemophilic patients who are obese.

**OBJECTIVE:** To describe utilization trends of antihemophilic factor products and analyze the potential cost-savings of a dose optimization program based on ideal body weight (IBW) dosing in obese patients with hemophilia in a regional health plan.

**METHODS:** Medical and pharmacy claims from 1/1/2010-12/31/2014 for both commercial and Medicare lines of business of a regional health plan covering 3.7 million lives were analyzed to describe utilization trends. Claims for adults (age ≥18) from 1/1/2014-12/31/2014 were used to predict potential annual savings using IBW in obese patients. 36% of patients were assumed to be obese based on literature. Obesity is defined as a BMI ≥30 based on CDC recommendations.

**RESULTS:** Number of claims increased by 25% from 2010 to 2014 while number of hemophilia patients remained stable. The use of recombinant factor products and von Willebrand factor products increased by 51% and 127%, respectively. The use of FEIBA increased by 671%. Annual cost for antihemophilic factor products increased from $8,865,065 in 2010 to $10,367,173 in 2014 per million lives. Cost per patient also increased from $138,400 in 2010 to $160,496 in 2014. 174 adult patients were included in the dose optimization analysis, of which, 63 were assumed to be obese. Overall, 9,289,168 IU ($33,649,541) of factor products were utilized. With dose optimization, the expected per-patient savings is $17,368 (62,915). This correlates to an annual savings of $1,071,238 per million lives or $0.09 per member per month (PMPM).

**CONCLUSIONS:** The cost to treat hemophilia has continued to rise in recent years leading to increased payer interest in the hemophilia category. In response, Magellan Rx Management has developed a comprehensive strategy including utilization management to ensure appropriate use of factor products and inhibitor therapy along with a dose optimization program. These strategies provide an opportunity to produce significant savings for health plans while maintaining quality of care.

**SPONSORSHIP:** Magellan Rx Management.

**D04 Comparison of Utilization and Outcomes in Hemophilia Patients Receiving Plasma-Derived Factors Versus Recombinant Factors**

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**BACKGROUND:** Hemophilia is a chronic, complex, and costly genetic disorder with management heavily impacted by disease severity, treatment regimen, and complications.

**OBJECTIVE:** To assess differences in utilization and outcomes between hemophilic plasma-derived (PDF) and recombinant factor (RF) products using administrative claims.

**METHODS:** A retrospective cohort of Medicare Advantage Prescription Drug and commercial plan patients, ≥ 89 years old with ≥ 1 paid PDF/RF pharmacy or medical claim between 1/1/2007 and 12/31/2014 was identified. The first factor claim date was the index date. There was no pre-index enrollment requirement but 3-months post-index enrollment was required. Patients with von Willebrand disease were excluded. Follow-up lasted until end of enrollment or study period, or death, whichever came first. Multivariate models compared PDF and RF cohorts on per user per month (PUPM) all-cause total cost, joint bleed, and joint arthropathy outcomes, controlling for gender, bleeding disorder, hypertension, diabetes, age, RxRisk-V score, and bypassing agent use.

**RESULTS:** The study cohort included 557 patients (PDF n=123, RF n=434). The PDF cohort was older (median, 63 year and 34 years, respectively; P < 0.001) with proportionately greater Medicare enrollment, hypertension, and diabetes than the RF cohort. Bypassing agent use (7.3% vs. 1.2%; P < 0.001), post-index switch to comparator (9.8% vs. 2.8%; P < 0.001), and “on demand” therapy (76.4% vs. 59.0%; P = 0.001) were significantly greater in the PDF cohort. Median factor units per month for the PDF and RF cohorts were 438 and 3,477, respectively (P < 0.001). Crude composite complication (joint bleed or arthropathy) rates were 2.3 and 1.7 complications per year for the PDF and RF cohorts, respectively, with no difference in time to first composite complication. There was no significant difference between PDF and RF cohorts in median unadjusted ($6,418 versus $6,475, respectively; P = 0.7426) or adjusted PUPM all-cause healthcare costs between (least square means, $11,344 versus $9,734, respectively; P = 0.3252).

**CONCLUSIONS:** Although interpretation of study findings is clouded by the age disparity found between the PDF and RF cohorts, there were no differences in clinical and cost outcomes between the 2 cohorts. Given the rarity of hemophilia, patient-specific scenarios rather than population similarities may drive complications and costs related to hemophilia treatment, and thus may provide the best opportunity to optimize outcomes and costs.

**SPONSORSHIP:** Comprehensive Health Insights and Humana.

**D05 Real-World Treatment Persistence and Dose Adjustment in Myelofibrosis Patients Newly Initiated with Ruxolitinib**

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**BACKGROUND:** Real-world data on ruxolitinib (RUX) utilization in myelofibrosis (MF) patients are limited.

**OBJECTIVE:** To characterize RUX persistence, dose adjustment patterns, and their healthcare cost impact among MF patients in the real world.

**METHODS:** Adults (≥ 18 years) with MF diagnosis (ICD-9-CM: 289.83, 238.76), newly initiated on RUX, and continuously enrolled in a health plan for ≥6 months pre and post the first RUX fill (index date) were identified from the Truven Commercial Claims and Encounters and Medicare Supplemental Databases (01/2011–12/2014). Treatment discontinuation was defined as interruption of treatment for ≥30 consecutive days. Dose adjustments, defined as change in the dose from the previous prescription, were assessed among patients with ≥2 RUX prescription fills. Cytopenia-related discontinuation/dose adjustment was identified based on a claim for anemia or thrombocytopenia between the last RUX fill date and the end date of follow up (30 days after the end of drug supply or end of continuous eligibility), and between the first date of dose change and the next fill date or the end of follow up, respectively. The Kaplan-Meier method was used to examine time to discontinuation and first dose adjustment. All-cause and MF-related total health care costs were compared between patients with and without dose adjustment using Wilcoxon rank-sum tests.

**RESULTS:** A total of 407 MF patients newly initiated on RUX were identified [median follow up: 7.4 months (range: 2.0-36.3); median age: 70 years; 46.9% male]. In the sample, 44% discontinued treatment within 6 months and 61.4% within 12 months, more than half of which were associated with cytopenias (26.5% and 37.2%, respectively). Among 363 patients with ≥2 RUX fills, 40.1% had a dose adjustment within 6 months and 45.4% within 12 months. Among patients with dose adjustments (n = 172), 28.5% increased, 36.6% decreased, and 34.9% increased and decreased dose; 57.0% had 1, 18.6% had 2, and 24.4% had ≥3 adjustments. The median time to first dose adjustment was 2.3 months (95% CI 1.9-2.9). Compared with
CONCLUSIONS: In a real-world setting, a considerable proportion of patients without dose adjustments, patients with dose adjustments incurred significantly higher costs (mean monthly cost difference: all-cause: $1,621; MF-related: $1,076; both P < 0.05).

SPONSORSHIP: This research was conducted by Baxalta U.S. without external funding.

D07 Impact of Immunoglobulin Utilization Management and Dose Optimization in a Regional Health Plan

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BACKGROUND: Due to the lack of consensus guidelines and the use of immunoglobulin (Ig) therapy in several disease states, the economic burden is significant for managed care organizations. As the utilization of Ig therapy expands with more FDA-approved and off-label uses, total spend continues to rise exponentially. To assist payers, Magellan Rx Management has developed and implemented an Ig utilization management and dose optimization program to curb rising costs.

OBJECTIVE: To measure the impact of a comprehensive utilization management and dose optimization program on overall Ig utilization and spend in a regional health plan.

METHODS: The program was executed in a regional health plan with approximately 700,000 lives. It consisted of implementing comprehensive criteria with steps through alternative therapies when clinically appropriate and pharmacist-suggested dose optimization recommendations based on adjusted body weight (ABW) instead of actual body weight in obese adults. Impact of dose optimization was assessed for the first year of program implementation, from 4/1/14 to 3/31/15 based on data collected from prior authorization (PA) reviews. Medical claims were also analyzed to compare between first quarter 2014 and first quarter 2015 to assess impact on Ig utilization.

RESULTS: Between 4/1/14 and 3/31/15, a total of 366 PA requests were approved for 221 unique members. Of these members, 23% were identified as being obese and eligible for ABW dosing. ABW dosing recommendations were made for 84 members, of which, 65% were accepted by the prescribing physician. Prescribers agreed to downward titrate dose in an additional 28 members based on pharmacist recommendations in attempt to find the lowest effective dose for maintenance treatment. Dose adjustments led to a savings of 8% or $607,186 over a one-year time frame. Medical claims analysis also demonstrated that total paid amount, cost per claim, and the number of claims, units, total spend continued to rise exponentially. To assist payers, Magellan Rx Management has developed and implemented an Ig utilization management and dose optimization program to curb rising costs.

CONCLUSIONS: Medical claims analysis revealed that a utilization management and dose optimization program was able to reduce total Ig spend by 17%. This correlates to an overall savings of approximately $1.4 million per year. A large proportion of this savings can be attributed to ABW dose recommendations. A reduction in claims and number of members utilizing Ig was also achieved through more comprehensive utilization management.

SPONSORSHIP: Magellan Rx Management.

D08 Real-World Costs of Treating PIDD with IV and SC Immunoglobulins

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BACKGROUND: Primary Immune Deficiency Disorder (PIDD) is a rare, chronic, debilitating disease which weakens a patient’s immune system, limiting their ability to fight off infection. This limited immune response leads to higher rates of office, emergency department, and inpatient hospital utilization thereby increasing healthcare expenses. Compounding these expenses are the high costs of immunoglobulin (Ig) treatments which commonly are nurse-infused intravenous (IV) or self-administered subcutaneous (SC) products.

RESULTS: A total of 170,913 patients were identified with a diagnosis of sarcoidosis with 58 (0.034%) receiving RCI. The average age of RCI patients was 50.4 years, 67.2% were female, 43.1% were from the South U.S. Census Region, and Charlson comorbidity index and chronic disease score (CDS) were 1.7 and 7.5, respectively. Most (74.1%) RCI patients previously received prednisone. Other pre-RCI treatments included methylprednisolone (27.6%), hydroxychloroquine (17.2%), and methotrexate (15.5%). Prior use of prednisone (OR = 2.0; 95% CI = 1.04, 3.85) and higher CDS (OR = 1.1, 95% CI = 1.00, 1.19) were positively predictive of RCI use, whereas prior use of methotrexate (OR = 0.2, 95% CI = 0.09, 0.44) and prior indication of cancer (OR = 0.3, 95% CI = 0.14, 0.77) were negatively predictive.

CONCLUSIONS: RCI is used to treat sarcoidosis with most patients receiving prednisone prior to initiating on RCI. Previous use of cytotoxic and anti-malarial treatments was fairly common. Prior prednisone use, prior non-use of methotrexate, and the absence of cancer diagnosis were predictive of future RCI treatment in this analysis. CDS, which indicates a wider range of prior medications, was mildly predictive.

SPONSORSHIP: Mallinckrodt.
OBJECTIVE: To compare real-world PIDD-related costs between patients receiving IV and SC-based Ig treatments.

METHODS: Using the Pharmetrics Plus dataset from 2011-13 we identified PIDD patients (ICD-9 code 279.XX) with at least two claims ≥90 days apart for PIDD who were treatment naive for at least one year prior to study period. Patients who switched administration routes were excluded, with the exception that subcutaneous patients could receive up to two IV loading infusions per treatment guidelines. Claims with a primary diagnosis of PIDD and costs related to therapy were identified as PIDD-related costs. To adjust for physician treatment preferences and large differences in base population characteristics, the two cohorts were matched on age, gender, and all 31 Elixhauser index criteria using propensity score matching. Median costs between the combined 3 most commonly used IV products were compared with median costs of SC products using t-tests for means and Wilcoxon Rank-Sum tests.

RESULTS: 1,639 PIDD patients met all inclusion/exclusion criteria with 986 being IV infused and 653 being SC treated. SC patients were significantly younger (mean age 40.3 versus 49.1 for IV), more female (63.1% versus 58.3%), and had lower Charlson Comorbidity Index scores (CCI, 1.7 versus 3.0) (P < 0.05 for all). After matching, there were 553 patients in each group with no differences in demographics. Post-period PIDD-related median costs were significantly lower for the IV group ($38,064 versus 43,266; P < 0.05).

CONCLUSIONS: This analysis gathered insight into two important aspects of PIDD patient care. First, patients initiating IV Ig treatment were clinically more severe than SC patients. Second, after patient matching, the PIDD-related costs incurred over the first year of treatment were significantly lower for IV patients compared to their SC treated peers. Further analysis needs to be conducted elucidating where these differences lie and how they impact patient treatment, preferences, and outcomes.

SPONSORSHIP: Grifols, SSNA.
from 9.4% (hip) to 16.6% (vertebral), and 7.5% (NHNV) to 14.4% (vertebral) in commercial. Unlike diagnosis rates, osteoporosis treatment rates improved only slightly after fracture, ranging in Medicare from 12.5% (NHNV) to 26.5% (vertebral), and 8.3% (NHNV) to 21.4% (vertebral) in commercial.

CONCLUSIONS: Patients who experience vertebral fractures have the highest rates of OP diagnosis and treatment, before and after fracture. OP diagnosis rates improve substantially after fracture, yet remain low overall, while OP treatment rates are low before fracture and only improve minimally during the follow-up despite fracture.

SPONSORSHIP: Merck & Co.

E18 The Relationship Between Digital Health Program Activity Tracking and Medication Adherence Among Members Ages 50+ Years
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BACKGROUND: A national community pharmacy offers a digital health program—Balance Rewards for healthy choices (BRhc)—to help members improve their health. Members earn points, redeemable for store purchases, for making healthy choices like tracking physical activity (PA), body weight, blood pressure (BP) and glucose (BG), connecting health devices and apps, and setting and achieving health improvement goals.

OBJECTIVE: To determine the relationship between BRhc engagement and adherence to antihypertensives, antihyperlipidemics, and oral antidiabetics for members age 50+ years.

METHODS: This retrospective cohort study compared members enrolled in the Walgreens BRhc program who logged ≥2 activities and had ≥2 fills of medication for diabetes (DB), hypertension (HTN), or hyperlipidemia (HL) between March 2014 and October 2014. Adherence was measured using Proporation of Days Covered (PDC) and calculated over a 12-month period from each member’s first prescription fill date. Optimal adherence (OA) was PDC≥80%. Multivariate logistic regression was used to assess the odds of OA, adjusted for demographics and drug utilization.

RESULTS: A total of 10,642 BRhc members 50+ years old met the inclusion criteria. Of these, 6,287 (59.1%) tracked PA, with 2,349 (37.4%) of members tracking ≥4x/week, 2,070 (19.5%), 7,965 (74.8%) and 5,274 (49.6%) were on medications for DB, HTN, and HL respectively; and of these, 1,817 (22.8%) and 763 (36.8%) tracked their BP and BG respectively. The median age of members was 57 years and 69.1% were female; median maintenance drugs count was 4. Higher levels of PA tracking—at least 4 times weekly—were associated with higher adherence to antihypertensives and antihyperlipidemics (HTN: PDC Δ = 5.6%; P < 0.0001; % OA Δ = 11.2%; P < 0.0001; HL: PDC Δ = 2.9%; P < 0.0001; % OA Δ = 4.5%; P = 0.0007). Higher biometrics activity tracking was also associated with higher adherence to antihypertensives and oral antidiabetics (HTN: PDC Δ = 3.0%; P = 0.0339; % OA Δ = 6.8%; P = 0.0192; DB: ≥1x weekly: PDC Δ = 5.2%; P = 0.0005; % OA Δ = 12.3%; P = 0.0002). After controlling for demographics and drug utilization, members with higher levels of PA and biometric tracking were more likely to be adherent to medications. {PA (HTN: OR = 1.68, P < 0.0001; HL: OR = 1.18, P = 0.0085); Biometrics (DB: OR = 1.86, P = 0.0009; HTN: OR = 1.29, P = 0.0615).}

CONCLUSIONS: This study demonstrated a significant relationship between higher levels of member engagement in BRhc and greater adherence to prescribed antihypertensives, antidiabetics, and antihyperlipidemics for members 50+ years.

SPONSORSHIP: Walgreens Co.
OBJECTIVE: To examine the impact of OOP costs on adherence and to assess whether there is a threshold where there is a substantial change in adherence.

METHODS: This was an observational, retrospective cohort study using data from a large U.S. administrative and medical claims database. Included patients were those with type 2 diabetes who initiated therapy to a branded diabetic medication during the index period (January 1, 2011, through December 31, 2011) and had 3 years of follow-up data. The primary outcome of interest was adherence, which was measured by the number of days covered or medication possession ratio. Propensity scores were calculated to estimate the probability of OOP medication costs >$35 using baseline sociodemographic and clinical characteristics. Four equal strata were created based on propensity scores. Multivariate regression models were conducted to estimate the causal relationship of OOP costs on adherence for each stratum.

RESULTS: A total of 15,416 patients were assessed. Across each stratum, mean patient age ranged from 46.6 to 61.6 years, mean chronic disease score ranged from 3.4 to 7.0, mean number of diabetic medication classes ranged from 1.9 to 2.4, and median household income was $62,500. Most patients were married (mean range, 62%-98%) and some used a commercial plan (mean range, 30%-98%). The adjusted R2 for the propensity matched multivariate regression model was 77%. The propensity stratified multivariate regression model revealed a negative relationship between OOP costs and adherence across several OOP cost levels (P<0.05). Across all strata, patients with the highest OOP costs (> $75) vs. those with the lowest OOP costs ($0-$10) had significantly lower adherence, and the mean number of days covered was 92 days (P<0.001) in addition, patients with OOP costs from $50 to $75 vs. patients with the lowest OOP costs ($0-$10) had significantly lower adherence, and the mean number of days covered was 92 days (P<0.001).

CONCLUSIONS: Higher OOP costs appear to be associated with lower adherence regardless of income level, chronic disease score, medication burden, sociodemographic, and clinical characteristics.

SPONSORSHIP: Eli Lilly and Company.

E22 Diabetes Mellitus (DM) Prevalence, Incidence, Drug Regimens, and Insulin Therapy Cost by Type Among 4 Million Commercially Insured Members Continuously Enrolled 4.5 Years

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BACKGROUND: Health plans are now assessing new long-acting insulins including the first “follow-on” Insulin Glargine (Basaglar) and novel Insulin Degludec (Tresiba).

OBJECTIVE: To estimate the prevalence and cost of insulin for Type 1 diabetics and higher among type 2 diabetics on basal+rapid-acting or premixed insulin therapy than those on basal insulin only. The absolute incidence rates were quite low in this commercially insured population.

SPONSORSHIP: Prime Therapeutics.

E23 Incidence Rate of Emergency Department Visits for Hypoglycemia by Diabetes Drug Regimen in a 4-Million Member Commercially Insured Population

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BACKGROUND: Prime Therapeutics is assessing the new long-acting Insulin Degludec (Tresiba) alone in combinations for safety and cost-effectiveness compared with alternatives. Ongoing clinical trials are comparing hypoglycemia (HG) risk between different treatment regimens. Administrative claims Hg emergency department (ED) visits, as a marker of severe episodes, may provide insight into the current absolute incidence rate (IR) of this adverse effect.

OBJECTIVE: To estimate, in a commercially insured population, the IR of ED visits for HG among members on diabetes mellitus (DM) drug therapy by the type of therapy from pharmacy claims (Rx).

METHODS: All commercially insured members in 12 health plans continuously enrolled between 1/1/2011 and 6/30/2015 were selected. ED visits with DM as a secondary diagnosis code (Dx) and HG as first-line Dx were identified using a published algorithm validated by medical record review. Members with any Rx for DM drugs were categorized as Type 1 (T1) or Type 2 (T2) using an algorithm based on Dxs and Rxs. Each member was assigned to a DM drug regimen category for each six-month interval. ED visits for HG were assigned to the member’s regimen category at the time of the visit. Patient-years (pt-yrs) of exposure to different DM regimens were summed and IRRs calculated per 1,000 (thou) pt-yrs.

RESULTS: There were 3,947,165 members in the sample who had a total of 4,128 HG ED visits and a total of 783,492 pt-yrs of DM drug therapy, for an IR of 5.3 HG ED visits per thou pt-yrs of treatment. 63,987 (8.2%) pt-yrs were for T1 therapy, 152,543 (19.5%) T2 therapy that included insulin, and 566,963 (72.4%) non-insulin only for T2, which were associated, respectively, with 1,635, 1,596, and 897 ED HG visits for IRs of 25.6, 10.5, and 1.6 per thou pt-yrs. The most frequent insulin categories were: 29,897 T1 pt-yrs of rapid-acting (RA) only, associated with 646 visits for IR of 21.6 per thou pt-yrs, 26,524 T1 pt-yrs of basal+RA, associated with 723 visits for IR of 27.3 per thou pt-yrs; 71,571 T2 pt-yrs of basal only associated with 506 visits for IR of T1 pt-yrs; 47,372 T2 pt-yrs of basal+RA associated with 661 visits for IR of 14.0 per thou pt-yrs, and 16,999 T2 pt-yrs of premixed associated with 208 visits for IR of 12.2 per thou pt-yrs.

CONCLUSIONS: The incidence rate of emergency department visits for hypoglycemia was highest for type 1 diabetics and higher among type 2 diabetics on basal+rapid-acting or premixed insulin therapy than those on basal insulin only. The absolute incidence rates were quite low in this commercially insured population.

SPONSORSHIP: Prime Therapeutics.
Glycemic Control in Type 2 Diabetes Patients Receiving Early and Late Combination Therapy

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BACKGROUND: American Diabetes Association guidelines recommend that patients with type 2 diabetes (T2DM) be treated with the addition of a second oral antidiabetic agent (OAD) if the HbA1c goal of <7% is not met within 3 months of initiation of first OAD. However, there is often a delay in initiating combination therapy, which may be an important contributor of glycemic burden.

OBJECTIVE: To examine the effect of early combination therapy on glycemic control.

METHODS: This retrospective analysis used medical claims, pharmacy claims, and laboratory value data from a large U.S. managed care database of commercial and Medicare Advantage part D members treated with an OAD from 1/1/11-2/28/14. The analysis included patients with >1 pharmacy claim for an OAD (first claim = index date), were assigned to a study cohort based on time from index date to first combination therapy: Early Combination (EC) ≤ 90 days; Late Combination (LC) ≥ 90 days. HbA1c values were assessed in the B/L (closest to index date) and F/U (closest to the end of the F/U period) period. Only patients with an HbA1c ≥7% in the B/L period were included. Patients were assigned to a study cohort based on time from index date to first combination therapy: Early Combination (EC) ≤ 90 days; Late Combination (LC) ≥ 90 days. HbA1c values were assessed in the B/L (closest to index date) and F/U (closest to the end of the F/U period) periods. The F/U value was required to be at least 90 days after initiation of combination therapy. Multivariate logistic regression analysis was used to examine the independent association of timing of combination therapy and glycemic control (HbA1c <7%).

RESULTS: Patients in EC (n = 1,368) and LC (n = 212) were similar in age (mean [SD]) (54.4 years [11.0] vs. 54.9 [11.0]; P = 0.560) and gender (63.0% vs. 62.3% male, P = 0.834). Mean B/L HbA1c was higher in the EC cohort (10.1 [2.2] vs. 9.0 [1.8]; P < 0.001). Mean change in HbA1c between the B/L and F/U period was greater in the EC cohort (-2.7 [2.5] vs. -1.7 [1.9]; P < 0.001). The proportion of patients with an HbA1c of <7% in the F/U period was greater in the EC cohort (53.1% vs. 44.8%; P = 0.023). After adjusting for B/L factors, differences in glycemic control remained statistically significant in the logistic regression model, with patients in the EC cohort being 1.46 times more likely to achieve glycemic control (P = 0.006).

CONCLUSIONS: In this large U.S. managed care database, a higher proportion of patients in EC cohort were found to be associated with glycemic control than patients in LC cohort.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals.
introducing Gla-300 for the treatment of type 2 diabetes (T2D) to a U.S. health plan.

**METHODS:** The CCM was implemented as a Markov cohort model with a 6-month cycle length using inputs based on the head-to-head comparison of Gla-300 with Glu-100 in U.S. patients with T2D. Three T2D patient-population subgroups were analyzed: previous basal-bolus (BB; n=807), previous basal+non-insulin antidiabetes agents (B+AD; n=811), insulin-naive (AD; n=878). Severe and non-severe hypoglycemia events (per EDITION protocols) were simulated with separate rates and separate costs within each population; results are reported as any hypoglycemia. Costs per hypoglycemia event were based on previously published rates of health care use; medication costs were based on average insulin daily dose in each group and cost per unit of insulin. The base case provides a 6-month analysis that assumes that daily insulin costs of Gla-300 and Glu-100 are the same on the entire T2D population.

**RESULTS:** Across T2D populations over 6 months, the incremental per-patient cost for treatment with Gla-300 vs. Glu-100 was -$33.19. In the overall T2D population and in two of the three groups, Gla-300 was dominant over Glu-100 in cost per hypoglycemic event avoided. The only T2D patient group where dominance was not estimated was that where patients added Gla-300 to a previous regime of non-insulin antidiabetes drugs. For this subgroup, Gla-300 was associated with $49.31 higher pharmaceutical costs, $9.52 lower medical costs, and 0.715 fewer hypoglycemic events per patient, and the cost per hypoglycemic event avoided was $55.64.

**CONCLUSIONS:** Gla-300 was associated with zero to minimal per-patient incremental costs compared with Glu-100 over the entire T2D population. The cost offset is driven by a lower rate of hypoglycemic events and hypoglycemia-associated costs. Previously insulin–naïve T2D patients encountered higher pharmaceutical costs offset by lower total cost per hypoglycemic event, if any.

**SPONSORSHIP:** Study funding and writing/editorial support was provided by Sanofi U.S.

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E28 Predictors of All-Cause Hospitalization Among Medicare Advantage Members Diagnosed with Type II Diabetes

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1Comprehensive Health Insights; 2Novo Nordisk; 3Humana

**BACKGROUND:** Patients with type-2 diabetes mellitus (T2DM) have increased risk for hospitalization and experience longer lengths of stay than individuals without diabetes.

**OBJECTIVE:** To identify patient and provider factors predictive of all cause hospitalization among Medicare Advantage and Prescription Drug plan members (MAPD) with T2DM.

**METHODS:** This was a retrospective cohort study of MAPD members with T2DM using administrative claims data from 1/1/12 through 12/31/2013. Subjects were between 18-90 years of age, with ≥12 months pre- and ≥12 months post- 1/1/2013 continuous enrollment. The index date for the hospitalized patients was the date of the first inpatient admission in 2013, while the index date for patients without hospitalization was randomly assigned to match the distribution of those hospitalized. Multivariate logistic regression was used to predict likelihood of hospitalization. The final analytic file was split into training and testing datasets to validate results. Over 200 candidate factors were considered for inclusion, which consisted of, but were not limited to, provider and patient demographics, baseline clinical conditions, and health care cost and utilization metrics.

**RESULTS:** Of 360,798 individuals, 73,893 (20.5%) experienced at least one hospitalization. Overall, patients were on average 71.5 years old, white, female, resided in the South, and had a health management organization plan. The predictive model identified 7 socio-demographic, 21 clinical, 3 utilizations, and 1 provider factor(s) that significantly contributed to the discriminant ability of the final model (C-statistic = 0.7). Age groups 65-69, and 70-75 had lower odds of hospitalization [OR, 95% CI; 0.91 (0.88, 0.95), 95 (0.91, 0.98)], respectively, while older age groups 75-79, 80-84 and 85-89 were associated with higher hospitalization risk [OR, 95% CI; 1.06 (1.01, 1.10), 1.15 (1.10, 1.21), 1.35 (1.27, 1.43), respectively]. Female sex [OR, 95% CI; 0.95 (0.93, 0.98)] and management by an endocrinologist [OR, 95% CI; 0.92 (0.87, 0.98)] were predictors of a lower likelihood of
hospitalization. Management by a cardiologist was predictive of higher likelihood of hospitalization [OR, 95% CI, 1.2 (1.1, 1.3)].

**CONCLUSIONS:** An algorithm with good discriminant ability between various clinical and demographic factors has been developed that identifies MAPD T2DM patients with higher and lower odds of hospitalization.

**SPONSORSHIP:** Novo Nordisk commissioned Comprehensive Health Insights to complete this study.

**E29 Predictors of All-Cause 30-Day Readmission Among Type II Diabetic Medicare Advantage Members**

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**BACKGROUND:** Close to one fifth of Medicare members who are hospitalized will experience a 30-day readmission. Readmission is costly among Medicare members with type II diabetes (T2DM), and identifying patients at high risk for readmission may be useful for targeting readmission reduction programs.

**OBJECTIVE:** To develop a claims-based algorithm to predict all cause 30-day readmissions among Medicare Advantage Prescription Drug plan members with T2DM.

**METHODS:** This was a retrospective study using administrative claims data from 1/1/2012 through 1/31/2014 from a cohort of Medicare Advantage Prescription Drug plan members with T2DM, aged 18-90 with ≥12 months’ continuous enrollment before an unplanned hospital admission and ≥1 month of continuous enrollment post-discharge. Patients in long term care >30 days pre-index were excluded. Multivariate logistic regression was used to predict the likelihood of all-cause 30-day readmission following hospitalization in 2013. The final analytic file was randomly split into a training dataset to build the model and test dataset to validate results. Candidate variables included provider and patient demographics, baseline clinical conditions, and health care utilization metrics. Baseline clinical conditions were classified using the healthcare cost and utilization project (H-CUP) clinical classification system (CCS) for ICD-9-CM.

**RESULTS:** Of 63,237 individuals, 10,783 (17.1%) experienced an all-cause 30-day readmission. Females had lower likelihood of readmission. Older age, number of emergency room visits and total length of stay in the baseline period were associated with higher likelihood of readmission. Comorbidities that were positively associated with higher odds of readmission included diseases of the urinary system, fluid and electrolyte disorders, diseases of white blood cells, other nervous system disorders, respiratory failure, gastrointestinal hemorrhage, heart, liver, and other lower respiratory diseases per CCS taxonomy. Of nearly 300 candidate variables, 15 were predictors of 30-day readmission. The final model demonstrated good discriminative ability (c-statistic = 0.82).

**CONCLUSIONS:** Provider characteristics did not appear to influence the likelihood of all cause 30-day readmission. Certain patients’ clinical and demographic characteristics and healthcare utilization were associated with higher likelihood of readmission, and resulted in an algorithm with good discriminable ability that could target readmission reduction programs.

**SPONSORSHIP:** Novo Nordisk commissioned Comprehensive Health Insights to complete this study.

**E30 Predictors of Type II Diabetes Treatment Modification Within 10-Days Post-acute Discharge from an Unplanned Admission Among Medicare Advantage Members**

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**BACKGROUND:** Hospitalization may provide an opportunity to assess type II diabetes (T2DM) treatment regimen and intensify treatment if warranted. Factors that influence diabetes drug treatment modification (TM) after an inpatient hospitalization have not been examined in detail.

**OBJECTIVE:** To identify factors that predict TM within 10-days post hospitalization among T2DM patients.

**METHODS:** A retrospective cohort study using claims data from Medicare Advantage Prescription Drug Plan members with T2DM. Members aged 18-90 with an unplanned admission during calendar year 2013 were included. TM was defined as addition of any new antidiabetic medication(s) within 10-days of discharge. Multivariate logistic regression was used to predict the likelihood of TM post-hospitalization. Candidate variables included provider and patient demographics, baseline (12 months pre-index hospitalization) clinical conditions, baseline antidiabetic medication(s), and health care utilization metrics. Baseline clinical conditions were classified using the healthcare cost and utilization project (H-CUP) clinical classification system (CCS) for ICD-9-CM.

**RESULTS:** Of 45,401 members included, 5,108 (11.25%) had evidence of TM within 10 days of discharge. Older age was associated with lower TM likelihood, while blacks had a higher likelihood of TM compared with whites. Members with more frequent outpatient physician encounters or prescribed a greater numbers of unique antidiabetic medications pre-hospitalization were less likely to have TM. Baseline uses of sulfonylureas, insulin sensitizers, dipeptidyl peptidase-4 inhibitors, and oral antidiabetics in combination were associated with higher TM likelihood. Insulin was associated with lower likelihood. Greater frequency of HbA1c monitoring during the inpatient stay and longer length of stay was associated with higher likelihood of TM. Trauma-related disorders, hyperlipidemia, and GI disorders before the unplanned hospital admission were associated with less likelihood of TM. Of ~300 variables, 17 were predictors of TM within 10-days of discharge and demonstrated good discriminant ability (c-statistic = 0.70).

**CONCLUSIONS:** In this study, more than 10% of patients experienced TM within 10-days of discharge. Characteristics of both pre-admission medical utilization (e.g., oral baseline antidiabetic medication regimen) and inpatient course of care (e.g., higher frequency of HbA1c monitoring) were associated with TM post discharge. The predictive model may be useful for identifying profiles of patients for targeted monitoring and/or intervention.

**SPONSORSHIP:** Novo Nordisk sponsored this study.

**E31 Cost-Effectiveness of a Pharmacist-Led Diabetes Intense Medical Management “Tune Up” Clinic from Three Perspectives and Time Frames**

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**OBJECTIVE:** To tune up a diabetes care model containing pharmaceutical care services to improve glycosylated hemoglobin (HbA1c) levels and medication adherence within a Medicare Advantage Prescription Drug Plan (MAPD) and evaluate the cost-effectiveness of this intervention from three different perspectives.

**METHODS:** A pharmacy-managed diabetes care clinic was implemented in a MAPD population. The impact of the clinic was measured as changes in HbA1c levels and medication adherence and savings of co-insurance and deductibles. The cost-effectiveness was calculated from the payer perspective.

**RESULTS:** The clinic resulted in a significant reduction in HbA1c levels and an increase in medication adherence. The savings from reductions in co-insurance and deductibles were also significant. The cost-effectiveness analysis showed that the clinic was cost-effective from the payer perspective.

**CONCLUSIONS:** The pharmacist-led diabetes care clinic was effective in improving diabetes outcomes and cost-effective from the payer perspective.

**SPONSORSHIP:** This project was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (R01 DK097671) and the California Blue Cross Foundation.
BACKGROUND: Interventions to improve patient clinical outcomes necessarily originate at the patient-provider clinic level. However, the economic value of outcomes achieved in the clinic may differ when various perspectives and time periods are considered.

OBJECTIVE: To estimate the cost effectiveness of a collaborative pharmacist-endocrinologist Diabetes Intense Medical Management (DIMM) “Tune Up” clinic vs. primary care provider (PCP) usual care from three perspectives and timeframes. Specifically, the cost per A1C benefit gained at 6 months from the clinic perspective, 3-year medical cost avoidance and ROI from the health system perspective, and 10-year complication risk reduction and cost per QALY gained from the societal perspective.

METHODS: The DIMM clinic uses a limited series of 60-minute pharmacist visits, combining medication therapy management with patient-specific diabetes education, to achieve treatment goals for complex diabetes patients before discharge back to the PCP. Data from a retrospective cohort study of DIMM vs. comparator PCP patients were used to evaluate cost effectiveness: incremental cost-effectiveness ratios at six months, 3-year estimated total medical costs avoided and Return on Investment (ROI). Absolute risk reduction of complications, resultant medical costs and Quality Adjusted Life Years (QALYs) over ten years were estimated using the Archimedes Model.

RESULTS: From the clinic perspective the DIMM clinic costs $21 per additional percentage point glycosylated hemoglobin (A1C) improvement and $115 to $164 per additional patient at A1C goal compared to the PCP group. From the health system perspective cost avoidance was $8,793 per DIMM patient vs. $3,506 per PCP patient (P = 0.009) and the ROI was $15.65 per dollar spent on the DIMM clinic. From the societal perspective DIMM patients had lower total medical costs, greater number of QALYs gained, and appreciable risk reductions for diabetes-related complications.

CONCLUSIONS: An intense, short term, pharmacist intervention for complex diabetes patients resulting in improved clinical outcomes was cost-effective from the clinic, health system and societal perspectives. Assessing economic value from multiple perspectives and timeframes produced value evidence that is meaningful to clinicians, health system administrators, and policy makers.

SPONSORSHIP: Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California, San Diego, La Jolla, CA, and Veterans Affairs of San Diego Healthcare System, San Diego, CA.

METHODS: Proportions of patients achieving A1C target and mean reductions in A1C with liraglutide (1.2 mg, 1.8 mg), sitagliptin 100 mg, canagliflozin (100 mg, 300 mg), dapagliflozin (5 mg, 10 mg), and empagliflozin (10 mg, 25 mg) were taken from a meta-analysis of 17 randomized controlled trials. Annual costs for each treatment were estimated from a payer perspective including the cost of study drug, concomitant metformin, and needles (for liraglutide). Cost-effectiveness in terms of cost per patient achieving an A1C target of ≤7% and cost per 1% reduction in A1C were evaluated in economic models developed in Microsoft Excel. Key parameters were varied when one-way and probabilistic sensitivity analyses were conducted.

RESULTS: Liraglutide 1.8 mg and liraglutide 1.2 mg were associated with the greatest proportions of patients achieving A1C target and the largest reductions in A1C. Combining the clinical efficacy data with the annual cost of treatments demonstrated that the cost of control (A1C ≤7%) and the cost per 1% reduction in A1C were comparable between all interventions. Empagliflozin 25 mg and liraglutide 1.2 mg were associated with the lowest cost per patient achieving target A1C, $9,777 and $9,815 respectively. For the cost per 1% reduction in A1C, liraglutide 1.2 mg and canagliflozin 300 mg were associated with the lowest cost; $4,777 and $4,942 respectively. In both scenarios, dapagliflozin 5 mg demonstrated the highest cost of control.

CONCLUSIONS: The strong clinical efficacy associated with liraglutide 1.2 mg and 1.8 mg resulted in low costs per patient achieving A1C target and per 1% reduction in A1C, despite higher wholesale acquisition costs. Liraglutide may, therefore, represent a cost-effective therapy to improve glycemic control in patients with type 2 diabetes.

SPONSORSHIP: This study was supported by funding from Novo Nordisk.

E32 Evaluating the Cost of Improving Glycemic Control in People with Type 2 Diabetes Mellitus in the USA Receiving Liraglutide, Sitagliptin or Sodium-Glucose Co-Transporter 2 Inhibitors

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BACKGROUND: Over 27 million Americans have type 2 diabetes mellitus (T2D), each accruing a mean lifetime medical cost attributable to the disease of $85,200. Controlling blood sugar levels forms the cornerstone of diabetes management, with evidence showing that improved glycemic control is associated with reduced risk of diabetes-related complications, lowering both the human and financial burden of the disease.

OBJECTIVE: To evaluate the cost per patient achieving the glycemic control target of glycated hemoglobin (A1C) ≤7% (recommended by the American Diabetes Association) and the cost per 1% reduction in A1C in patients with T2D in the USA receiving liraglutide, sitagliptin or sodium-glucose co-transporter 2 (SGLT2) inhibitors.

METHODS: The DIMM clinic uses a limited series of 60-minute pharmacist visits, combining medication therapy management with patient-specific diabetes education, to achieve treatment goals for complex diabetes patients before discharge back to the PCP. Data from a retrospective cohort study of DIMM vs. comparator PCP patients were used to evaluate cost effectiveness: incremental cost-effectiveness ratios at six months, 3-year estimated total medical costs avoided and Return on Investment (ROI). Absolute risk reduction of complications, resultant medical costs and Quality Adjusted Life Years (QALYs) over ten years were estimated using the Archimedes Model.

RESULTS: From the clinic perspective the DIMM clinic costs $21 per additional percentage point glycosylated hemoglobin (A1C) improvement and $115 to $164 per additional patient at A1C goal compared to the PCP group. From the health system perspective cost avoidance was $8,793 per DIMM patient vs. $3,506 per PCP patient (P = 0.009) and the ROI was $15.65 per dollar spent on the DIMM clinic. From the societal perspective DIMM patients had lower total medical costs, greater number of QALYs gained, and appreciable risk reductions for diabetes-related complications.

CONCLUSIONS: An intense, short term, pharmacist intervention for complex diabetes patients resulting in improved clinical outcomes was cost-effective from the clinic, health system and societal perspectives. Assessing economic value from multiple perspectives and timeframes produced value evidence that is meaningful to clinicians, health system administrators, and policy makers.

SPONSORSHIP: Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California, San Diego, La Jolla, CA, and Veterans Affairs of San Diego Healthcare System, San Diego, CA.

METHODS: Proportions of patients achieving A1C target and mean reductions in A1C with liraglutide (1.2 mg, 1.8 mg), sitagliptin 100 mg, canagliflozin (100 mg, 300 mg), dapagliflozin (5 mg, 10 mg), and empagliflozin (10 mg, 25 mg) were taken from a meta-analysis of 17 randomized controlled trials. Annual costs for each treatment were estimated from a payer perspective including the cost of study drug, concomitant metformin, and needles (for liraglutide). Cost-effectiveness in terms of cost per patient achieving an A1C target of ≤7% and cost per 1% reduction in A1C were evaluated in economic models developed in Microsoft Excel. Key parameters were varied when one-way and probabilistic sensitivity analyses were conducted.

RESULTS: Liraglutide 1.8 mg and liraglutide 1.2 mg were associated with the greatest proportions of patients achieving A1C target and the largest reductions in A1C. Combining the clinical efficacy data with the annual cost of treatments demonstrated that the cost of control (A1C ≤7%) and the cost per 1% reduction in A1C were comparable between all interventions. Empagliflozin 25 mg and liraglutide 1.2 mg were associated with the lowest cost per patient achieving target A1C, $9,777 and $9,815 respectively. For the cost per 1% reduction in A1C, liraglutide 1.2 mg and canagliflozin 300 mg were associated with the lowest cost; $4,777 and $4,942 respectively. In both scenarios, dapagliflozin 5 mg demonstrated the highest cost of control.

CONCLUSIONS: The strong clinical efficacy associated with liraglutide 1.2 mg and 1.8 mg resulted in low costs per patient achieving A1C target and per 1% reduction in A1C, despite higher wholesale acquisition costs. Liraglutide may, therefore, represent a cost-effective therapy to improve glycemic control in patients with type 2 diabetes.

SPONSORSHIP: This study was supported by funding from Novo Nordisk.

E34 Secondary Prevention of Diabetes through Workplace Health Screenings

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BACKGROUND: Workplace health screenings offer a unique opportunity to screen individuals for diabetes and are becoming increasingly common.

OBJECTIVE: To evaluate (1) the association between workplace diabetes screening and subsequent diagnosis, and (2) changes in last plasma glucose (FGP), HbA1c and body mass index (BMI) among individuals who screened positive for diabetes.

METHODS: Between 2012 and 2014, 21,931 individuals (mean age: 44.6 ± 10.9 years, 50.1% female) without a prior diagnosis of diabetes participated in workplace health screenings by 45 employers. The employers belong to a diverse group of industries located throughout the United States, and use various regional and national health plans and pharmacy benefit managers. Diabetes cases were identified using a claims-based algorithm and ICD-9-CM diagnosis codes. Discrete-time survival analysis was used to estimate the monthly rate of new diabetes cases after screening, relative to the three-month period before screening. Paired t-tests were used to evaluate one-year changes in blood glucose measures and BMI among diabetic individuals.

RESULTS: A total of 871 (4.0%) individuals screened positive for diabetes. In a model adjusted for age, gender, education, race, BMI, hypertension, and hyperlipidemia, a significantly greater rate of new diabetes diagnoses was observed during the first month after screening, compared to the three month period before screening (Odds Ratio [OR]: 2.67, 95% Confidence Interval [CI]: 2.02-3.55). Among 517 diabetic individuals who returned for a screening one year later, significant
improvements were observed in BMI (mean ± SD = -0.69 ± 2.67 kg/m², P < 0.001) and FPG levels (mean ± SD = -10.3 ± 69.6 mg/dL, P = 0.002). Mean changes in HbA1c levels were not significant (-0.05% ± 1.52%, P = 0.13).

CONCLUSIONS: Workplace health screenings in an insured population were associated with a subsequent increase in physician visits for diabetes. Individuals identified as diabetic at screening demonstrated an improvement in BMI and plasma glucose levels after one year. Even in an insured population, workplace screening benefits a significant number of individuals through both increased access to care as well as improved outcomes.

SPONSORSHIP: Health Advocate and West.

E35 Comparative Effectiveness Analysis of Rapid-Acting Insulin Therapies in a Large National Health Plan

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BACKGROUND: There is a paucity of data regarding comparative outcomes of rapid-acting insulins (RAIs) for use in formulary decision-making.

OBJECTIVE: To assess differences in outcomes and costs between RAI products (lispro versus aspart) and presentations (vial versus pen) using administrative claims.

METHODS: A retrospective cohort of Medicare Advantage Prescription Drug and commercial patients with diabetes and ≥ 1 paid RAI pharmacy claim between 1/1/2008 and 12/31/2013 was identified. The first RAI claim date was the index date. A 12-month pre- and post-index period was required. Subjects with insulin use or gestational diabetes in the pre-index period, or pregnancy during the study period, were excluded. Multivariate models compared product and presentation groups on 12-month post-index all-cause healthcare costs, hypoglycemic events, new or worsening complications, and persistence, while controlling for age, gender, region, plan type, population density, index year, risk, pre-index physician office visits, pre-index count of hemoglobin Alc (HbA1c) tests, pre-index antidiabetic therapies, RAI adherence, and pre-index comorbidities. Change in HbA1c was also assessed in subjects with ≥ 1 pre-index HbA1c level and ≥ 1 post-index HbA1c level.

RESULTS: Of the 8,189 patients included in the study cohort, 2,825 used lispro and 5,354 used aspart. Vial and pen cohorts included 6,135 and 2,054 patients, respectively. After adjustment for baseline covariates, there were no significant differences in lispro vs. aspart or pen vs. vial cohorts in the occurrence of post-index hypoglycemic events (OR 0.97, P = 0.53; OR 0.95, P = 0.48), or change in baseline to post-index HbA1c values (OR 1.14, P = 0.14; OR 0.95, P = 0.60). Adjusted mean costs were also not significantly different between lispro and aspart cohorts ($26,089 versus $25,939, respectively; P = 0.7781), or between pen and vial cohorts ($25,300 versus $26,626, respectively; P = 0.0511). Although pen users were 27% less likely to discontinue over time relative to vial users (adjusted HR, 0.731; CI, 0.677-0.790; P < 0.0001), there was no difference in risk of discontinuation over time between the lispro and aspart cohorts.

CONCLUSIONS: Little to no differentiation was found between rapid-acting insulin products or pen and vial presentations. While it may be ideal for research to uncover differences that are both clinically and statistically significant, similarity of products can also be used as a consideration for formulary offerings.

SPONSORSHIP: Comprehensive Health Insights.

E36 Assessment of Glycosylated Hemoglobin (HbA1c) in Patients with Type 2 Diabetes Mellitus (T2DM) Initiating Alogliptin and Pioglitazone (AP) Combination Therapy

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BACKGROUND: Co-administration of alogliptin, a dipeptidyl peptidase-4 inhibitor, and pioglitazone, a thiazolidinedione (TZD) has resulted in HbA1c improvements in patients with T2DM in clinical trial settings. Real-world evidence on the effectiveness of AP is sparse.

OBJECTIVE: To assess HbA1c control post AP initiation using real-world data.

METHODS: This retrospective study used IMS’s ambulatory electronic medical records database, which comprises 26 million patients. The study sample consisted of patients with T2DM aged ≥ 18 years who initiated AP between 2/1/2012 and 6/30/2015. Patient inclusion required ≥ 1 pre-index and 1 post-index HbA1c result, with the post-index measure ≥ 3 months after AP initiation, and with ≥ 90 days of AP prescription orders.

RESULTS: A total of 204 patients were available for analysis. The mean age was 58.3 years (SD = 11.9) with 60.8% being male. The most frequently observed baseline comorbidities were hypertension (66.7%) and dyslipidemia (57.8%). The mean body mass index at baseline was 33.0 kg/m² (SD = 6.0). During the pre-index period, more than one quarter of the cohort (n = 54, 26.5%) had orders for ≥ 3 anti-diabetic (AD) agents of interest, with metformin (n = 87, 42.7%), sulfonylureas (n = 39, 28.9%) and TZDs (n = 35, 27.8%) being the most common. Average length of prescription orders for AP therapy was 177.6 days (SD = 10.1) out of the 180-day post-index period. In addition to AP, most patients (n = 170, 83.3%) had post-index orders for another AD. Mean HbA1c values were significantly reduced post-index (from 8.7% to 7.9%, P < 0.0001) with an absolute HbA1c decrease of ≥ 0.5% seen in 78.3% (n = 112) of the sample. Almost half (49.6%) of all patients that failed to meet the Healthcare Effectiveness Data and Information Set (HEDIS) HbA1c target for glycemic control (i.e., HbA1c < 8%) during the pre-index period went on to meet the goal after AP initiation (P < 0.0001). HbA1c decreases were larger in patients with higher pre-index values, with a mean HbA1c decrease of 1.6 (SD = 2.0) in those with pre-index HbA1c of ≥ 9% (P < 0.0001).

CONCLUSIONS: This real-world study demonstrates significant reductions in HbA1c and glycemic control after initiating AP.

SPONSORSHIP: This study was funded by Takeda Pharmaceuticals U.S.A.

E37 All-Cause Healthcare Utilization and Costs Among Type 2 Diabetes Mellitus Adults with Cardiovascular History

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BACKGROUND: Multiple studies have reported that Type 2 Diabetes Mellitus (T2DM) is a major risk factor for Cardiovascular Diseases (CVD), and presence of both T2DM and CVD increases risk of death. There is growing interest in examining the effects of antidiabetic treatments on the reduction in CV events in T2DM adults with a history of CVD and thus at higher risk of CV events.

OBJECTIVE: To estimate the incremental all-cause healthcare utilization and total healthcare costs among T2DM adults with a history of CVD relative to those without history of CVD.
METHODS: Using nationwide administrative claims and EMR databases, adults (≥18 years) with evidence of at least one claim or medical encounter with a diabetes-related ICD-9 diagnosis code or anti-diabetic medication (earliest occurrence defined as index) in calendar year 2012 were identified. All adults were required to have coverage 12-months pre-index as well as at least 30-days post. Based on evidence of CVD (myocardial Infarction, ischemic stroke, unstable angina, transient Ischemic attack or coronary revascularization procedures) in the 12-months pre-index period, the population was divided into two cohorts (with and without CVD history). Multivariable generalized linear models were used to assess differences in healthcare utilization and total costs between the two groups during one-year post-index, adjusting for important demographics and clinical characteristics.

RESULTS: A total of 138,018 adults with T2DM were identified, of which 16,547 (12%) had CVH history. The T2DM adults with CVH history were older than those without CVH history (67 vs. 58 years, P value: <0.0001). The prevalence of comorbid conditions and concomitant medication use were significantly higher in CVH history group. The models revealed that adults with CVH history had 31% higher number of ER visits (Risk Ratio [RR], 1.31, 95% Confidence Interval [CI], 1.25-1.37), 27% more inpatient visits (RR, 1.27, 95% CI, 1.21-1.34), 15% higher mean inpatient days (RR, 1.15, 95% CI, 1.06-1.25) and 11% higher outpatient visits (RR, 1.11, 95% CI, 1.09-1.13). Furthermore, the difference in total healthcare cost was found to be 16% higher in CVH history group (RR, 1.16, 95% CI, 1.13-1.19).

CONCLUSIONS: The findings highlight the association between CVH and healthcare resource utilization and costs among adults with T2DM. Given increasing prevalence of adults with T2DM, the current study underscores the importance of interventions that may reduce economic burden of CVH in this population.

SPONSORSHIP: Boehringer-Ingelheim.

E39 Achievement of Individualized Glycemic Targets and Cost-Effectiveness: Comparison Between Two Insulin Delivery Methods in Patients with Diabetes

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BACKGROUND: Intensified insulin therapy (IIT) can provide tight glycemic control and reduce the risk of diabetes complications impacting health care costs. When basal-only insulin regimens are insufficient to achieve glycemic control, insulin therapy is often intensified to include prandial insulin. IIT is traditionally administered by multiple daily injections (MDI) which can negatively impact adherence. Incorporating less complex insulin regimens that address patient needs may improve treatment effectiveness. V-Go Disposable Insulin Delivery device is a wearable device that administers basal-bolus insulin therapy with one application per day.

OBJECTIVE: To compare the percent of patients that achieved individualized A1C targets and the direct pharmacy cost difference per patient per month (PPPM) between two different insulin delivery methods used to administer IIT.

METHODS: Patients with poor glycemic control (A1C>8%) that were transitioned from basal insulin regimens to IIT administered by V-Go or MDI were identified from a query of electronic medical records at a large multi-center diabetes system. For this analysis, individualized A1C targets (≤6.5%, ≤7.0% or ≤8.0%) were established for each patient based on age, diabetes related complications and comorbid conditions using national recommendations. Direct pharmacy costs were calculated using wholesale acquisition costs and inclusive of insulin (including delivery mode) and concomitant anti-hyperglycemic agents with the exception of generic oral agents.

RESULTS: Ninety-two patients previously administering basal-only insulin ±concomitant agents intensified to include prandial insulin were identified. IIT was administered by V-Go for 46 patients and by MDI for 46 patients. At baseline both groups had the same mean A1C (9.98%), similar basal insulin doses (V-Go 0.52 vs. MDI 0.51 units/kg) and a similar duration of diabetes (V-Go 13 vs. MDI 11 yrs). Individualized A1C target distribution was similar between groups.

Is 80% Proportion of Days Covered a Meaningful Quality Measure Threshold for Glucagon-Like Peptide-1 Receptor Agonist Therapy in U.S. Patients with Type 2 Diabetes? A Retrospective Cohort Study

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BACKGROUND: The threshold of ≥80% Proportion of Days Covered (PDC) for oral antidiabetes medications, an administrative claims-based measure of medication adherence, is used by the Centers for Medicare and Medicaid Services as quality measure for Part D Star Ratings.

OBJECTIVE: To examine whether the ≥80% PDC threshold is a potential meaningful quality measure for glucagon-like peptide-1 receptor agonist (GLP-1RA) therapy by examining its association with healthcare costs, which often increase with adverse health outcomes, in U.S. patients with type 2 diabetes (T2D).

METHODS: This retrospective cohort study used a large U.S. administrative claims database. Patients were included if they had T2D, were GLP-1RA-naïve, initiated GLP-1RA therapy from 2/1/2012–10/1/2012 (date of initiation = index), were aged ≥18 years at index, and had continuous enrollment for 12 months before (baseline) to 12 months after index (follow-up). The PDC for the initiated GLP-1RA was calculated over the follow-up period and patients were classified as either adherent (≥80% PDC) or non-adherent (<80% PDC). The study outcomes were overall (all pharmacy and medical claims) and diabetes-specific (antidiabetes pharmacy and medical claims with diagnoses for T2D) healthcare costs. Multivariable regressions compared the study outcomes between adherent and non-adherent patients, adjusting for potential confounders.

RESULTS: Study sample included 17,275 patients (10,829 initiating liraglutide, 6,446 initiating exenatide [either once weekly or twice daily]). Overall, 5,305 (30.7%) were adherent and 11,970 (69.3%) were non-adherent. In multivariable-adjusted analyses, adherent patients had significantly lower overall medical costs compared with non-adherent patients, ($6,577 adherent vs. $9,011 non-adherent, P<0.001), and diabetes-specific medical costs ($1,989 adherent vs. $2,784 non-adherent, P<0.001). Total healthcare costs were higher for adherent patients than for non-adherent patients ($13,373 adherent vs. $14,604 non-adherent, P=0.003) due to the cost of GLP-1RA therapy ($14,161 adherent vs. $1,825 non-adherent, P<0.001).

CONCLUSIONS: In U.S. patients with T2D newly-initiating GLP-1RA therapy, adherent patients (≥80% PDC for GLP-1RA therapy) had substantially lower overall and diabetes-specific medical costs when compared with non-adherent patients. If medical cost offsets can be interpreted as a proxy measure for improved outcomes in patients with T2D, the ≥80% PDC threshold is indeed a potentially meaningful quality measure for GLP-1RA therapy.

SPONSORSHIP: AstraZeneca.
After a mean of 27 weeks on IIT, overall 43% of patients on V-Go and 33% of patients on MDI achieved established A1C targets. For those patients with an A1C target ≤ 8.0%, a greater portion achieved glycosylated hemoglobin (A1C) and fasting plasma glucose. However, few studies have used U.S.-based data to investigate this statin-associated increased risk of diabetes.

**OBJECTIVE:** To examine whether the use of statins (as a class) increases the risk of incident diabetes mellitus. This is warranted because there are inconsistencies in the findings linking statin therapy to the development of incident diabetes. In addition, the association of each statin type (i.e., atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, and simvastatin) with risk of diabetes was estimated.

**METHODS:** This study was a retrospective cohort analysis utilizing data from the Thomson Reuters MarketScan Commercial Claims Database for the period of 2003-2004. The study population included new statin users who were aged 20-63 years at index and who did not have a history of diabetes. Diabetes risk was estimated using the Cox proportional hazards regression (hazard ratio) and the binary logistic regression (odds ratio). Several sensitivity analyses were conducted including controlling for time-dependent covariates and using propensity score covariate adjustment.

**RESULTS:** The proportion (3.4%) of statin users (N = 53,212) who had incident diabetes was higher compared to the proportion (1.2%) of non-statin users (N = 53,212) who had incident diabetes. Compared to no statin use and controlling for demographic and clinical covariates, statin use was significantly associated with increased risk of incident diabetes (hazard ratio = 2.01, 99% CI = 1.74-2.33, P < 0.0001). In addition, risk of diabetes was highest, respectively, among users of lovastatin, atorvastatin, simvastatin, and fluvastatin. Diabetes risk was lowest among pravastatin and rosuvastatin users.

**CONCLUSIONS:** Because the potential for diabetogenicity differs among different statin types, health care professionals should individualize statin therapy by identifying patients who would benefit more from less diabetogenic statin types.

**SPONSORSHIP:** None.
adherence, and persistence. A majority of the literature on this topic evaluates adult patients with type-2 diabetes. In this study, Partners For Kids (PFK), a pediatric Accountable Care Organization (ACO) affiliated with Nationwide Children’s Hospital, compares the medical utilization consumed by pen and vial users in a pediatric Medicaid managed care population.

**OBJECTIVE:** To compare the medical utilization of pediatric T1DM patients who use insulin vials versus insulin pens.

**METHODS:** Prescription and medical claims were extracted from an ACO database from five contracted Medicaid managed care plans between 10/1/11-6/30/15 (observation period). Patients were identified by presence of >1 insulin claim during this time period. Patients with ≥1 medical claim(s) for T2DM or ≥1 prescription claim(s) for metformin were excluded. Index date for each patient was defined as date of first prescription claim for insulin. Episodes of six or more months of continuous enrollment after index date were queried for medical utilization. Association between medical utilization and months on vial or pen was evaluated using logistic regression models. Medical utilization was defined as an event for the following: ED visits, inpatient visits, and outpatient visits.

**RESULTS:** After adjusting for day supply, the odds of ED visits among vial users was 1.3 times greater than that of pen users ($P < 0.0001$) and odds of inpatient visits among vial users was 1.5 times greater than that among pen users ($P < 0.0001$). In contrast, the odds of outpatient visits among vial users was 0.9 times lower than that among pen users ($P = 0.0023$).

**CONCLUSIONS:** ED visits and inpatient hospital visits were significantly greater in vial users compared to pen users, however, outpatient visits were significantly greater in pen users compared to vial users. As managed care plans make access decisions for insulin pens and vials, this study provides evidence to show a correlation between insulin pen utilization and a reduction in unfavorable healthcare expenditures (ED visits and inpatient hospital stays) and increase favorable healthcare utilization (outpatient provider visits).

**SPONSORSHIP:** Partners For Kids.

**E45** Characteristics and Clinical Outcomes of Patients with Type 2 Diabetes Switching to the New Basal Insulin Glargine 300 U/mL from Other Basal Insulins in the USA

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**BACKGROUND:** The new basal insulin glargine 300 U/mL (Gla-300; Toujeo) has demonstrated efficacy and safety in treating patients with type 2 diabetes (T2D) in randomized clinical trials (EDITION I-III), and entered the U.S. market in February 2015. This retrospective study assessed the effectiveness of Gla-300 in the management of T2D in the real-world clinical setting in the USA.

**OBJECTIVE:** To assess patient characteristics and clinical outcomes of patients with T2D who recently started treatment with Gla-300 (early users) in real-world U.S. treatment settings.

**METHODS:** Data from ambulatory patients with T2D who switched from other basal insulins to Gla-300 (defined as having ≥1 prescription order of Gla-300) were extracted from electronic medical records in the Predictive Health Intelligence Environment database between March 2015 and December 2015. Data were assessed for up to 6 months prior to Gla-300 initiation (baseline), and up to 6 months after Gla-300 initiation (follow-up). Only data from patients with a follow-up period ≥3 months were included in this study. Patients simultaneously prescribed other basal insulin during the follow-up period were excluded. Hypoglycemia events were identified by ICD-9-CM diagnosis codes for hypoglycemia or blood glucose ≤70 mg/dL.

**RESULTS:** Of the 449 patients who switched from other basal insulins to Gla-300, 53.2% were male, and 57.5% were Caucasian. Average age was 59.6 years, and mean body mass index was 35.7 kg/m2. Comorbid hypertension (85%), dyslipidemia (88%), and diabetes-related complications (neuropathy [34%], nephropathy [14%], and retinopathy [11%]) were prevalent. For the group of patients (n = 211) with AIC measures both at baseline and during follow-up, mean AIC was 8.85% in the 6-month period prior to starting Gla-300 therapy. After Gla-300 initiation, there was significant reduction in mean AIC to 8.20%, corresponding to an estimated reduction of 0.63% (95% CI, 0.44, 0.87, $P < 0.0001$) between baseline and 6-month follow-up. A numerical lower percentage of hypoglycemia events was associated with switching to Gla-300 (6.0% vs 5.1%, 3-month baseline vs. 3-month follow-up period, respectively).

**CONCLUSIONS:** In patients with T2D, switching to Gla-300 from other basal insulins was associated with an improvement in glycemic control, and a trend towards less hypoglycemia.

**SPONSORSHIP:** Study funding and writing/editorial support was provided by Sanofi U.S.
BACKGROUND: Cystic fibrosis (CF), a genetic disorder affecting over 30,000 people in the U.S., is associated with significant clinical and economic burden. Previously, there was no single data source that included clinical outcomes, health care utilization (HRU), and costs. Interest in comparative effectiveness and value-based research highlighted the need to develop an integrated data resource.

OBJECTIVE: To describe the demographic and clinical characteristics of CF patients in a linked clinical and administrative claims database and assess insurance and HRU status for this population.

METHODS: Clinical data was obtained from the CF Foundation Patient Registry (CFFPR) and Inovalon’s MORE2 database provided administrative claims. All individuals in the CFFPR between 1/1/2000 and 12/31/2014 were linked with patients with ≥1 CF-related diagnosis claim (ICD-9 code 277.0) in the MORE2 database during the same time period. An IRB approved, deterministic linkage using combinations of first and last name, sex, birth date and current zip code was performed. Demographic and clinical characteristics, insurance status, and HRU were described for the linked database.

RESULTS: The CFFPR had 37,582 patients of which 9,730 were linked with CF patients in the MORE2 database; 8,709 patients in the linked database had overlapping data in CFFPR and MORE2 database of which 6,674 patients were continuously enrolled for ≥1 year; mean duration of continuous enrollment for 8,709 patients was 3.41 (±2.86) years. Mean age for 6,674 patients was 15.6 (±12.8) years, 49% were female, and 93% were white. There was a wide distribution of lung function indicating the inclusion of patients with varying disease severity. Based on the MORE2 data, the majority of 6,674 patients were covered by Medicaid (45.0%) or commercial insurance (33.9%). Almost all of the 6,674 CF patients had at least one outpatient visit (99.8%), 49.7% and 13.0% patients had one or more hospitalizations and home service claims, respectively. Other HRU variables were skilled nursing facility (3.6%) and hospice care (1.4%). Inpatient and outpatient prescriptions claims were available for 29.7% and 88.1% patients, respectively.

CONCLUSIONS: The linked database provides a comprehensive resource for CF research to determine the clinical and economic impact of various treatment approaches. Further work is needed to assess the generalizability of this resource to determine its strengths and limitations for research along with the availability of cost data.

SPONSORSHIP: Cystic Fibrosis Foundation.

E62 An Evaluation of the Burden of Hyperkalemia in the Medicare Population

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BACKGROUND: Epidemiologic, utilization, and cost parameters for Medicare (MDCR) beneficiaries with hyperkalemia (HK) have not been analyzed in large populations. Improving treatment for HK in the MDCR population requires a better understanding of HK clinical and economic burden.

OBJECTIVE: To quantify the burden of HK for MDCR, focusing on prevalence, mortality, medical utilization and cost.

METHODS: This was a descriptiveclaim-based analysis using the 2014 MDCR 5% sample database. Beneficiaries were required to have at least one month of eligibility in 2014, no enrollment in a MDCR Advantage plan and Part A and B eligibility for all months of eligibility. Identification of HK required >1 qualifying claim type (in-person encounter with a medical professional) coded with ICD-9 diagnosis code 276.7 in any position on the claim. Chronic kidney disease (CKD) identification was based on ICD-9 diagnosis codes 585.1-585.5, 585.9. Mortality and eligibility type (aged non-dual, aged dual, disabled, ESRD) were captured using the MDCR eligibility data. Costs represent allowed amounts (MDCR payments to providers and patient cost sharing). Per member (PMPM) or per patient (PPPMP) monthly costs reflect all costs for the respective population divided by the total member months for that population.
**RESULTS:** 1,674,010 MDCR fee-for-service (FFS) beneficiaries met study inclusion criteria and 39,056 beneficiaries were identified with HK (2.3% prevalence rate). HK prevalence varied by eligibility category: 1.9%, 4.0%, 1.6% and 26.4% for aged non-dual, aged dual, disabled and ESRD respectively. Average age of the HK population was 72.9 and 52% were female, compared with total MDCR population average age of 70.3 and 55% female. Prevalence of CKD (including ESRD) among the HK population was 64.8%, while prevalence of HK among the total CKD population was 13.3%. Average HK PPPM cost was $5,645 versus average PPPM cost of $1,035 for the total MDCR population. The annual inpatient admission rate for HK patients was 7 times higher than the total MDCR population: 2,223/1,000 versus 320/1,000, respectively. Among the non-ESRD CKD population, CKD severity-adjusted PPPM costs for patients with HK were $4,922 versus $2,036 for those without HK, or $2,887 higher (P < 0.001). Similarly, mortality was 24.2% for those with HK versus 9.4% for those without HK.

**CONCLUSIONS:** Costs and mortality are higher for non-ESRD CKD patients with HK versus those without HK, which may suggest a significant clinical and economic burden of HK in the MDCR population.

**SPONSORSHIP:** ZS Pharma.

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**E64 Healthcare Resource Utilization (HCRU) and Clinical Characteristics of Medicaid Patients with Cystic Fibrosis (CF)**

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**BACKGROUND:** A significant proportion of patients with CF are covered by government programs for people with low incomes, with U.S. Medicaid being the largest public health insurance provider. While CF is associated with substantial HCRU, limited data exist specifically describing HCRU among patients with CF in Medicaid.

**OBJECTIVE:** To describe the clinical characteristics and HCRU of Medicaid-insured patients with CF.

**METHODS:** A retrospective study using the Truen Health MarketScan Medicaid Multi-State administrative claims database (2010-2014) was conducted. Patients aged ≥6 years with a CF diagnosis who were continuously enrolled for 12 months were identified. Demographics, comorbidities, and HCRU (hospitalizations, ER and outpatient visits, and medication use) over the most recent 12-month enrollment period were analyzed for all patients and stratified by age group.

**RESULTS:** In total, 1,196 patients met the inclusion criteria from a database of approximately 10 million Medicaid patients. Mean age (SD) was 16.1 (8.8) years. A greater proportion of patients were in younger age groups (6-11 [35.5%], 12-17 [29.1%], 18-26 [25.6%], 27-34 [6.7%], and ≥35 years [3.2%]). Common comorbidities identified in claims during the 12-month enrollment period included pulmonary infection (37.8%), asthma (31.7%), sinus disease (27.8%), diabetes (25.5%), and bronchiectasis (19%). Approximately 15% of patients had claims for depression, and 12% had claims for anxiety. Inpatient admissions were reported for 47.2% of patients (with an average length of stay of 10-11 days) and ER visits for 43.5% of patients. On average, patients required 2.8 (2.5) admissions with one quarter (26.8%) of patients experiencing 2 or more admissions during the 12-month period. Patients received an average of 20.2 (12.4) different prescription drugs during the 12-month period. Most patients (90.9%) had used an antibiotic (oral, 88.0%; inhaled, 48.5%; outpatient intravenous, 27.9%). Other commonly used medications were bronchodilators (87.1%), pancreatic enzymes (78.8%), mucolytics (71.5%), corticosteroids (65.1%), medications for gastroesophageal reflux (64.7%), and anti-inflammatory agents (47.2%).

**CONCLUSIONS:** In this analysis, Medicaid patients with CF had substantial comorbid disease burden and HCRU over a 12-month period. Although variations in HCRU were observed across age groups, high rates of hospitalizations and ER visits, along with considerable outpatient and pharmacy HCRU, demonstrate the significant burden of CF on patients in the Medicaid program.

**SPONSORSHIP:** Prime Therapeutics, Eagan, MN.

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**E68 Treatment Patterns Among Patients with Cystic Fibrosis Using Twice Daily Dornase Alfa Regimen**

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**BACKGROUND:** The use of mucolytic agents such as dornase alfa, together with bronchodilators and antibiotics, reduces the risk of
respiratory infections and improves pulmonary function in patients with cystic fibrosis (CF). The recommended dosage of dornase alfa is once-daily (QD), although certain CF patients may benefit from a twice-daily (BID) regimen.

**OBJECTIVE:** To examine the extent of Pulmozyme BID use.

**METHODS:** This retrospective analysis of commercial insurance claims data examined treatment patterns of patients with CF (ICD-9-CM: 277.0x) who initiated BID dornase alfa regimens in the identification (ID) period (1/1/2009-10/31/2011). The first fill date of BID use in the ID period was defined as the index date. Patients not continuously enrolled in the 3 months before or 1 year after (follow-up) the index date were excluded. Baseline characteristics were measured, in addition to BID treatment uptake, duration, and discontinuation in the year following index. We evaluated patterns of use by plotting medication dispensed over time. The analysis was repeated for patients ≥21 years old (n = 89).

**RESULTS:** We identified 170 patients, among 6,815 CF patients (2.5%), with new BID use. Mean (SD) age for BID users was 24 years (14.1), 47.6% were female, and evenly distributed among U.S. regions. Patients had a mean Charlson Comorbidity Index of 1.8 (1.8) and varied rates of comorbidities: diabetes (17.1%), pancreatic insufficiency (71.2%), pseudomonas infection (55.3%), gastroesophageal reflux (14.1%), chronic sinusitis (32.4%), malnutrition (9.4%), osteoporosis (1.8%), and allergic bronchopulmonary aspergillosis (4.7%). Patients initiating BID use received on average 4.2 BID fills (SD: 3.1; median: 3), corresponding to a mean days supply of 132.5 (SD: 109.9; median: 90). Less than half of patients (41.2%) continued BID for 6 months, with even fewer (38.8%) on the regimen at 1 year. Three-month pre-index exacerbation rates were 69.4% for BID users, with a mean of 2.4 (3.5) exacerbations/patient. Three-month follow-up exacerbation rates in this group dropped to 62.4% (a 10.2% decline), with a mean of 2.2 (4.2) exacerbations. Results for patients ≥21 years were similar.

**CONCLUSIONS:** On average, patients continued BID use for about 4 months before switching to QD or stopping. Most patients discontinued BID use by month 6, with a further drop over the remainder of the year. The relatively small uptake of, and later decline in, BID dornase alfa use, whether due to patient or provider factors, suggests access to the dosage regimen may be limited.

**SPONSORSHIP:** Genentech.

**E69 Frequency and Costs of Pulmonary Exacerbations and Association with Percent Predicted FEV1 (ppFEV1) in Patients with Cystic Fibrosis (CF)**

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**BACKGROUND:** Patients with CF experience repeated episodes of worsening respiratory signs and symptoms, known as pulmonary exacerbations (PEX); these events are associated with reduced health-related quality of life and higher mortality risk. Despite the clinical significance of PEX, there is limited information regarding the cost of PEX among patients with CF in the United States.

**OBJECTIVE:** To investigate the frequency and costs of PEX and associations between PEX and lung function (assessed by percent of predicted forced expiratory volume in 1 second, ppFEV1) in patients with CF.

**METHODS:** Chart data were linked to claims from patients with CF aged ≥6 years identified between July 2008 and May 2013 and enrolled for ≥18 months in a U.S. commercial health plan. Claims information from the most recent 12 months (follow-up) were used to calculate outcomes. A PEX was defined based on at least one of the following: inpatient (IP) stay coded ICD-9-CM 277.02 or with ICD-9-CM for respiratory infection, and/or new intravenous (IV) or oral antibiotics administered during IP stay or outpatient setting (chronic use antibiotics were excluded). New PEX required a preceding interval of ≥7 days with no claims meeting PEX criteria. The best ppFEV1 recorded in patient charts during the 6 months prior to the follow-up period (baseline) was used to categorize lung dysfunction as severe (<40% ppFEV1), moderate (40%–70%), or mild (≥70%).

**RESULTS:** A total of 268 patients were included (mean age, 24 years). 88.1% of patients had at least 1 PEX and 48.1% had at least 1 PEX treated with IV antibiotics and/or IP stay (overall rate 2.9/year and 0.87/year, respectively). For any PEX, mean cost was $13.1K and duration was 21 days. For a PEX requiring IV antibiotics and/or IP stay, mean cost and duration was $36.6K and 27 days, respectively; 69% of these required an IP stay, with mean cost of $47.1K. Of 241 patients with available baseline ppFEV1 data, 71.8% were categorized as mild, 23.2% as moderate, and 5.0% as severe. A higher percentage of patients with moderate and severe lung disease had ≥1 PEX and ≥1 PEX requiring IV antibiotics and/or IP stay and incurred higher unadjusted mean annual PEX costs (severe, $119.9K; moderate, $40.8K; mild, $30.1K; P<0.001 for comparison across groups).

**CONCLUSIONS:** The majority of patients with CF experienced at least 1 PEX/year; frequency and costs of PEX increased in patients with a history of lower lung function.

**SPONSORSHIP:** Vertex Pharmaceuticals.

**E71 Correction of the Underestimation of Statin Utilization Metrics in a Typical Administrative Claims Dataset Through Augmentation with the IMS Retail Prescription Point of Sale Database**

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**BACKGROUND:** Statin non-adherence has been cited as a major challenge to optimal lipid management, with many studies reporting 1-year drop-out rates of approximately 50%. Most of these analyses have used fully-adjudicated administrative claims datasets with information on paid prescriptions. These databases can only report on medications that are submitted to and adjudicated via a claims-based system. Many pharmacy outlets offer low cost generic prescriptions for cash pay, which if not captured in health plan claims datasets, could lead to systematic underestimation of statin adherence metrics.

**OBJECTIVE:** To estimate how augmenting traditional health plan claims data with point of sale pharmacy data would change estimates of statin use.

**METHODS:** The PharMetrics Plus (P+) claims dataset was linked to an IMS open source pharmacy point of sale database (LRx) capturing >85% of all outpatient prescriptions, to evaluate potential under-reporting of statin use. Patients with ≥1 statin claim (index) in P+ between January 1, 2012 and December 12, 2014 (study period) that could be linked between datasets, were identified. Patients in P+ had to have ≥12 month’s pre and post-index continuous eligibility, while patients in LRx were required to use pharmacies consistently reporting data over the study period. To augment P+, all statin claims in LRx were identified during the study period. Statin utilization in P+ was then compared to utilization when the P+ database was augmented with data from LRx. The impact of missing statin claims in P+ was assessed on measures of new to therapy (using a 12 month washout) and adherence (using a 12 month medication possession ratio (MPR).

**RESULTS:** There were 893,519 statin using patients in P+ qualified for the analysis. Mean age was 56.6 years and 57% were male. In P+, 263,805 (29.5%) had ≥1 missing post-index statin claims using the
augmented analysis, while 16.2% were misclassified as non-statin users in P+. In P+, 16.6% of patients were misclassified as new statin user. Adherence was underestimated in the P+ claims only analysis versus the augmented analysis: 76.2% vs. 80.1% (P < 0.0001) for all patients and 58.9% vs. 62.7% (P < 0.0001) for patients new to therapy.

CONCLUSIONS: Traditional health insurance claims databases may systematically underreport statin utilization. This study found a sizeable portion of patients with missing statin data in the health plan claims-only analysis. Augmenting health plan claims with point of sale data has the potential to provide a more accurate assessment of statin utilization metrics.

SPONSORSHIP: Amgen.

F05 Follow-up Care After Psychiatric Hospital Admission for Medicaid and Commercially Insured Patients with Schizophrenia or Bipolar Disorder

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BACKGROUND: Evidence suggests that over forty percent of patients with serious mental illness do not receive timely outpatient mental health follow-up care after hospital discharge.

OBJECTIVE: To examine rates and predictors of follow-up care among Medicaid and commercially insured inpatients with schizophrenia or bipolar disorder.

METHODS: A retrospective cohort analysis of MarketScan Commercial (2010-Q3 2014) and Medicaid (2010-2013) databases was conducted. Rates of outpatient follow-up care at 7 and 30 days following hospital discharge for adults with schizophrenia or bipolar disorder were determined. Outpatient follow-up care was defined as the percentage of patients with an outpatient visit, an intensive outpatient encounter or a partial hospitalization with a mental health provider within 7 or 30 days of discharge. Separate logistic regressions for each diagnostic group estimated odds of 30-day outpatient follow-up care in relation to age, sex, insurance type, length of stay, and several pre-hospital (within 120 days prior to the hospitalization) mental health and pharmacological treatment variables.

RESULTS: This study included 27,929 inpatients with schizophrenia and 50,660 inpatients with bipolar disorder. The 7- and 30-day follow-up rates were 47.3% and 71.0%, respectively, for commercially insured inpatients with schizophrenia or bipolar disorder, and 39.5% and 63.0%, respectively, for Medicaid insured inpatients. Regression results showed that 30-day follow-up care was most strongly related to having seen a mental health provider during the 120-day pre-hospital period (schizophrenia model: odds ratio [OR] = 3.4, 95% confidence interval [CI] = 3.0-3.7/bipolar model: OR = 2.6, 95% CI = 2.4-2.8), and not having received a substance use disorder diagnosis (schizophrenia model: OR = 1.3, 95% CI = 1.4-1.6/bipolar model: OR = 1.3, 95% CI = 1.5-1.6).

CONCLUSIONS: Rates of 7- and 30-day follow-up care among Medicaid insured patients with serious mental illness using real-world data were consistent with reported national rates (43.9% and 63.0%, respectively) in 2014. Across diagnostic groups, patient connectedness to systems of care was the strongest predictor of treatment continuity following discharge. More assertive discharge planning is needed for patients with serious mental illness who do not have recent connections to outpatient care.

SPONSORSHIP: This study was funded by Sunovion Pharmaceuticals.

F07 Controlled Substances Triple Threat Overlapping Days: Relationship with Healthcare Utilization and Costs

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BACKGROUND: Concurrent use of (1) opioids, (2) benzodiazepines/nonbenzodiazepines sedative/hypnotics, and (3) muscle relaxants (triple threat) may increase the risk of overdose and death. However, there is a paucity of data quantifying the number of triple threat overlapping days and negative outcomes.

OBJECTIVE: To examine the association between the number of consecutive triple threat overlapping days with health care utilization (i.e., hospitalizations [hosp] and emergency department [ED] visits) and total cost of care.

METHODS: We used pharmacy and medical claims from over 15 million commercial members from across the U.S. Members were required to be continuously enrolled in 2013 through 2014 and 19 or older on 12/31/13. For members with at least one triple threat overlap day in 2013, all 2014 pharmacy and medical claims were evaluated to examine the association between the number of consecutive overlap days with health care use and total cost of care. A logistic regression model was used to measure the association. Total cost of care was analyzed using a generalized linear model with gamma distribution. Both models were adjusted for the following 2013 covariates: age, gender, Charlson Comorbidity Index score, number of unique drugs, number of prescribers and pharmacies used, ZIP code derived: race, education, and income; hosp, ED and office visits; and total cost of care.

RESULTS: Approximately 9 million members were continuously enrolled for 2 years and 34,775 (0.4%) had at least one day of triple threat overlap in 2013. 18,114 (52%) members had 1-20 consecutive days overlap (reference group), 8,528 (25%) 21-30 days, 5,696 (16%) 31-90 days and 2,437 (7%) 91+ days. Members average age was 50 and 32.2% were male. We found a statistically significant trend between number of triple threat days and higher hosp, ED visits, and total cost of care which remained after covariate adjustment. In multivariate models beginning at 21+, consecutive triple threat days were statistically significantly (P < 0.01) associated with higher total cost of care (Relative Risk [RR] 1.2, 95% confidence interval [CI] 1.1-1.2); with the statistically significant association beginning at 31+ triple threat days for hosp (RR 1.2, 95% CI 1.1-1.3) and ED visits (RR 1.2, 95% CI 1.1-1.2).

CONCLUSIONS: This analysis demonstrated that the number of consecutive triple threat overlapping days is associated with higher healthcare utilization and total health care costs. Insurers should improve and develop clinical programs aimed at decreasing triple threat use and days.

SPONSORSHIP: Prime Therapeutics, Eagan, MN.

F11 Subdermal Buprenorphine Implants Improve Societal Outcomes and Patient Morbidity and Mortality Relative to Sublingual Buprenorphine: Results of a Markov Model

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Outcomes and Patient Morbidity and Mortality Relative to Sublingual Buprenorphine: Results of a Markov Model.
BACKGROUND: Agonist therapy reduces cravings and relapse risk during recovery from opioid dependence. Fewer relapses equate to reduced societal consequences such as illicit drug use, disease transmission, criminal activity, mortality, and harm to community members. Sublingual buprenorphine-naloxone (SL-BPN), the standard-of-care in outpatient opioid dependence treatment, lacks intrinsic safeguards from diversion and non-adherence. Investigational subdermally implanted buprenorphine (Bl, Probuphine) was more effective than SL-BPN in Phase-3 clinical trials, including a large double-blind, double-dummy trial in stable opioid-dependent patients. The extent that these clinical benefits translate into meaningful societal benefits has not been previously quantified.

OBJECTIVE: To assess the benefits of SD-BP from a societal perspective.

METHODS: Using Phase 3 clinical trial data of Bl versus SL-BPN, a Markov model simulated monthly progression of nationally-representative cohorts through 5 health-states for 6 months: on agonist therapy (1) with and (2) without illicit drug use, discontinued therapy (3) with and (4) without illicit drug use, and (5) death. Each cycle applied health-state- and time-dependent risks of: opioid diversion and misuse, illicit drug use, accidental pediatric exposure, detox program entry, and death (suicide/drug-related non-suicide). Cohorts were derived from state-specific, agonist treatment utilization data. Model robustness was assessed by univariate and probabilistic sensitivity analyses.

RESULTS: Bl was associated with an overall 45% reduction in treatment failure over 6 months of treatment. Modeled reductions in societal-level consequences were: opioid diversion and misuse (-92%), illicit drug use (-45%), accidental pediatric exposure (-98%), detox program entry (-80%), and drug-related death/suicide (-24%). A State-wise comparison demonstrated the greatest benefits for Pennsylvania and the fewest benefits for Idaho.

CONCLUSIONS: Benefits of Bl vs. SL-BPN included improved morbidity/mortality and improved societal-level outcomes. Benefits were largely driven by the relative difficulty of diverting an implantable formulation. Patient-level benefits may be driven by the increased adherence and pharmacokinetico profile of the implants. While these results should be confirmed in subsequent studies, it can be conservatively concluded that Bl treatment used for stable opioid dependent patients will have a positive societal benefit beyond the current standard of care.

SPONSORSHIP: Braeburn Pharmaceuticals.

F15 Healthcare Cost Burden of Opioid Abuse Among Employees with Injury-Related Workers Compensation or Short-Term Disability Events: A Retrospective, Observational Cohort Study

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BACKGROUND: Injuries often result in the use of opioid medication for pain management. Little information exists regarding the patterns and healthcare cost consequences of opioid abuse among employees with injury-related workers' compensation (WC) or short-term disability (STD) events.

OBJECTIVE: To (a) describe opioid use patterns and (b) compare healthcare costs between employees with vs. without evidence of opioid abuse among employees with an injury-related WC or STD event.

METHODS: Retrospective, observational cohort study based on U.S. insurance claims data linked to administrative data on WC/STD events (MarketScan). Employees were selected for study if they initiated an injury-related WC or STD event (identified via diagnosis coding on WC/STD event claims) between 1/1/2004-12/31/2012 (date of first WC/STD claim = index) and had continuous insurance enrollment for 6 months before (baseline) to 12 months after (follow-up) index. An ‘opiod user’ sample comprised employees with ≥1 prescription for opioid medication within 30 days before, to 90 days after, index. Opioid users were classified as ‘abusers’ if they had ≥1 non-diagnostic medical claim with a diagnosis (ICD-9-CM 304.0x, 304.7x, 305.5x, 965.00, 965.02, 965.09) of opioid abuse or opioid dependence during follow-up and as ‘non-abusers’ otherwise. Outcomes measured during follow-up were opioid utilization and healthcare costs. Multivariable models compared healthcare costs in abusers vs. non-abusers, adjusting for potential confounding variables.

RESULTS: Study included 137,593 employees with an injury-related WC event, of whom 35,967 (26%) were opioid users; for STD, these figures were 102,113 and 72,008 (71%). Among opioid users, 189 and 386 were abusers in the WC and STD cohorts, respectively. In both the WC and STD cohorts, hydrocodone was the most commonly-prescribed opioid (74% in STD 73% in WC). The mean number of prescription fills for opioids was substantially greater in abusers vs. non-abusers (13.4 vs. 4.5, P < 0.001 in WC; 13.7 vs. 4.5, P < 0.001 in STD). Mean adjusted total healthcare costs were also substantially greater in abusers vs. non-abusers ($18,073 vs. $8,470, P < 0.001 in WC; $23,693 vs. $14,939, P < 0.001 in STD). Predicted abuse risk-based sensitivity analyses intended to address low sensitivity for identification of opioid abuse were confirmatory.

CONCLUSIONS: Opioids are commonly prescribed to individuals with injury-related WC/STD events. The excess healthcare costs of opioid abuse to employers are substantial. Employers may benefit from proactively addressing the issue of opioid abuse in these populations.

SPONSORSHIP: Purdue Pharma L.P.; Analysis Group

F16 Drivers of Excess Costs Associated with Opioid Abuse Among Commercially Insured Patients

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BACKGROUND: Prior research has documented that diagnosis of abuse, dependence, and poisoning/overdose (hereinafter referred to as “Abuse”) of prescription opioids are associated with substantial excess medical costs in commercially insured patients. However, little is known about the specific drivers of these excess costs.

OBJECTIVE: To assess drivers of excess medical costs among commercially insured patients diagnosed with opioid Abuse.

METHODS: We analyzed data from OptumHealth, a large national commercial claims database. We selected patients ages 12-64 with a diagnosis of opioid abuse, dependence, and/or poisoning/overdose [ICD-9-CM diagnosis codes: 304.0x, 304.7x, 305.5x, 965.00, 965.02, 965.09] and matched them to similar patients (1:1) without such diagnoses using propensity score methods. We examined healthcare costs over a 1-year observation period centered on the first abuse diagnosis date and assessed the 15 most costly 3-digit ICD-9-CM diagnosis code groupings overall and by place of service: inpatient, emergency department (ED) and outpatient/other.

RESULTS: 1-year mean medical costs were $17,518 for patients diagnosed with opioid Abuse and $7,671 for matched controls (N = 7,658 pairs), resulting in mean excess costs of Abuse of $9,847 (2012 US$).
Excess costs were observed across all places of service: outpatient/other (41%), inpatient (36%), and ED (23%). Treatment specific to opioid abuse, dependence, and poisoning/overdose accounted for $2,536 of excess costs. Other drivers of excess medical costs included: (1) $1,680 for treatment associated with non-opioid drug abuse and dependence and alcohol dependence; (2) $1,031 for mental health-related diagnoses (i.e., episodic mood disorders, drug-induced mental disorders, and depression); and (3) $808 for intervertebral disc disorders and other/ unspecified disorders of back of excess medical costs. Results were largely consistent across place of service.

CONCLUSIONS: Opioid Abuse is associated with substantial excess medical costs. The largest driver of excess costs is treatment for opioid abuse/dependence/poisoning. The second largest driver is treatment for conditions known to be associated with opioid Abuse: other substance abuse and mental health conditions. The third largest driver, treatment for back disorders, could represent differences in patient severity (i.e., residual confounding) or drug-seeking behavior reflected in unspecified back pain diagnoses, although data was not collected to assess this. These results support the need for continued efforts to detect, deter and treat opioid Abuse.

SPONSORSHIP: This research was funded by Purdue Pharma L.P.

F18 Impact of a Concurrent Drug Utilization Review Edit Designed to Curb Opioid Misuse
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PROBLEM DESCRIPTION: In 2013, CMS implemented the opioid Overutilization Monitoring System (OMS) to identify potential overuse. The OMS targets those using more than 120mg Morphine Equivalent Dose (MED) daily for at least 90 consecutive days with > 3 prescribers and > 3 pharmacies for their opioids during a 12 month period. Part D sponsors are expected to case manage OMS identified members. Although there has been a substantial decrease in the number of members identified as potential opioid over utilizers, opportunity still exists to curb opioid overuse before OMS and decrease case management.

GOAL: To assess the effectiveness of a concurrent drug utilization review (DUR) edit designed to alert pharmacists of potential opioid abuse/misuse (OPMISUSE).

PROGRAM DESCRIPTION: The OPMISUSE edit was implemented in one Medicare plan and identified members who, over a 180 day period, used more than 100mg MED per day for at least 60 consecutive days with > 2 prescribers and > 2 pharmacies for their opioids. On October 30, 2015, the edit was set to “soft reject” claims to alert pharmacists to potential opioid overdose by their patient; pharmacists could override the reject. The data capture period for the analysis was October 30, 2015 to December 4, 2015. Member behavior following the edit was examined to determine any impact and cross over with the OMS member list. Call center data were used to assess impact (i.e., complaints) on members and network pharmacies.

OBSERVATIONS: In the first 35 days, the OPMISUSE edit identified 16 members (0.02%). Four of the 16 members’ claims were not rejected; these 4 members had previously been assessed through case management after OMS reports, and overrides had been applied. Two members with rejected claims did not subsequently attempt to fill an opioid. For two other members, claims were subsequently delayed until the edit did not apply. For the remaining 8 members, pharmacists submitted the appropriate ‘prescriber consulted’ override codes. All 12 members not exempt (75%) had not yet been identified by the OMS. The plan has not received any complaints from providers or members.

FINDINGS/RECOMMENDATIONS: A concurrent DUR opioid misuse edit was effective at delaying or stopping opioid prescriptions for members with potential overutilization. The edit identifies members at the time they are trying to submit their opioid prescription and before the majority were identified by the OMS. Prevention and detection of opioid overutilization is a high priority for health insurers. Early pilot results suggest continued use of the edit may help reduce the number of members identified for case management.

SPONSORSHIP: This research was funded by Purdue Pharma L.P.
Real-World Dosing Patterns Among Patients Receiving Buprenorphine for Opioid Dependence in the United States

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BACKGROUND: Buprenorphine maintenance treatment of opioid dependence requires individualized dosing. Treatment guidelines and product labeling suggest optimal dosing will be in the range of 12-24 mg/day, after titration, for most patients.

OBJECTIVE: To examine real-world buprenorphine dosing patterns among opioid dependent patients.

METHODS: Patients of any age with ≥1 buprenorphine outpatient pharmacy claim were selected from the MarketScan Commercial and Medicaid databases (2008-2014). The date of the earliest claim was the index date. Patients were required to have no claims for buprenorphine in the 3 months pre-index, a claim with a diagnosis of opioid dependence prior to or on the index date, and continuous enrollment with medical and pharmacy benefits for the 6 months pre- and post-index. Buprenorphine average daily dose was calculated from all buprenorphine claims in the first 6 months post-index. Patient and clinical characteristics were examined during a 6 month pre-index period and compared by dose groups.

RESULTS: A total of 22,563 Commercial and 7,811 Medicaid patients were included in the study. In the Commercial sample, 39% of patients received an average daily dose of buprenorphine <12 mg, 57% received 12-24 mg, and 4% received >24 mg. In the Medicaid sample, 24% received <12 mg/day, 70% received 12-24 mg/day, and 6% received >24 mg/day. In both the Commercial and Medicaid samples, higher rates of baseline alcohol use disorder, substance use disorder (other than opioids), schizophrenia, and depressive disorders were observed in those receiving <12 mg/day compared to the patients receiving 12-24 mg/day (all P<0.05). Consistent with the comorbidities observed, patients receiving <12 mg/day had significantly higher use of sedative/hypnotics, antidepressants, and antipsychotics than those receiving 12-24 mg/day. Commercial patients receiving <12 mg or >24 mg had higher use of narcotic pain medication than those dosed at 12-24 mg while those receiving >24 mg had higher rates of benzodiazepine and sedative/hypnotic use than those receiving 12-24 mg (all P<0.05), but this was not observed in the Medicaid sample.

CONCLUSIONS: The majority of patients with opioid use disorder received 12-24 mg/day of buprenorphine, but about one-fourth of Medicaid and one-third of Commercial patients received lower doses. Higher rates of mental health comorbidities were observed in patients receiving lower doses. Future research is needed to assess if these patients are being underdosed or optimally treated.

SPONSORSHIP: This study was funded by Indivior.

Antipsychotic Users to Long-term Injectables

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BACKGROUND: Maintaining appropriate levels of therapy are critical when treating psychosis with antipsychotic (AP) therapy in order to avert expensive relapses. Poor medication adherence is one of the major barriers to maintenance of AP therapy. Long-acting injectable APs have been promoted as one method of addressing poor adherence and improving patient outcomes. However, long-acting injectables are considerably more expensive than oral APs and this differential will only become greater as more generic oral products become available.

OBJECTIVE: To assess the association between poor adherence with oral AP medications and the likelihood physicians will switch patients to long-acting injectable APs.

METHODS: A retrospective case-control study was conducted using Mississippi Medicaid administrative claims data from January 1, 2013 through June 30, 2013. Cases were identified as beneficiaries initiating therapy with oral APs and switching to injectable APs after 6 months or more. The date of switching was considered the index date.

A Comparison of Characteristics, Health Resource Utilization, and Costs of Dual Medicare-Medicaid and Medicare-Only Eligible Patients with Schizophrenia

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BACKGROUND: Patients with schizophrenia have a high prevalence of comorbidities and utilize large quantities of healthcare resources. The majority of patients with schizophrenia are insured by Medicare, Medicaid, or both (dual eligible). Current data on the burden of comorbid disease, health resource utilization (HRU), and healthcare expenditures among dual eligible (DE) patients with schizophrenia are sparse.

OBJECTIVE: To compare demographic and clinical characteristics including the prevalence of medical and mental health-related comorbidities among DE and Medicare-only (MO) insured patients with schizophrenia and to compare HRU and healthcare expenditures by site of care.

METHODS: A cross-sectional analysis was conducted of patients diagnosed with schizophrenia (first diagnosis as the index date) with at least 12 months of either dual or MO enrollment. Patients with any dual enrollment during the study period were classified as DE. The first 12 months of post-index experience were used to descriptively contrast the DE and MO populations. Full DE and MO populations were analyzed, thus statistical comparisons were not needed.

RESULTS: A total of 171,544 (86.8%) and 26,186 (13.2%) DE and MO patients were included, respectively. A greater proportion of MO patients were aged 65 and older (29.8%) compared with DE patients (20.8%). Dementia (10.1%), chronic obstructive pulmonary disease (14.0%), and diabetes (25.7%) were more prevalent among DE patients versus MO patients (6.8%, 8.5%, and 20.6%, respectively). Substance abuse (3.3% vs. 2.1%), schizoaffective disorder (28.7% vs. 19.3%), and bipolar disorder (15.3% vs. 12.2%) were also more prevalent among DE versus MO patients. HRU was consistently greater among DE patients. Nearly a quarter (22.8%) of DE patients utilized inpatient services, compared with 18.0% of MO patients. Almost thirty percent of DE patients had a long-term facility stay (29.8%), compared with 10.1% of MO patients. Mean annual expenditures were roughly $4,000 larger for the DE patients compared with MO ($14,987 vs. $10,907). This difference was mainly driven by acute hospital, psychiatric hospital, and skilled nursing facility expenditures which were $3,452, $3,908, and $2,215, respectively, among DE patients and $2,289, $3,479, and $772, respectively, among MO patients.

CONCLUSIONS: The burden of co-morbid conditions was considerable among patients with schizophrenia and was incrementally larger for DE patients. This difference in disease burden translated into higher annual expenditures, driven by costs of inpatient and skilled nursing services.

SPONSORSHIP: Janssen Scientific Affairs.

Medication Adherence as a Predictor of Switching Oral Antipsychotic Users to Long-term Injectables

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Dual-eligible and long term care beneficiaries were excluded. Cases were matched with controls (beneficiaries not using injectables) based on the month they started oral therapy and were assigned the index date of the matched case. A 1:2 match was performed using the Mayo greedy match algorithm. Adherence to oral AP therapy was computed for the 6-month period before the index date. Multivariable logistic regression was used to assess the association between adherence and likelihood of switch to injectable therapy while controlling for other factors.

**RESULTS:** The final sample consisted of 435 cases and 870 controls. 71% of cases had poor adherence as compared to only 28% of the matched controls. After adjusting for age, gender, race, and other comorbidities, beneficiaries with poor medication adherence were 7 times more likely to be switched to injectable therapy as those with good medication adherence (Odds Ratio = 7.027, 95% Confidence Interval 5.326-9.272).

**CONCLUSIONS:** The results indicate that poor medication adherence is a strong predictor of physicians switching patients on APs to injectable therapy. Considering the higher cost of injectable APs, it may be more cost-effective to address poor adherence through a patient management program. Managed care plans could use medication adherence measures to prospectively identify patients for enrollment in such programs or could make failure in a patient management program a prerequisite for switching to injectable APs.

**SPONSORSHIP:** Mississippi Division of Medicaid.

**F24 Evaluation of Long-Acting Injectable (LAI) Antipsychotic Medications in Medicare Beneficiaries: A Utilization Review and Cost Analysis**

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**BACKGROUND:** The LAI antipsychotic medications were developed to improve adherence, which can be a major challenge in patients with schizophrenia. While the LAI antipsychotics may improve compliance and reduce relapse and rehospitalization, high acquisition and administration costs present a challenge to payers. Debate continues regarding medication coverage responsibilities by medical or pharmacy benefits, secondary to significant, complex differences between the two benefit programs.

**OBJECTIVE:** To gain insight into cost and prescribing trends associated with LAI antipsychotic medication use in the Medicare population using the Centers for Medicare and Medicaid Services (CMS) claims data for 2013.

**METHODS:** This study was conducted using the publicly available Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use File (PUF) and the Physician and Other Supplier PUF datasets. LAI medication claims were identified by drug name and HCPCS code for Part D and Part B, respectively. Medications were grouped in low-cost or high-cost categories using a threshold of $200 Medicare spend per month, based on average selling price (ASP) and recommended dosage range and frequency. Low-cost medications were haloperidol decanoate and fluphenazine decanoate. High-cost medications included the newer, second-generation agents: risperidone microspheres, paliperidone palmitate, aripiprazole monohydrate, and olanzapine pamoate.

**RESULTS:** Total Medicare spend on LAI antipsychotics in the study population was $667 million, 99% of which was under Part D. For both Part B and Part D, paliperidone palmitate represented the highest total drug spend ($384 million), followed by risperidone microspheres ($243 million). Utilization varied by Medicare benefit program. For Part B, haloperidol decanoate (59%) had the highest utilization by beneficiary count, versus paliperidone palmitate (44%) for Part D.

**CONCLUSIONS:** The study findings suggest a notable difference in utilization of high-cost versus low-cost medications between benefit programs. Total Medicare spend is dominated by the newer, high-cost, second generation agents for both benefit programs. However, utilization trends vary by program with the lower cost medications making up a much larger percentage of Part B utilization (85%) vs. Part D (36%). For Part B and Part D respectively, high-cost medications accounted for (15% vs. 64%) of utilization and (82% vs. 97%) of spend.

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


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**BACKGROUND:** Studies examining the impact of paliperidone palmitate (PP) in schizophrenia patients with limited antipsychotic (AP) exposure in the prior 12 months are few.

**OBJECTIVE:** To compare healthcare resource utilization and costs in veterans with schizophrenia treated with PP versus oral atypical antipsychotics (OAA) who were previously exposed to 0 or 1 AP in the prior 12 months.

**METHODS:** Veterans Health Administration electronic health record data were used to conduct a retrospective longitudinal study among veterans with schizophrenia newly treated with PP or OAA between 1/1/10-6/30/15 (date of first dispensing defines the index date), with ≥12 months of enrollment prior to treatment initiation (defines the baseline period), and with exposure to 0 or 1 AP agent and ≥1 Global Assessment of Functioning (GAF) score during the baseline period. Inverse probability of treatment weighting (IPTW) was used to adjust for baseline differences. Weighted regression models were used to estimate adjusted cost differences (CD) and incidence rate ratios (IRR) for the effect of PP versus OAA on all-cause healthcare costs and resource utilization during the 12 months post-index. Bootstrapped P values and confidence intervals were computed for CD. A sensitivity analysis was performed in patients with exposure to only 1 AP during baseline. No adjustment was made for multiplicity.

**RESULTS:** Of the total 6,441 veterans included in the study, 590 (9.2%) and 5,851 (90.8%) were treated with PP and OAA, respectively. The distribution of baseline covariates in the PP (weighted n = 3,024) and OAA (weighted n = 3,417) cohorts was well-balanced after applying IPTW. After adjustments, PP was associated with significantly fewer inpatient stays (IRR=0.90, P<0.001), mental health stays (IRR=0.80, P<0.001), long-term care stays (IRR=0.55, P<0.001), but a greater number of mental health intensive case management (MHICM) visits (IRR=1.10, P<0.001) compared to OAA. These reductions in resource utilization associated with PP resulted in lower average annual inpatient stay costs (CD=-$15,454, P<0.001), which offset higher average annual total pharmacy costs (CD=$3,498, P<0.001), resulting in a significant annual total cost savings (CD=-$10,042, P=0.032) for PP users relative to OAA users. Similar results were found in patients with 1 AP at baseline.

**CONCLUSIONS:** Treatment with PP was associated with a significant cost savings relative to OAA as a result of fewer hospitalizations among
patients with schizophrenia who received 0 or 1 AP agent during baseline.

SPONSORSHIP: Janssen Scientific Affairs.

F26 Regional Differences in HEDIS Measure Results for Schizophrenia Treatment Adherence in State Medicaid Programs

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BACKGROUND: Following methodology for the Healthcare Effectiveness Data and Information Set (HEDIS) measure of “Adherence to Antipsychotic Medications for Individuals with Schizophrenia (SAA)”, this study estimated the proportion of Medicaid beneficiaries with schizophrenia who are adherent to antipsychotics (APs) across state Medicaid programs.

OBJECTIVE: To examine variation in AP adherence and identify predictors of improvement in adherence and decreased inpatient utilization and cost.

METHODS: Analyses utilized claims data from 25 state Medicaid programs from 2006 to 2010. Patients were aged 19-64 years, with ICD-9-CM diagnosis code of 295.xx (excluding 295.4x and 295.7x) on ≥1 inpatient or ≥2 outpatient claims at least 30 days apart. Adherence was analyzed separately for each measurement year using proportion of days covered (PDC) methodology. Patients with a PDC≥0.80 were considered adherent. Multivariable logistic regression was used to assess predictors of nonadherence using patient-level data for measurement year 2010. In addition, we analyzed state-level aggregated data (n=25) for patients with ≥12 months of follow-up available after the schizophrenia diagnosis to assess predictors of inpatient admissions and cost.

RESULTS: Between 19,500 and 29,000 patients were included in the analysis across the study period. Results showed an increasing trend in adherence to APs between 2006 and 2010. The average PDC for antipsychotic medications for all 25 states combined was 0.76 in 2006, which increased to 0.80 in 2010. The percentage of adherent patients for all 25 states combined increased from 58.3% in 2006 to 64.4% in 2010. Regression analyses indicated that initiation of long-acting injectable (LAI) AP, and percentage of residents with at least a high school (HS) education, were predictive of improved adherence, while being African American or Hispanic (versus White) and being younger were predictive of poorer adherence. The aggregated state-level analyses showed that with each one-month delay in starting an LAI, there was a 1.6% increase in inpatient admissions and a 7% increase in hospital costs. Also, with each 1% decrease in the proportion of a state’s population with at least a HS diploma, inpatient admissions and hospital costs increased by 1% and 8%, respectively.

CONCLUSIONS: Overall, substantial variations were observed in terms of adherence to AP among patients with schizophrenia across Medicaid programs. LAI initiation and higher levels of education were predictive of improved adherence and decreased inpatient utilization and cost.


F27 Estimating the Value of New Technologies that Provide More Accurate Drug Adherence Information to Physicians for Their Patients with Schizophrenia

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BACKGROUND: New wearable technologies offer the possibility of real-time patient monitoring data to improve clinical decisions. The digital feedback system (DFS), for instance, relies on an ingestible sensor imbedded in a tablet to measure antipsychotic medication adherence among patients with schizophrenia. However, the economic benefit of accurate patient drug adherence information (PDAI) is unknown.

OBJECTIVE: To estimate the effect of PDAI on physician decision making and economic outcomes for patients with schizophrenia.

METHODS: We used a decision tree modeling framework to measure the effect of PDAI on annual cost (in 2015 USD) for patients with schizophrenia who initiated therapy with an atypical antipsychotic. We used two large health insurance claims databases and published peer-reviewed studies to identify cost and benefit parameters, including baseline adherence levels. Based on whether or not patients were adherent, we compared treatment decisions with PDAI to either: (1) current treatment practices measured in claims data, or (2) idealized decisions made by a fully informed physician lacking nothing other than PDAI. The economic value of PDAI was calculated as the difference between the expected annual patient total cost when physicians made decisions with PDAI compared to costs generated either by current practice or idealized physicians making decisions without PDAI.

RESULTS: Among patients with schizophrenia with poorly controlled symptomology, 91% of patients were non-adherent (PDC<80%); 75% of all schizophrenia patients were non-adherent. Among poorly controlled patients, adherence-related interventions—such as long acting injectables—were received by 12% of patients under current practice, by 75% of patients under the idealized treatment scenario without PDAI and by 100% of patients when physicians had access to PDAI. Among non-adherent patients, use of adherence interventions saved $5,065 compared to current practice. Across all schizophrenia patients with poor symptom control (i.e., including both adherent and non-adherent patients), access to PDAI reduced annual healthcare cost by $4,962 relative to current practice and by $2,361 relative to the idealized informed physician baseline without PDAI.

CONCLUSIONS: DFS offers potential cost savings by allowing physicians to identify and treat patients with schizophrenia who are non-compliant with their medication regimen. Future research should examine how DFS use in the real world would affect health and economic outcomes among patients with a variety of serious mental illnesses.


F28 Description of Health Care Utilization and Costs Among Young, Recently Diagnosed Schizophrenia Patients One Year Prior to Treatment with Paliperidone Palmitate Once Monthly Injectable

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We used two large health insurance claims databases and published peer-reviewed studies to identify cost and benefit parameters, including baseline adherence levels. Based on whether or not patients were adherent, we compared treatment decisions with PDAI to either: (1) current treatment practices measured in claims data, or (2) idealized decisions made by a fully informed physician lacking nothing other than PDAI. The economic value of PDAI was calculated as the difference between the expected annual patient total cost when physicians made decisions with PDAI compared to costs generated either by current practice or idealized physicians making decisions without PDAI.

RESULTS: Among patients with schizophrenia with poorly controlled symptomology, 91% of patients were non-adherent (PDC<80%); 75% of all schizophrenia patients were non-adherent. Among poorly controlled patients, adherence-related interventions—such as long acting injectables—were received by 12% of patients under current practice, by 75% of patients under the idealized treatment scenario without PDAI and by 100% of patients when physicians had access to PDAI. Among non-adherent patients, use of adherence interventions saved $5,065 compared to current practice. Across all schizophrenia patients with poor symptom control (i.e., including both adherent and non-adherent patients), access to PDAI reduced annual healthcare cost by $4,962 relative to current practice and by $2,361 relative to the idealized informed physician baseline without PDAI.

CONCLUSIONS: DFS offers potential cost savings by allowing physicians to identify and treat patients with schizophrenia who are non-compliant with their medication regimen. Future research should examine how DFS use in the real world would affect health and economic outcomes among patients with a variety of serious mental illnesses.

BACKGROUND: Few studies have described the characteristics of young, recently diagnosed schizophrenia patients treated with multiple unique oral antipsychotics prior to initiating a long acting injectable antipsychotic such as paliperidone palmitate once monthly (PP1M).

OBJECTIVE: To describe baseline characteristics, healthcare resource utilization (HRU) and costs over a one year period among young, recently diagnosed schizophrenia patients with ≤ 2 or > 2 unique antipsychotics prior to index PP1M therapy.

METHODS: Adults aged 18–35 years with ≥ 2 medical claims for schizophrenia (ICD-9-CM Code: 295.xx), and ≥ 2 PP1M injections from 01JUL2009-31DEC2013 were identified from California Medicaid claims data. Twenty-four months of continuous enrollment (no schizophrenia diagnosis before the first schizophrenia diagnosis date were required to establish recent diagnosis. Patients were grouped based on having ≤ 2 or > 2 unique antipsychotics during the one year baseline period prior to PP1M. Demographic, clinical, HRU and costs were compared between the 2 groups using t-tests for continuous variables and chi square tests for categorical variables.

RESULTS: A total of 196 PP1M patients were included: 139 (70.9%) had ≤ 2 and 57 (29.1%) had > 2 unique prior antipsychotics. The mean age was 24 years for both groups, and males comprised 70% and 63%, respectively. Patients in the > 2 group had 3.6 (mean) unique antipsychotics (vs. 1.6, P < 0.0001), a higher percentage with a typical antipsychotic prescription (50.9% vs. 8.6%, P < 0.0001), greater frequency of polypharmacy (24.6% vs. 5.0%, P < 0.0001), and a higher percentage of patients (59% vs. 30%, P = 0.0002) with poor adherence (based on proportion of days covered 0–50) vs. patients in the ≤ 2 cohort. More patients with > 2 unique prior antipsychotics had prescriptions for psychiatric medications: anticholinergics (71.9% vs. 52.0%, P = 0.0124), mood stabilizers (59.7% vs. 38.1%, P = 0.0059), anxiolytics (42.1% vs. 23%, P = 0.0072), and sleep agents (31.6% vs. 8.6%, P < 0.0001). PP1M patients with > 2 unique prior antipsychotics had significantly more mean outpatient office visits (8.2 vs. 4.3, P = 0.0082), and mean pharmacy visits (25.3 vs. 14.6, P < 0.0001) per patient over the 12-month period prior to initiating PP1M as well as higher mean inpatient stay costs ($13,227 vs. $8,092, P = 0.0278), mean pharmacy costs ($8,714 vs. $4,642, P = 0.0007), and mean total costs ($27,683 vs. $16,801, P = 0.0003).

CONCLUSIONS: These data suggest that, among patients initiating treatment with PP1M, differences exist between those with a > 2 vs. ≤ 2 prior antipsychotic medications.

SPONSORSHIP: Janssen Scientific Affairs.

F30 Analysis of Medical Resource Utilization Secondary to Automated Prior-Authorization Criteria for the Oral Atypical Antipsychotics in a Medicaid Population
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BACKGROUND: Automated prior authorization criteria was put in place for West Virginia Medicaid for the oral atypical antipsychotics. A proprietary rules system evaluated two years of medical and pharmacy claims data in an algorithm-based yes-no format, to determine authorizations. Criteria focused on age, diagnosis, step therapy, and use of preferred agents.

OBJECTIVE: To describe the impact of prior authorization approval versus denial of the oral atypical antipsychotic medications on medical resource utilization (e.g. emergency room visits and hospital admissions).

METHODS: Between May 1, 2014 and March 30, 2015, prior authorization criteria for the oral atypical antipsychotics was in place with no significant criteria changes. Members included were limited to those who remained eligible during the study period. Utilization of emergency room (ER) and hospital admissions were measured from the index point of sale date of the prescription, to six months later. A retrospective claims database analysis categorized members into three groups: 1-approved (approved and received requested therapy), 2-denied and no utilization (received a denial and did not receive an oral antipsychotic during the next six months), and lastly, 3-denied-then approved (denied initially but later approved). Per member per month medical utilization rates were calculated by dividing the number of events by the count of members multiplied by six months. The category of “Rejected and then approved” was split by days with or without antipsychotic therapy.

RESULTS: After eliminating members that did not have eligibility for six months post-index, there were 1,834 members in the approved category, 748 members who were denied and had no utilization, and 1,137 members who had an initial denial and later received an oral antipsychotic. The denied then approved group was evaluated based on days without therapy and days with therapy. There was no increase in ER utilization or hospital admissions for members who were denied and did not receive oral antipsychotic medication when compared with the members that were initially approved or with members who were initially denied and later approved. Members in the third group who were denied and later approved saw no difference in medical resource utilization when evaluating days without therapy versus days with therapy.

CONCLUSIONS: The data indicates this prior authorization criteria for the oral atypical antipsychotics did not adversely increase medical utilization for the members who were denied therapy.

SPONSORSHIP: This research was funded internally by Xerox State Healthcare, Richmond, VA.

F31 Comparing Fall Risk Among Antidepressant Classes in the Elderly: A Nested, Case-Control Study of a Medicare Database
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BACKGROUND: Falls are the most common cause of death from injury, non-fatal injuries, and hospital admissions for trauma in the elderly. Numerous studies have highlighted the association between SSRIs or non-fatal injuries, and hospital admissions for trauma in the elderly. Falls are the most common cause of death from injury, non-fatal injuries, and hospital admissions for trauma in the elderly. Numerous studies have highlighted the association between SSRIs or TCAIs and fall risk yet few have evaluated second-generation antidepressants.

METHODS: This nested, case-control study used claims data from the Medicare database and included all patients ≥ 65 years of age with a recent depression diagnosis and an inpatient admission in 2011. Patients with an inpatient admission for a fall (ICD-9: E880-E888) were matched to controls, those admitted for any other diagnosis aside from fall, fracture, or trauma, in a 1:3 ratio based on age, sex, and osteoporosis diagnosis. Initially, the increased fall risk with antidepressant use was reestablished by comparing the odds of filling a prescription for an antidepressant prior to admission, based on Part D claims data, to the controls. To compare fall risk among antidepressant classes, a second cohort, limited only to patients receiving antidepressants, was subsequently re-matched. Multivariate logistic regression analysis was used to control for concomitant medications and comorbidities that may increase fall risk.
RESULTS: The first cohort consisted of 54,068 cases and 162,204 controls. The mean age was 81.7 ± 8.1 years, 76.2% were female, and 33.6% had osteoporosis. Fifty-nine percent of cases were diagnosed with a fracture or trauma, with the most common being a femur or vertebral fracture, or traumatic brain injury. Antidepressant use was associated with a higher risk of falls with odds ratio (OR) of 1.20 (95% CI: 1.18 - 1.23, P < 0.001). The second cohort consisted of 28,450 cases and 85,377 controls. SSRIs accounted for 64% of all antidepressant use. As compared to SSRIs, the risk of falls was lower for patients receiving mirtazapine (OR 0.82, 95% CI: 0.75 - 0.90, P < 0.001) and bupropion (OR 0.74, 95% CI: 0.70 - 0.79, P < 0.001). Conversely, fall risk was higher for those receiving a combination of antidepressants vs. SSRI monotherapy (OR 1.08, 95% CI: 1.04 - 1.13, P < 0.001). No difference in fall risk was found amongst SNRIs, TCAs, and MAOIs compared to SSRIs. Multivariable analysis revealed similar results.

CONCLUSIONS: Mirtazapine and bupropion are associated with a lower risk of falls resulting in hospitalization as compared to SSRIs, while combination antidepressant use increases fall risk.

SPONSORSHIP: University of the Incarnate Word Feik School of Pharmacy.

G00-G99 Diseases of the Nervous System (e.g., Multiple Sclerosis, Migraine, Seizures, Restless Leg, Sleep Apnea)

G02 Budget Impact Analysis of Botulinum Toxin A Therapy for Adult Upper Limb Spasticity (AULS) in the United States

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BACKGROUND: Adult upper limb spasticity (AULS) is a common outcome of upper motor neuron syndrome. It usually follows a stroke, brain injury, spinal cord injury, multiple sclerosis, or cerebral palsy and profoundly impacts patients. Botulinum toxin A (BoNT-A) is an effective treatment for reducing the burden of AULS. Variation in the pharmacodynamics and costs of BoNT-As can influence the overall budget to treat AULS patients.

OBJECTIVE: To estimate the expected annual budget impact of BoNT-A use in AULS patients on United States (U.S.) health plans using market share scenarios.

METHODS: A budget impact model was developed to determine the financial impact over 3 years of shifting market share of the 3 BoNT-As used to treat a hypothetical U.S. health plan of one million members, with the portion of BoNT-A treated patients estimated using published epidemiological data. In the modeled scenario, annual market share of abobotulinumtoxinA (ABO) increased by 10%, while combined market share of onabotulinumtoxinA (ONA) and incobotulinumtoxinA (INCO) decreased by 10%. The cost of treatment was calculated by multiplying the cost per administration by the average number of treatment cycles per year. The model assumed patients received BoNT-As at the minimum retreatment intervals, every 12 weeks (4.3 cycles per year). The model used wholesale acquisition costs as of August 2015 (from AnalySource). The average dose per patient was assumed to equal the maximum dose from the FDA or published clinical trial for each BoNT-A. One-way sensitivity analyses were performed to assess the impact of individually varying model inputs by ±10%.

RESULTS: Based on national prevalence estimates, 156 individuals in the hypothetical health plan per year were eligible to receive BoNT-A for the treatment of AULS. The annual cost of treating an AULS patient was $7,613 for ABO, $10,683 for ONA, and $8,857 for INCO. Assuming estimated market share shifts, the total BoNT-A treatment cost is predicted to decrease from $1,651,144 (baseline) to $1,509,568 in year 3, resulting in a savings of $141,575 in year 3 (or an annual cost savings of $49,384 over years 1 to 3). Sensitivity analyses revealed the most influential inputs were dose, frequency and unit cost for ONA, followed by the frequency, unit cost and dose for ABO.

CONCLUSIONS: The annual cost of treating a patient for AULS with ABO was projected to be the lowest compared to ONA and INCO assuming model market share changes. Our analysis suggests health plans may achieve cost savings shifting BONT-A market share to ABO for treatment of AULS.

SPONSORSHIP: Ipsen Biopharmaceuticals.

G03 Healthcare Resource Utilization Among Commercially Insured Clobazam-Treated Patients with Lennox-Gastaut Syndrome

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BACKGROUND: Since FDA approval in 2011, clobazam (CLB) has been used as an adjunctive treatment for patients ≥2 years of age with Lennox-Gastaut syndrome (LGS).

OBJECTIVE: To characterize healthcare resource utilization (HCRU) among commercially insured CLB-treated patients with probable LGS pre- and post-CLB initiation.

METHODS: De-identified data from MarketScan Commercial and Medicare Supplemental databases (10/1/2010 through 3/31/2014) were used to identify patients with probable LGS (≥2 medical claims for generalized convulsive or non-convulsive epilepsy and ≥1 medical claim for developmental disorder or cognitive impairment). Patients who initiated antiepileptic drug (AED) treatment with CLB following the first claim suggestive of LGS were identified. Seizure-related HCRU in the 12 months post-CLB initiation was compared with HCRU in the 12 months post-CLB initiation.

RESULTS: A total of 314 CLB-treated patients with probable LGS and a minimum of 12-months follow-up post-treatment initiation were identified. Most patients (40.1%) were 6 to 12 years old (mean age = 13.2 y) and had a filled prescription for ≥1 AED prior to CLB use (mean AEDs = 1.7 ± 1.1 SD). Compared with the 12-month pre-CLB period, significantly smaller proportions of patients had seizure-related hospitalizations (38.2% pre-CLB vs. 30.9% post-CLB, P = 0.03), emergency room visits (31.9% vs. 18.5%, P < 0.001) or laboratory visits (46.2% vs. 39.5%, P = 0.04) in the 12 months following CLB initiation. Mean seizure-related hospital stays, emergency room visits, and neurologist visits post-clobazam initiation also were significantly reduced. An increase in mean seizure-related prescription costs following CLB initiation ($9,549 pre-CLB vs. $15,125 post-CLB, P < 0.0001) was largely offset by significantly reduced total seizure-related medical costs ($23,740 vs. $19,958, P = 0.004), representing a net average total cost increase of $1,794. Similarly, an increase in mean all-cause total costs following CLB initiation ($73,319 vs. $81,389, P < 0.001) was primarily driven by increased prescription costs ($16,229 vs. $22,098, P < 0.001). Mean medical costs between groups did not significantly differ (P = 0.41).

CONCLUSIONS: Among commercially insured patients with probable LGS and prior exposure to 2 AEDs, seizure-related HCRU (inpatient and outpatient services and medical costs) were reduced following CLB initiation compared with an analogous period before CLB.
initiation. Indirect costs that may have been impacted following CLB initiation were not accounted for in this study.

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

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**G04** Specialty Drug Coupons Are Frequently Used and Significantly Reduce Out-of-Pocket Costs

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**Prime Therapeutics**

**BACKGROUND:** Specialty drugs are used by less than 1 percent of members, however, they account for more than 25 percent of all pharmacy benefit drug expenditures. The vast majority of specialty drugs dispensed through a pharmacy have a copay offset program (i.e., coupon) available. Coupons provide member financial assistance and can increase adherence. At the same time, coupons may ultimately lead to increased premiums by helping a member fulfill their deductible or lead to non-formulary drug use.

**OBJECTIVE:** To evaluate pharmacy benefit specialty drug coupons prevalence, dollar value, and amount of member saving.

**METHODS:** Among 15 million commercially insured individuals, we examined specialty drug prescriptions dispensed with and without coupons by a specialty pharmacy from 1/1/15 through 10/31/15. We used data on all prescriptions from the specialty pharmacy that were billed to the pharmacy benefit manager (PBM) to obtain prescription counts, member cost shares, plan shares, and total amounts paid. By linking data from the specialty pharmacy to the PBM’s claim records, we were able to identify specialty drug prescriptions that had been filled with and without the use of a coupon. We then calculated each coupon’s value by comparing the member’s cost share as defined by the insurer with what the member actually paid after the coupon was applied. Descriptive statistics were used to examine the proportion of members who used drug coupons and how much these coupons reduced members’ cost share.

**RESULTS:** January 2015 through October 2015 expenditures for the specialty pharmacy dispensed prescriptions totaled $1.98 billion, of which $771.1 million (3.9 percent) was paid out of pocket by members. Specialty drug coupons were associated with $214,659 (51.0 percent) of $421,083 specialty prescriptions and covered $52.9 million (68.6 percent) of members out-of-pocket costs. The true amount members’ paid was $242.2 million or $57 per specialty prescription. On average, members who used one or more drug coupons saved $1,196 during the first 10 months of 2015 after the drug coupons were applied and members true average out-of-pocket costs per prescription were 3 fold less than the insurer had expected the member to pay, $183 and true $57.

**CONCLUSIONS:** Specialty drug coupons saved members almost $7 of every $10 that they are asked to pay out of pocket. However, future research should be focused on evaluating the percentage of time coupons are used to help a member reach their out of pocket maximum or result in members selecting non-formulary medications and the potential impact on premiums.

**SPONSORSHIP:** AbbVie.

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**G05** Adherence to Disease-Modifying Therapies Among Patients with Multiple Sclerosis

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**BACKGROUND:** Multiple sclerosis (MS) is a chronic progressive condition affecting the central nervous system. MS patients are treated with disease modifying therapies (DMT). Currently, there are multiple DMTs delivered via different routes of administration and dosing frequencies.

**OBJECTIVE:** To evaluate medication adherence in MS patients newly initiating treatment with DMTs.

**METHODS:** MS patients (age 18-65, ≥ 2 MS diagnosis, ≥ 2 DMT claims) with continuous eligibility 12 month pre- and post-index, and no DMT claim during the pre-index period were identified from the Truven MarketScan database from 1/1/2008-12/31/2014. Adherence was measured by 12-month post-index proportion of days covered (PDC) and medication possession ratio (MPR). Fisher and Wilcoxon tests were used in unadjusted statistical comparisons. Logistic regression was used to evaluate the likelihood of adherence (defined as PDC or MPR ≥ 0.8) to DMTs.

**RESULTS:** The study included 19,930 MS patients (mean age: 46.2 years) on 9 different DMTs, 18,187 on injectables and 1,343 on orals. PDC ranged from 0.7 to 0.81. On average, PDC was greater in the injectable than the oral group (0.79 vs. 0.76, P=0.001). Compared with patients on orals, patients on injectables were less likely to discontinue, but more likely to switch (discontinuation rate: 13.8% vs. 18.3%; switch rate: 7.9% vs. 5.5%; both P<0.001). Time to discontinuation or switch was also significantly different between the injectable and the oral groups (mean number of days before discontinuation: 148.4 vs. 135.2; days before switch: 191.3 vs. 144.8; both P<0.01). After controlling for age, gender and co-morbidities, route of administration did not have a significant impact on overall adherence. Male, older age group (vs. 18-34) were associated with significantly higher likelihood of adherence (odds ratio [OR]: 1.34, ORs: 1.26-1.60, respectively; P<0.001). Higher comorbidities were associated with a lower likelihood of adherence (ORs: 0.85-0.99, P<0.05). Similar results were observed when using MPR as adherence measure.

**CONCLUSIONS:** This study showed that overall, route of administration did not impact adherence. However, patients on injectables were less likely to discontinue and discontinue later than patients on orals. They were also slightly more likely to switch. In addition, male and older age were associated with better adherence and higher comorbidities were associated with worse adherence.

**SPONSORSHIP:** AbbVie.

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**G07** Cost-Utility Analysis of Botulinum Toxin Type A Products for the Treatment of Cervical Dystonia

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**BACKGROUND:** Botulinum toxin type A products are well established as first-line agents for cervical dystonia (CD). Their use in patients with CD have been found to reduce pain and improve quality of life. However, botulinum toxin type A products are high-cost agents and their efficient use is important in providing cost-effective care for a healthcare system. Sufficient pharmacoeconomic analyses comparing these agents are lacking.

**OBJECTIVE:** To conduct a cost-utility analysis of botulinum toxin type A products for the treatment of CD from a United States (U.S.) government perspective.

**METHODS:** A cost-utility analysis of botulinum toxin type A products was conducted using a decision-analysis model with a one-year time horizon. Probabilities of the model were taken from several studies using the three botulinum toxin type A products approved by the Food and Drug Administration for the treatment of CD: onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), and incobotulinumtoxinA...
(Xeomin). The main outcome measurement was successful treatment response with botulinum toxin type A, measured in quality-adjusted life years (QALYs). Response was defined as a patient who experienced improvement of CD symptoms without a severe adverse event. Probabilistic sensitivity analysis was conducted to test robustness of the base-case results.

RESULTS: All three botulinum toxin type A agents were cost-effective at a willingness-to-pay threshold of $100,000 per QALY. Xeomin was the most cost-effective with a cost-effectiveness ratio of $27,348 per QALY. Xeomin was dominant over the alternative agents with equivalent efficacy outcomes and lower costs. Dysport had the second lowest cost-effectiveness ratio ($36,678), followed by Botox ($49,337). The probabilistic sensitivity analysis supported the results of the base-case analysis. Dysport was associated with the lowest wastage (2.2%), followed by Xeomin (10%) and Botox (22.9%).

CONCLUSIONS: A cost-utility analysis found that Xeomin was the more cost-effective botulinum toxin type A product compared with Botox and Dysport for the treatment of CD. Wastage associated with the respective products may have a large effect on the cost-effectiveness of the agents.

SPONSORSHIP: This study was unfunded.

G13 Healthcare Utilization in a Contemporary Cohort of Primary Progressive Multiple Sclerosis

NARCOMS Registry Participants

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BACKGROUND: As potential therapies for primary progressive multiple sclerosis (PPMS) emerge, a better understanding of the characteristics of persons with PPMS is needed.

OBJECTIVE: To describe the healthcare utilization and insurance status of North American Research Committee on Multiple Sclerosis (NARCOMS) registry participants who report having PPMS.

METHODS: NARCOMS is a voluntary registry for persons with MS, designed to capture a wide range of health-related information. Each participant completes an enrollment survey, updated semi-annually with routine information on disability using Patient Determined Disease Steps (PDDS), healthcare utilization, and disease-modifying therapy (DMT) use. We analyzed data from participants who reported having PPMS in the Spring 2015 semi-annual survey. Information from their enrollment and update surveys was linked to provide a comprehensive description of their demographic/clinical characteristics, and data was analyzed using descriptive statistics.

RESULTS: Of 8,004 survey participants, 632 (7.9%) reported having PPMS. The cohort consisted of 396 (62.7%) women, with an average age of 64.3 (SD, 8.9) years; 93.8% were white. The average age of MS onset was 36.0 (SD, 11.0) years. The median PDDS was 6 (Bilateral Support, which falls between steps 5 [Late Cane] and 7 [Wheelchair/Scooter]). A high proportion were not working (89%), and almost all had health insurance (99.2%). Among those with health insurance, 44.3% had Medicare; 18.2% had private insurance, and 28.8% had both. Of all the PPMS participants, 201 (33.1%) reported taking a DMT. Most of the PPMS cohort received MS care from a private neurologist (45.7%), specialized MS center (31.3%), or general practitioner (10.5%). Other providers most frequently visited in the past 6 months were a primary care physician (57.3%), physiotherapist (28.2%), urologist (24.5%) and physician assistant (20.6%).

CONCLUSIONS: The prevalence of PPMS in the self-described patient cohort from the Spring 2015 NARCOMS survey was almost 8%. The range of healthcare provider visits and potential off-label use of DMTs suggest an unmet need for treatments in this less researched and less understood form of MS.

SPONSORSHIP: This study was funded by Genentech; NARCOMS is supported in part by the Consortium of MS Centers and its foundation.

G14 Differences in Preferences for Disease-Modifying Treatments Across Subgroups of U.S. Patients with Relapsing Multiple Sclerosis

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OBJECTIVE: To describe the impact on overall MS relapse-related costs in real-world settings.
BACKGROUND: The growing number of disease-modifying treatments (DMTs) for relapsing multiple sclerosis (RMS) highlights the need to consider patient preferences in treatment decisions, which could lead to better adherence and outcomes.

OBJECTIVE: To estimate and compare treatment preferences and adherence among patients with RMS.

METHODS: A web-based, discrete choice experiment survey presented 10 choices between pairs of hypothetical MS DMTs to patients who self-reported a physician diagnosis of RMS. Treatment attributes, informed by the literature and clinician input and tested in patient interviews, included chance of MS progression, years between relapses, risk of serious infection, route of delivery and frequency of administration, and chance of flu-like and gastrointestinal (GI) symptoms. Random-parameters logit was used to estimate part-worth utilities. Importance scores and preference shares were calculated to compare subsamples on disability level and current treatment.

RESULTS: Of 301 patients who completed the survey, 56% rated their disability as normal or mild, 79% reported currently receiving treatment and 42% reported using an injectable DMT. Overall, respondents with normal or mild disability had significantly different preferences than respondents with moderate or worse disability (P < 0.05). Patients with worse disability placed the most weight on reducing the chance of MS progression and risk of serious infection. Patients with normal or mild disability placed the most weight on avoiding injections with flu-like symptoms, followed by reducing the chance of progression. Patients using injectable DMTs had significantly different preferences than those who were not (P < 0.05). Patients using injectable DMTs placed the most weight on reducing the chance of progression and risk of serious infection. Oral dosing with no side effects had the highest preference share, but IV administration every 6 months was preferred when oral dosing had moderate GI symptoms. The largest percentage of patients stated highest likely adherence to daily oral dosing and IV administration every 6 months and lowest likely adherence to daily injection and daily oral.

CONCLUSIONS: The preferences of patients with RMS varied depending on their current treatment and disability level. Considering patient preferences for efficacy, side effects and dosing may lead to higher treatment satisfaction and adherence.

SPONSORSHIP: This study was funded by Genentech.

G15 Healthcare Utilization and Comorbidities in Working Age Persons with Different Types of Multiple Sclerosis
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BACKGROUND: The North American Research Committee on Multiple Sclerosis (NARCOMS) registry is a voluntary registry for persons with MS that captures health-related information, including healthcare utilization and comorbidities.

OBJECTIVE: To evaluate healthcare utilization and frequency of comorbidities in a working-age MS cohort.

METHODS: NARCOMS participants complete an enrollment survey that is updated semi-annually. We conducted a cross-sectional comparison using Spring 2015 survey data from the NARCOMS registry. U.S. and Canadian participants who reported having relapsing-remitting (RR) or secondary progressive (SP; group 1) or primary progressive (PP; group 2) MS were identified. The cohort was further restricted to working-age participants (18-65 years). PP participants were matched to RR/SP participants on age, disability as measured by Patient Determined Disease Steps (PDDS), and sex using propensity scores. χ² tests were used to examine differences in healthcare provider visits, comorbidities, and whether the participants were treated for the reported comorbidities.

RESULTS: Of 8,004 survey participants, 5,148 met the inclusion criteria (RR, 3,700 [71.8%]; SP, 1,107 [21.5%]; PP, 341 [6.7%]). The matching process retained 648 participants (RR, 157 [24.2%]; SP, 168 [25.9%]; PP, 323 [49.9%]). The study population had a mean (SD) age of 58 (6) years and median PDDS of 4 (IQR, 3-5); 58.1% were female, and 99.2% had health insurance (32.0% private, 37.0% Medicare, 21.2% both). In this matched cohort, a similar number of provider visits were reported between the groups, with the exception of the PP group reporting more visits to an occupational therapist (P = 0.028) and a non-MS nurse (P = 0.011). Of the 16 comorbidities included in the survey, group 1 reported having at least 1 comorbidity (RR/SP 82.9% vs. PP 76.5%; P = 0.0414), however, no differences emerged between the 2 groups in the number of comorbidities reported or proportion treated for their comorbid conditions.

CONCLUSIONS: After matching for age, disability and gender, working-age registry participants with PPMS demonstrated slightly higher healthcare utilization and comorbidities than those with RRMS or SPMS. As approved treatments for PPMS emerge, differences in healthcare utilization and comorbidities by MS type should be re-evaluated.

SPONSORSHIP: This study was funded by Genentech. NARCOMS is supported in part by the Consortium of MS Centers and its foundation.

G16 The Impact of Multiple Sclerosis Treatment Persistence and Adherence on Emergency Room Visits and Inpatient Hospital Stays
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BACKGROUND: There are several disease-modifying treatments (DMTs) approved for multiple sclerosis (MS) to reduce relapses and delay disease progression. Persistence and adherence to therapy are important to achieve positive clinical outcomes and favorable economic consequences.

OBJECTIVE: To evaluate the impact of treatment persistence and adherence on emergency room (ER) visits, inpatient hospital stays and patients’ out-of-pocket costs.

METHODS: A retrospective claims database analysis was performed to evaluate persistence and adherence over a 12-month period in patients with MS who received natalizumab, interferon β-1a (intramuscular and subcutaneous), interferon β-1b, glatiramer acetate, or fingolimod. Persistence was defined as the duration of treatment from initiation to discontinuation of treatment or the end of the 12-month study period. Patients with a medication possession ratio of >0.8 were considered to be adherent. The primary analysis evaluated the likelihood of inpatient hospital stays and ER visits in patients who were persistent and adherent compared with patients who had lower persistence or were non-adherent. Patients’ out-of-pocket costs were also evaluated.

RESULTS: A total of 16,218 patients (mean age ±45 years; 77.1% female) were evaluated. Of these, 13.9% were not adherent while on treatment and 35.3% discontinued treatment in the follow-up period. Ten percent of all patients underwent inpatient hospital admission, and nearly 1 in 4 (24.9%) had an ER visit during the 12-month study period. In an adjusted analysis, patients who were persistent and/or adherent were significantly less likely to have an inpatient hospital stay (odds ratio [OR] = 0.50 and 0.83, respectively) or an ER visit (OR = 0.65 and 0.86, respectively). In an unadjusted analysis, a greater proportion of patients who were persistent and adherent had copays <$25 compared with non-persistent or non-adherent patients (24.9%...
OBJECTIVE: To describe first-switch treatment patterns amongst MS-diagnosed, disease-modifying therapy (DMT) users in a large U.S. commercial claims database.

METHODS: Patients with an MS diagnosis between 10/1/2010 and 5/31/2014 were identified from the HealthCore Integrated Research Database, a nationally representative U.S. commercial health plan covering >37 million lives. Patients were aged ≥18 years, with ≥12 months of continuous medical and pharmacy eligibility before and after the earliest MS diagnosis date (index date), with no DMT claims in the pre-index period, and ≥1 DMT in the post-index period. Patient characteristics, treatment patterns, and time to first switch are described.

RESULTS: A total of 1,639 patients were identified; mean age was 42.4 years (SD, 11.3), 72.2% were female. The most frequently used index DMT was glatiramer acetate (41.9%), then interferon beta-1a (32.7%), dimethyl fumarate (13.0%), natalizumab (5.6%), fingolimod (4.9%), teriflunomide (1.9%), and interferon-beta-1b (0.1%). Mean time from index DMT initiation to first switch are described. The overall first-switch rate was 24.6%. The proportion of patients switching index DMT to a non-index first-switch DMT was 16.9% in the 12-24 month group, 26.1% in the 25-36 months group, and 31.6% in the >36 months group. Mean time from index DMT initiation to first switch was 169 days (median, 155 days) in the 12-24 month group, 342 days (median, 305 days) for the 25-36 month group, and 491 days (median, 458 days) in the >36 months group. Patients in all three groups (31.7-46.0%) switched to dimethyl fumarate. The proportion of first switches to fingolimod was 7.9% in the 12-24 months and 17.1% in the >36 months.

CONCLUSIONS: In a nationally representative, commercially insured population, about 16.9%-31.6% of patients with MS switched DMTs during the 1 to 3+ years follow-up period. Thus, a sizeable proportion of DMT-treated patients rely on second-line treatment options to persist on DMT treatment. The availability of more first- and second-line treatment options would fulfill an important unmet medical need in the treatment of MS.

SPONSORSHIP: This study was funded by Genentech.

BACKGROUND: Since the emergence of the first oral multiple sclerosis (MS) treatment in 2010, several highly effective treatments have been approved in the U.S., shifting the traditional MS treatment paradigm. Several highly effective disease-modifying therapies (DMTs) for multiple sclerosis (MS) have not been comprehensively studied in a real-world setting.

OBJECTIVE: To compare the annual relapse rate (ARR) of MS in patients initiating delayed-release dimethyl fumarate (DMF, also known as gastro-resistant DMF), glatiramer acetate (GA), interferon (IFN), fingolimod (FTY), and teriflunomide (TER).

METHODS: This study used MarketScan, a large U.S. commercial insurance database. Adult MS patients (18-64 years) who initiated a DMT of interest in 2013 were included. The main outcome of interest, ARR, was calculated based on the number of MS-related relapses (identified from inpatient and outpatient claims) within 1 year post-DMT initiation. Poisson regression was used to compare the adjusted ARR while controlling for the difference in demographics, comorbidities, MS symptoms, DMT use, and ARR at baseline. Subgroup analyses were conducted based on the DMT used within the year prior to index date.

RESULTS: A total of 3,352 DMF, 1,057 GA, 884 IFN, 579 FTY, and 500 TER patients were included in the analysis. Baseline differences were seen in age (46.7, 43.5, 43.6, 43.8, and 49.6, respectively; P<0.01), proportion of females (76.6%, 79.0%, 78.6%, 76.2%, vs. 80.0%, respectively; P=0.21), proportion with other DMT in the prior year (68.7%, 15.7%, 13.9%, 64.2%, and 66.0%, respectively; P<0.01), and ARR in the prior year (0.43, 0.31, 0.37, 0.44, and 0.38, respectively; P<0.01). After DMT initiation, the unadjusted ARR was 0.30 (1.46) for DMF, 0.33 (1.03 for GA, 0.34 for IFN, 0.31 for FTY, and 0.35 for TER (P<0.01). Using DMF as the reference, the adjusted incidence rate ratio was 1.34 (95% confidence interval [CI]: 1.17-1.53) for GA, 1.27 (1.10-1.46) for IFN, 1.03 (0.88-1.21) for FTY, and 1.23 (1.05-1.45) for TER. Consistent findings were observed in the subgroups stratified by DMT use in the prior year.

CONCLUSIONS: DMT demonstrated significantly better effectiveness than GA, IFN, and TER in the real-world setting. No significant difference was observed between DMF and FTY.

SPONSORSHIP: This study was sponsored by Biogen.

G18 Real-World Comparison of Relapse Rates in Multiple Sclerosis Patients Treated with Disease-Modifying Therapies

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BACKGROUND: Disease-modifying therapies (DMTs) have dramatically changed the disease management of multiple sclerosis (MS). However, literature has limited information on the relative economic value of different DMTs in a real-world setting.

OBJECTIVE: To compare the change in costs and health resource utilization of MS patients who initiated delayed-release dimethyl fumarate (DMF, also known as gastro-resistant DMT), glatiramer acetate (GA), interferon (IFN), fingolimod (FTY), and teriflunomide (TER).
METHODS: A large administrative U.S.-based claims database (MarketScan) was used. Adult MS patients (18-64 years) who initiated a DMT of interest in 2013 were included. Patients were not treated with DMT in the year prior to the date of DMT initiation (index date). Total healthcare cost and non-prescription medical cost were compared for one year pre- and post-the index date. Difference-in-differences estimate was used to assess the difference in cost between DMT and other DMTs over time while adjusting for demographics and Charlson Comorbidity Index (CCI).

RESULTS: Among the patients previously untreated with a DMT, total of 1,048 initiated DMF, 891 GA, 765 IFN, 207 FTY, and 170 TER. Baseline differences between these groups were seen in age (45.4, 43.2, 43.7, 44.4, and 48.6, respectively; \( P<0.0001 \)), CCI (0.65, 0.78, 0.73, 0.48, and 0.69, respectively; \( P=0.02 \)), and annual healthcare cost before the index date ($21,905, $17,646, $16,823, $23,541, and $20,130, respectively; \( P<0.01 \)). Total annual healthcare cost increased by $38,561, $44,599, $44,942, $53,626, and $43,137 after the initiation of DMF, GA, IFN, FTY, and TER, respectively (\( P<0.01 \)). Among these groups, the reduction in annual non-prescription medical cost was $6,747 for DMF, $1,453 for GA, $2,746 for IFN, $4,246 for FTY, and $581 for TER (\( P<0.01 \)). The difference between DMF and other DMTs remains consistent after controlling for confounders.

CONCLUSIONS: DMF had the lowest increase in total healthcare cost and the highest reduction in non-prescription medical cost among the DMTs compared.

SPONSORSHIP: This study was sponsored by Biogen.

G20 Patients with Active RRMS and an Inadequate Response to Prior Therapy Demonstrate Persistent Improvements in Relapse and Disability Following Treatment with Alemtuzumab: 5-Year Follow-up of the CARE-MS II Study
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BACKGROUND: In CARE-MS II (NCT00548405), in active relapsing-remitting MS (RRMS) patients with an inadequate response (≥1 relapse) to prior therapy at baseline, alemtuzumab showed superior efficacy versus SC interferon beta-1a over 2 years. Efficacy persisted through 5 years in the absence of continued treatment and associated treatment burden.

RESULTS: Of 354 randomized subjects, 59.0% had relapsing remitting RRMS patients (891 GA, 765 IFN, 207 FTY, and 170 TER). Baseline differences between these groups were seen in age (45.4, 43.2, 43.7, 44.4, and 48.6, respectively; \( P<0.0001 \)), CCI (0.65, 0.78, 0.73, 0.48, and 0.69, respectively; \( P=0.02 \)), and annual healthcare cost before the index date ($21,905, $17,646, $16,823, $23,541, and $20,130, respectively; \( P<0.01 \)). Total annual healthcare cost increased by $38,561, $44,599, $44,942, $53,626, and $43,137 after the initiation of DMF, GA, IFN, FTY, and TER, respectively (\( P<0.01 \)). Among these groups, the reduction in annual non-prescription medical cost was $6,747 for DMF, $1,453 for GA, $2,746 for IFN, $4,246 for FTY, and $581 for TER (\( P<0.01 \)). The difference between DMF and other DMTs remains consistent after controlling for confounders.

CONCLUSIONS: Alemtuzumab demonstrated persistent improvements in clinical efficacy over 5 years despite most patients not receiving alemtuzumab for 4 years. Based on these findings, for the majority of RRMS patients, alemtuzumab may provide an innovative treatment approach with efficacy persisting through 5 years in the absence of continued treatment and associated treatment burden.

SPONSORSHIP: Sanofi Genzyme; Bayer Healthcare Pharmaceuticals.

G21 A Randomized, Double-Blind, Parallel Group Study to Compare the Safety and Efficacy of Arbaclofen Extended Release Tablets to Placebo and Baclofen for the Treatment of Spasticity in Patients with Multiple Sclerosis
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BACKGROUND: Spasticity is common in MS and is associated with significant morbidity. The standard treatment is oral administration of baclofen, a γ-aminobutyric acid-b (GABA-b) receptor agonist. Baclofen is a racemic mixture and its efficacy is thought to be due to the R-enantiomer (arbaclofen). Therapeutic doses of baclofen can cause CNS side effects and decreased adherence and tolerability. AERT can reduce dosing frequency and adverse events.

OBJECTIVE: To compare the efficacy and safety of Arbaclofen Extended Release Tablets (AERT) to placebo and baclofen over 12 weeks of treatment in patients with spasticity due to multiple sclerosis (MS).

METHODS: This was a multicenter, randomized, double blind, active and placebo controlled parallel group study in adults with spasticity due to MS. The study compared AERT 20 mg BID with baclofen tablets 20 mg QID and matching placebo. The dose was titrated over 4 weeks followed by a 12-week maintenance period. The co-primary endpoints were the mean changes in Total Numeric-transformed Modified Ashworth Scale (TNmAS) and Clinician Global Impression of Change (CGIC) at the end of the maintenance period.

RESULTS: Of 354 randomized subjects, 59.0% had relapsing remitting and 36.7% had secondary progressive MS. The average baseline TNmAS score was 7.78. TNmAS and CGIC were statistically significant in favor of AERT group compared with placebo, while differences between AERT and baclofen were not statistically significant. MS Spasticity Scale (MSSS-88) showed a statistically significant improvement in AERT group compared with placebo. Epworth Sleepiness Scale (ESS) showed a statistically significant increase in sleepiness in the baclofen group, but not in the AERT group compared to placebo. Drowsiness and dizziness were less frequent in AERT group compared with baclofen.

CONCLUSIONS: This study demonstrated that AERT administered twice a day was efficacious, safe, and better tolerated than baclofen in MS patients with spasticity.

SPONSORSHIP: Osmotica Pharmaceutical.
Multiple sclerosis (MS) is a chronic, inflammatory neurodegenerative condition that requires the use of disease-modifying therapies (DMTs). With increasing DMT options and newer outcome measures, payers are challenged to identify pertinent clinical and economic metrics to manage the condition. To understand the payer’s approach in current and future MS management, to gain insights on the key clinical considerations of coverage policy and on the type of health economic tools useful to payers, and to identify opportunities to improve the management of MS.

**PROGRAM DESCRIPTION:** Data were collected using a survey via a face-to-face (FTF) and a virtual (VIR) interaction with payer respondents, the VIR interaction utilized an advisory board format. The same list of questions was used during both interactions. The questions assessed treatment efficacy, impact of treatment paradigm change and increasing MS drug options, effective tools to manage drug spending, and tools used to assess clinical and economic value of the drug. These questions were approved by a Sanofi Genzyme internal medical review committee for external use.

**OBSERVATIONS:** Nearly 130 and 300 insights were gained from the FTF and VIR groups, respectively. The most common measures to determine efficacy of the DMTs are annualized relapse rate (ARR) and disability progression. Brain lesions or atrophy on MRI are not considered by respondents in the FTF group, and adherence and NEDA (no evidence of disease activity) data have more limited value in both groups. Payers consider MS a difficult condition to model. Cost-effectiveness models sponsored by the manufacturer are a valuable tool, and transparency in the model’s assumptions improves the payers’ confidence of the model. Economic models with ”actionable data” are more valued by payers in the VIR group. In the absence of comparative data, price serves a more important role in formulary decision-making than efficacy or safety measures.

**FINDINGS/RECOMMENDATIONS:** There is slow adoption of the use of nontraditional outcome measures by payers. Payers lack confidence in utilizing manufacturer-sponsored tools and would prefer more comparative, real-world evidence. Payers can collaborate with manufacturers to conduct observational studies to validate the value of DMTs. Education for payers on the importance of newer outcome measures in assessing MS is needed. Manufacturers can provide actionable data in a transparent health economic model to assist payers to evaluate a drug’s value.

**SPONSORSHIP:** Sanofi Genzyme.
RESULTS: A total of 7,491 patients (77.3% female) met inclusion criteria, of whom 78.4% demonstrated high adherence to DMTs (PDC > 80%) throughout the study period. Patients aged 41-50 years had the highest average PDC (87%), with PDC increasing 0.1% for each year of age on average. PDC for all DMTs were comparable, ranging from 88% to 93% for oral DMTs, and 81% to 88% for injectables. Eighteen percent of patients switched therapies, of which 57% were from injectable to oral therapies. On average, patients with a PDC ≥ 80% had copayments that were approximately 10% lower than those with a PDC < 80%.

CONCLUSIONS: Overall, the majority of patients adhered to MS therapies, but adherence rates can be improved. Targeted programs should focus on improving adherence in the younger population, and benefit designs should take into consideration keeping out-of-pocket costs affordable. Programs enhancing adherence may improve clinical outcomes, potentially decreasing relapse rates, and reducing or delaying a decline in patient functional status and the risk of early disability. Ultimately, improving patient outcomes may reduce the cost of RMSCare, making treatment programs more cost-effective.

SPONSORSHIP: Sanofi Genzyme.

G25 Twelve-Month MS-Related Direct Cost Analysis of Relapse Outcomes with Alemtuzumab Versus IFNB-1a in Active Relapsing-Remitting MS (CARE-MS II)
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BACKGROUND: The Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis (CARE-MS) II study (NCT00548405) was a 2-year, phase 3, head-to-head trial in patients with active relapsing-remitting MS who had an inadequate response to previous disease-modifying therapy. Alemtuzumab 12 mg reduced the relapse rate over 2 years by 49% compared with subcutaneous interferon beta-1a (SC IFNB-1a) 44 μg thrice weekly (TIW). This reduction in relapse rate also translated into additional clinically meaningful benefits, such as a 56% reduction in the rate of relapses treated with steroids (P < 0.0001), a 48% reduction in the rate of severe relapses (P = 0.0121), and a 55% reduction in the rate of relapses that led to hospitalization (P = 0.0045).

OBJECTIVE: To assess the MS-related direct costs associated with alemtuzumab and SC IFNB-1a on relapses that were severe or led to steroid treatment or hospitalization.

METHODS: Costs from a published analysis of direct cost burden associated with MS relapses were applied to the relapse results of CARE-MS II. Annualized rates for each relapse outcome were calculated per 100 patients treated, and 12-month MS-related direct costs per patient were applied. MS-related direct costs included hospitalization, ER visits, and outpatient visits (excluding pharmacy costs). All costs were adjusted to 2015 dollar value.

RESULTS: Twelve-month direct cost per patient (excluding drug costs) for those with relapses requiring steroids (low/moderate severity) were estimated to be $3,676. For hospitalization and severe relapses, the 12-month costs per patient were estimated to be $16,345 and $22,121, respectively. Annualized rates for severe relapses, relapses treated with corticosteroids, and relapses that led to hospitalizations were used to estimate the MS-related direct cost per 100 patients. Annual estimated MS direct costs per 100 patients for relapses requiring steroids were $69,844 and $158,069 for alemtuzumab and SC IFNB-1a, respectively (difference = $88,225). Annual costs per 100 patients for relapses requiring hospitalization (hospitalization cost only) were estimated to be $80,723 and $177,591, respectively (difference = $96,868). Annual estimated severe relapse costs per 100 patients were estimated to be $88,486 and $176,971, respectively (difference = $88,485).

CONCLUSIONS: Alemtuzumab was associated with an economic benefit compared with SC IFNB-1a by demonstrating decreased MS-related direct costs due to relapses that were severe or led to steroid treatment or hospitalization.

SPONSORSHIP: Sanofi Genzyme.

G26 Resource Use Associated with Outpatient Management of Multiple Sclerosis: Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs
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BACKGROUND: Medical claims data are valuable for examining real-world healthcare resource use to evaluate outcomes associated with multiple sclerosis (MS) treatments in the outpatient setting.

OBJECTIVE: To evaluate resource use associated with outpatient management of patients with MS newly initiating subcutaneous interferon beta-1a (scIFNB1a) vs. oral disease-modifying drugs (DMDs; i.e., teriflunomide, fingolimod, dimethyl fumarate) using real-world data.

METHODS: Patients were identified from the IMS LifeLink PharMetrics Plus Database between 1/1/2012 and 6/30/2013. The criteria for inclusion in the study were: MS diagnosis (ICD-9-CM: 340.xx); initiation of scIFNB1a, teriflunomide, fingolimod, or dimethyl fumarate (1st claim=index date); continuous eligibility 12 months pre- and post-index; no DMD 12 months pre-index (treatment-naive), and age 18-63 years. Resource use associated with outpatient management was assessed 12 months following DMD initiation and included outpatient visits, neurologist visits, magnetic resonance imaging (MRI), liver function tests (LFTs), and complete blood counts (CBCs). Generalized linear models with gamma distribution and log link assessed resource use controlling for age, sex, region, and clinically-meaningful measures of disease severity (i.e., 90-day pre-index indicators for relapse, neurologist visits, and MRI).

RESULTS: 1,665 patients (868 scIFNB1a, 118 teriflunomide, 455 fingolimod, 406 dimethyl fumarate) met inclusion criteria (mean age of 44.4 years and 75.9% female). After adjustment for demographic and 90-day pre-index indicators, the estimated mean number of outpatient visits per patient was lowest for scIFNB1a (18.2) vs. fingolimod (21.1; P = 0.002), dimethyl fumarate (21.5; P = 0.001), and teriflunomide (22.9; P = 0.003). On average, patients receiving scIFNB1a had fewer MS-related outpatient visits (6.6) vs. dimethyl fumarate (8.7; P < 0.001), fewer neurologist visits (5.3; P < 0.001), fewer laboratory tests (3.9; P < 0.001), and fewer MRIIs (0.54) vs. fingolimod (0.72; P = 0.018) and dimethyl fumarate (0.77; P = 0.007). The mean number of LFTs was lower for dimethyl fumarate (0.45) vs. scIFNB1a (0.63; P = 0.037) and higher for teriflunomide vs. scIFNB1a (1.16; P = 0.010). Mean number of CBCs did not differ among DMDs.

CONCLUSIONS: In this real-world population, the initiation of scIFNB1a was associated with lower usage of several outpatient management-related healthcare resources compared with the initiation of oral DMDs.

SPONSORSHIP: EMD Serono, Rockland, MA (a business of Merck KGaA, Darmstadt, Germany).
G27 Validation of a Novel Measure of Multiple Sclerosis Disease Severity Using Real-World Data

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BACKGROUND: Identifying patients with greater disease severity in multiple sclerosis (MS) may help to distinguish patient populations most likely to benefit from intervention. Using all-cause medical costs as a potential marker of disease activity, a retrospective claims-based algorithm was developed to categorize patients into levels of disease severity.

OBJECTIVE: To test and validate a MS disease severity composite measure for use in retrospective claims database analyses.

METHODS: A negative binomial regression was estimated to predict annual all-cause medical costs among patients with MS using retrospective healthcare claims data from the IMS LifeLink PharMetrics Plus Database (January 2006 to June 2013). Coefficients reaching statistical significance (P<0.05) and increasing costs by ≥5% were selected for inclusion into an MS-specific severity score (scale of 0 to 100). Individual components of the score included rehabilitation services, altered mental state, pain, disability, stiffness, balance disorder, urinary incontinence, numbness, malaise/fatigue, and infections. The original regression was reevaluated using the MS severity score as a covariate, and then tested by comparing each patient’s predicted vs. actual costs. Model bias was further evaluated by MS score tertile, representing low, medium, and high MS severity. The predictive model was derived using a random 50% sample and tested/validated using the remaining 50%.

RESULTS: Overall (i.e., without stratification by severity), the average predicted annual total medical cost was $11,134 for the original model sample (n=11,389, vs. $10,528 actual) and $11,303 for the validation sample (vs. $10,620 actual). Therefore, the model had consistent bias (approximately $600 or 6% of actual costs) for both the original and validation sample. Among the validation sample, the mean severity scores were 0.24, 8.95, and 21.77 for the low, medium, and high MS severity tertiles, respectively. On average, the model predicted costs most accurately among patients with lower disease severity ($5,233 mean predicted vs. $5,233 mean actual cost for lowest tertile).

CONCLUSIONS: The performance of this predictive model is in line with other published validated models. Monitoring such disease activity scores over time may represent a new approach for identifying MS disease progression using administrative claims data.

SPONSORSHIP: EMD Serono, Rockland, MA (a business of Merck KGaA, Darmstadt, Germany).

G28 Real-World Assessment of Cost Among Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs

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BACKGROUND: Use of healthcare claims data enables the assessment of real-world outcomes to evaluate treatments for multiple sclerosis (MS).

OBJECTIVE: To utilize real-world data to evaluate relapse rates of patients with MS newly initiating subcutaneous interferon β-1a (scIFNβ1a) vs. oral disease-modifying drugs (DMDs; i.e., teriflunomide, fingolimod, dimethyl fumarate).

METHODS: Patients with third party payer coverage were identified from the IMS LifeLink PharMetrics Plus Database from 1/1/2012-6/30/2013. Inclusion criteria were: MS diagnosis (ICD-9-CM: 340.xx); initiation of scIFNβ1a, teriflunomide, fingolimod, or dimethyl fumarate (1st claim=index date); continuous eligibility 12 months pre- and post-index; no DMD 12 months pre-index (treatment-naïve); and age 18-63 years. Total (all-cause) and medical costs (excluding DMD costs) were assessed during the 12-month post-index period (reported in 2014 U.S. dollars). Generalized linear models with gamma distribution and log link assessed cost controlling for demographics (i.e., age, sex, and region) and clinically-meaningful measures of disease severity (i.e., 90-day pre-index indicators for relapse, neurologist visits, and MRI).

RESULTS: A total of 1,665 patients (686 scIFNβ1a, 118 teriflunomide, 455 fingolimod, and 406 dimethyl fumarate) met inclusion criteria (mean age = 44.8 years, 75.5% female). After adjustment for demographics and clinically meaningful disease severity indicators, the estimated least square mean 12-month total cost for scIFNβ1a was $57,558 compared with teriflunomide ($55,414; P = 0.4977), fingolimod ($69,478; P < 0.0001) and dimethyl fumarate ($69,798; P < 0.0001). The estimated least square mean 12-month medical cost for scIFNβ1a was $13,562 compared with fingolimod ($15,840; P = 0.0234), teriflunomide ($17,148; P = 0.0350), and dimethyl fumarate ($20,987; P < 0.0001).

CONCLUSIONS: In this real-world MS patient population, after controlling for demographics and clinically meaningful measures of disease severity, 12-month total cost was significantly lower in patients initiating scIFNβ1a compared with those initiating fingolimod or dimethyl fumarate, and 12-month medical cost was significantly lower in patients initiating scIFNβ1a compared with patients initiating any oral DMD.

SPONSORSHIP: EMD Serono, Rockland, MA (a business of Merck KGaA, Darmstadt, Germany).

G29 Real-World Relapse Rates Among Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs

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BACKGROUND: The Institute for Healthcare Improvement’s ‘Triple Aim’ framework to optimize health system performance suggests healthcare payers and providers must simultaneously improve patient quality of care, improve the health of populations, and lower healthcare costs. Administrative claims datasets can provide information on outcomes and costs in real-world settings to assist decision makers in reaching these goals.

OBJECTIVE: To utilize real-world data to evaluate costs among patients with multiple sclerosis (MS) initiating subcutaneous interferon beta-1a (scIFNβ1a) vs. oral disease-modifying drugs (DMDs; i.e., teriflunomide, fingolimod, dimethyl fumarate).

METHODS: Patients with third party payer coverage were identified from the IMS LifeLink PharMetrics Plus Database from 1/1/2012-6/30/2013 met the inclusion criteria: MS diagnosis (ICD-9-CM: 340.xx); initiation of scIFNβ1a, teriflunomide, fingolimod, or dimethyl fumarate (1st claim=index date); continuous eligibility 12 months pre- and post-index; no DMD 12 months pre-index (treatment-naïve); and age 18-63 years. Relapse was assessed 12 months following DMD initiation and was defined as: MS-related hospitalization, MS-related emergency room (ER) visit, or MS-related outpatient visit with corticosteroid prescription ≥ 7 days. Analyses included pairwise chi-square tests and logistic regression controlling for age, sex, region, and clinically-meaningful measures of disease severity (i.e., 90-day pre-index indicators for relapse, neurologist visits, and MRI).
RESULTS: A total of 1,665 patients (686 scIFNβ1a, 118 teriflunomide, 455 fingolimod, 406 dimethyl fumarate) met the inclusion criteria. Mean age was 44.4 years; 75.5% of patients were female. Unadjusted analyses showed that MS-related hospitalizations and ER visits did not differ among DMDs; however, the proportion of patients with an MS-related outpatient relapse was lower in patients initiating scIFNβ1a (19.7%) vs. teriflunomide (32.2%; \( P = 0.003 \)) and dimethyl fumarate (26.8%; \( P = 0.006 \)). Proportion of patients with ≥1 MS relapse of any type was lower with scIFNβ1a vs. oral DMDs (21.7% and 26.1%, respectively; \( P = 0.039 \)). Logistic regression controlling for demographic and 90-day pre-index clinically-meaningful disease severity indicators showed that initiation of teriflunomide or dimethyl fumarate was associated with higher likelihood of relapse (odds ratio \( OR = 2.1, P = 0.001 \) and \( OR = 1.5, P = 0.005 \), respectively) vs. scIFNβ1a. A neurologist visit (\( P = 0.034 \)) and MS relapse (\( P < 0.0001 \)) in the 90 days before treatment initiation were predictive of relapse.

CONCLUSIONS: In this real-world population, patients initiating scIFNβ1a had a lower likelihood of experiencing surrogates for relapse in the first year than patients initiating teriflunomide or dimethyl fumarate.

SPONSORSHIP: EMD Serono, Rockland, MA (a business of Merck KGaA, Darmstadt, Germany).

G30 Potential Cost Savings Due to Alemtuzumab Persistent Reduction in Disease Endpoints Through 5 Years Without Retreatment for Majority of Patients

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BACKGROUND: In the CARE-MS II study (NCT00548045) in patients with active relapsing-remitting multiple sclerosis (RRMS) who had an inadequate response to prior therapy, alemtuzumab had superior efficacy over subcutaneous interferon beta-1a (SC IFNβ1a) and manageable safety over 2 years (0-24 months). The 3-year (Months 24-60) follow-up to the core study showed 59.8% of these patients received only the initial 2 annual courses (at 0 and 12 months), whereas 28.8%, 9.9%, and 1.5% received 1, 2, or 3 additional courses, respectively.

OBJECTIVE: To assess potential cost savings associated with the persistent efficacy of alemtuzumab over 5 years after initiation of therapy in the absence of retreatment for the majority of patients.

METHODS: A cost model, using a payer perspective, was constructed with results from the CARE-MS II study attributing direct costs of alemtuzumab and SC IFNβ1a, adverse effects, monitoring, and relapse. A hypothetical 2,500,000 beneficiary population was used to determine the cost of treatment of RRMS patients with alemtuzumab or SC IFNβ1a exclusively. Progression of disability was not considered in this model.

RESULTS: Total treatment cost of an RRMS patient population in Year 1 of the model was higher for alemtuzumab than for SC IFNβ1a ($396,046,399 vs. $282,310,834, respectively). Costs decreased over the next 4 years to result in cost savings of $23,452,716, $150,775,000, $210,895,144, and $231,561,444 in Years 2, 3, 4 and 5, respectively. The total relapse cost per year for the population was $4,800,992 less in the alemtuzumab group ($9,603,494 in the SC IFNβ1a vs. $4,802,502 in the alemtuzumab group). Adverse effect costs per year were higher in the alemtuzumab group versus the SC IFNβ1a group ($1,010,401 vs. $454,197, respectively). Within the hypothetical 2,500,000 beneficiary population, alemtuzumab resulted in a per-member, per-month (PMPM) savings in Years 2, 3, 4, and 5 of $0.85, $5.03, $7.03, and $7.72, respectively.

CONCLUSIONS: Alemtuzumab total treatment cost was lower than SC IFNβ1a in a 5-year treatment scenario due to cost avoidance in relapse rate reduction and drug cost associated with alemtuzumab’s persistent efficacy over 5 years after initiation of therapy in the absence of retreatment for the majority of patients. Savings from alemtuzumab therapy also reduced PMPM cost during the study period. The cost savings estimate of alemtuzumab may be conservative as the reduction of disability associated with its use was not considered in this analysis.

SPONSORSHIP: Sanofi Genzyme, Bayer Healthcare Pharmaceuticals.

G34 Literature Review of Studies Assessing Direct Costs Associated with Migraine

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BACKGROUND: Migraine is a debilitating disease which is associated with a substantial economic burden.

OBJECTIVE: To synthesize and summarize current published literature on direct costs in adults with chronic (CM) or episodic migraine (EM) in the United States (U.S.).

METHODS: A comprehensive literature search was conducted on multiple data sources including biomedical databases and health technology assessment (HTA) websites from January 2005 to November 2014 to identify studies assessing costs and health resource use associated with migraine. Bibliographic searches of relevant studies were performed to identify relevant publications. The search included several countries but this abstract focuses on U.S. studies assessing direct costs associated with migraine. Studies were initially screened based on titles and abstract followed by full-texts screening by two independent reviewers using predefined inclusion and exclusion criteria. Disagreements were resolved by consulting a third independent reviewer.

RESULTS: A total of 41 studies were included in the review; of which 22 presented direct costs associated with migraine in the U.S. Age of patients across the included studies ranged between 34 to 54 years and patients were predominately female. Over 80% of the patients were white. The American Migraine Prevention and Prevalence (AMPP) study (U.S.-specific) and the International Burden of Migraine Study (IBMS) (global) are the two major population-based studies. The mean annual costs for EM ranged from $1,533 to $1,757 and that for CM (or transformed migraine) ranged from $4,144 to $7,750 as observed from the AMPP and IBMS studies. In two separate studies, the total health resource utilization cost (excluding drug cost) and annual total direct cost (including drug cost) for commercially insured migraine patients were $4.3 billion and $11.07 billion, respectively. Medication use, specifically opioid and triptan use, were the key interventions contributing to high medication costs. Emergency room visits also contributed to total direct costs associated with migraine in the U.S.

CONCLUSIONS: There is a substantial direct cost burden in the U.S. due to migraine which increases with increase in number of headaches; costs associated with CM were nearly 3-4 times those for EM. Future research should focus on identifying cost drivers among migraine patients, especially for those transforming from EM to CM.

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G35 Off-Label Prescribing for Children with Migraines in U.S. Ambulatory Care Settings

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BACKGROUND: Migraines can significantly impair quality of life in children that affect about 10% of school-age children in U.S. Despite the potential disability, many children do not receive treatment or prophylaxis due to significantly less medications approved for them. With regards the controversy surrounding off-label medication use, off-label prescribing is often common in children. However, very little research is available to identify its prescribing patterns.

OBJECTIVE: To investigate the prevalence and pattern of off-label prescribing for children with migraines.

METHODS: A secondary data analysis was conducted from the pooled National Ambulatory Medical Care Survey (NAMCS) 2011 and 2012. Patients 17 years or younger with a diagnosis of migraines were included. A series of weighted descriptive analyses were used to estimate the prevalence of medications recommended from American Academy of Neurology. A weighted logistic regression was constructed to compare the variables associated with prescribing patterns between off-label and FDA-approved medications. All analyses utilized SAS 9.4 statistics software and incorporated sample weights to adjust for the complex sampling design employed by NAMCS.

RESULTS: Among 12.9 million outpatient visits that took place in 2010 and 2012 with migraine diagnosis, 1.2 million visits were from children. Female accounted for nearly twice of migraine visits than males (66% vs. 34%). Children aged 12-17 years accounted for the highest frequency than those aged 6-11 years, and aged 0-5 years (84% vs. 16% vs. 0%). 66.7% of the visits with migraine diagnosis received at least one migraine drug. Of these, off-label medication is 2.6 times more than FDA-approved medications for children (72.5% vs. 27.5%). The results of logistic regression showed significant likelihood of prescribing off-label medications on physician’s specialty, patient’s race and reason of visit. Neurologists (OR = 0.28, P < 0.05) and pediatricians (OR = 0.095, P < 0.05) were less likely to prescribe off-label drugs than general/family practitioners. The major visit reason for preventive care (OR = 5.8, P < 0.05) and chronic problems (OR = 3.0, P < 0.05) were more likely to receive off-label drugs than the visits for new problems.

CONCLUSIONS: This study provides significant real-world evidences that off-label prescribing is widespread in the children with migraines. Although literature has reported that off-label prescribing may not always be harmful, there is much needed research and practice guideline to enforce evaluation to the extent of prescribing appropriate medications to children.

SPONSORSHIP: None.

GOAL: To measure the impact of a clinical program on the proportion of Medicare patients utilizing HRMs.

PROGRAM DESCRIPTION: The HRM treatment rate is calculated by taking the number of member-years of enrolled Medicare beneficiaries ≥ 65 years who received ≥ 2 prescription fills for the same HRM (numerator) divided by the number of member-years of enrolled Medicare beneficiaries ≥ 65 years during the 2015 calendar year (denominator). The potential outreach population consists of members who fill ≥ 1 HRM during the 2015 calendar year. Additional criteria including specific HRM class, member prescription history, and prescriber demographics are utilized to determine the final outreach population and stratify interventions. A clinical program was implemented to improve (minimize) the HRM treatment rate through pharmacist-led telephonic outreach to providers, pharmacies, and patients. Outreach was focused on recommending discontinuation of HRM and/or switching to safer alternatives, when clinically appropriate.

OBSERVATIONS: Between January and December 2015, a total of 1,163 members were identified for outreach through a recurring process on a weekly basis. Preliminary results based on January through October 2015 pharmacy data indicate that 686 members were prevented from entering the numerator for the HRM treatment rate, either due to HRM discontinuation and/or change to a safer alternative. The 686 successful conversions have resulted in a treatment rate of 4.6% (5 stars). Full results for 2015 will be available in February 2016.

FINDINGS/RECOMMENDATIONS: As of October 2015, the clinical program has resulted in a 1-star improvement for the HRM measure from 2014, at which time the treatment rate was 7.8% (4 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 study was conducted by Magellan Rx Management without external funding.

G36 Impact of a Clinical Outreach Program on the Utilization of High-Risk Medications for CMS STAR Ratings

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PROBLEM DESCRIPTION: 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 measure, D11-High Risk Medications (HRM), is the inappropriate utilization of drugs with a high risk of serious side effects in the elderly when safer choices may be available.

METHODS: Descriptive cohort analysis using 2008-2011 data from the National Hospital Ambulatory Medical Care Survey (NHAMCS-ED component). ED sample visits with a clinician diagnosis of epilepsy or non-febrile convulsion were selected and NHAMCS sampling weights were applied to the 1,249 qualifying sample visits to calculate national weighted estimates.

RESULTS: There were an estimated 4.8 million ED visits for epilepsy and convulsions between 2008-2011 related to epilepsy and convulsions and the characteristics of those visits.

OBJECTIVE: To estimate the number of U.S. ED visits between 2008-2011 related to epilepsy and convulsions and the characteristics of those visits.

BACKGROUND: Approximately 30% of patients with epilepsy experience recurrent seizures despite treatment with one or more antiepileptic drugs (AEDs). Seizures may result in unplanned emergency department (ED) visits, which can be expensive and stressful for patients and caregivers.

OBJECTIVE: To estimate the number of U.S. ED visits between 2008-2011 related to epilepsy and convulsions and the characteristics of those visits.
ED arrival via ambulance (or not) was captured for 3.6 million visits; 60.3% arrived by ambulance. Resource use during the 4.8 million visits: blood tests: 78.8%, diagnostic testing/screening services (e.g., cardiac monitoring, urinalysis): 62.1%, and diagnostic imaging services (e.g., CT scan, X-ray, <2% received MRI): 54.7%. Anticonvulsant medications were used and/or prescribed during 52.5% of visits; lorazepam, phenytoin, and levetiracetam were most commonly recorded AEDs. At ED discharge, the majority of patients (63.0%) were advised to follow up directly with their physician; 22.6% of ED visits resulted in a hospital admission (average stay 4.7 days).

CONCLUSIONS: With an estimated 1.3 million U.S. ED visits annually for patients with epilepsy and convulsions, the data suggest there continues to be an unmet need in seizure management and coordination of care. Understanding ED resource utilization for this population at a national level may assist in evaluating methods to help reduce unplanned ED visits such as rescue treatment options or seizure action plans.

SPONSORSHIP: Upsher-Smith Laboratories.

G39 Uncontrolled Epilepsy in the U.S.: A Major Clinical and Economic Problem
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BACKGROUND: 1% of U.S. adults have active epilepsy according to data from 2010 National Health Interview Survey (Centers for Disease and Prevention 2012). About one third of patients have break through seizures, requiring visits to emergency departments and hospitalizations.

OBJECTIVE: To study clinical and economic consequences of uncontrolled epilepsy in the U.S.

METHODS: We examined the prevalence of all hospitalizations, and Emergency department visits, with primary diagnosis of ICD-9 codes 345.xx and 780.39 in the U.S. community population aged 18 years or older in 2013 using the Nationwide Inpatient Sample (NIS) data and Nationwide Emergency Department Sample (NEDS). NIS is a stratified random sample of all U.S. community hospitals. It is the largest inpatient care database with information on all inpatient care regardless of insurance status. NEDS is a 20-percent stratified sample of all U.S. community hospitals. It is the largest emergency department (ED) database in the United States. Prior studies have demonstrated a positive predictive value (PPV) for a diagnosis of epilepsy of 98.9% for ICD-9 code 345.xx, and a PPV of 84% for 780.39. Prevalence was calculated per 100,000 U.S. population. U.S. population data was taken from U.S. Census Bureau.

RESULTS: In 2013 there were 218,365 hospitalizations for primary diagnosis of epilepsy in U.S. in patients 18 years and older among a population of 243 million of same age, with a prevalence of 90/100,000 people. The prevalence increased with age, reaching 196 per 100,000 in the extreme elderly (age 85 years or more). The average charges per hospitalization were $33,210 and the total charges were over $7.25 billion. Medicare and Medicaid paid 61% of the charges and private insurance paid 27.25% of the charges. There were 842,994 Emergency department visits for primary diagnosis of epilepsy in U.S. in patients 18 years and older with a prevalence of 347/100,000 population. Surprisingly the prevalence was highest in 18-44 age group population with a prevalence of 404/100,000. Most (88%) of these younger age group patients were treated and discharged from the emergency room. The total charges of these visits was more than $931 million. Medicare and Medicaid paid 56% of the total charges, and private insurance paid 22% of the total charges.

CONCLUSIONS: Uncontrolled epilepsy hospitalizations and ER visits resulted in over $8 billion in charges in 2013. Improved measures to control seizures are essential to reduce the large clinical and economic consequences of uncontrolled epilepsy.

SPONSORSHIP: This project was supported by Acorda Therapeutics.

G40 Uncontrolled Epilepsy Hospitalizations in the U.S.: A Dramatic Increase in Costs over Last 15 Years
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BACKGROUND: Epilepsy affects about 2.9 million adults and children in U.S. Almost one-third patients have uncontrolled or “breakthrough” seizures, often requiring hospitalization. Many patients are also non-compliant with their medications leading to seizures.

OBJECTIVE: To determine trends in hospitalizations for primary diagnosis of epilepsy from 1998 to 2013.

METHODS: We examined the prevalence and charges of all hospitalizations with primary diagnosis of epilepsy (ICD-9 codes 345.xx (epilepsy and recurrent seizures) or 780.39 (other convulsions) in the U.S. community population from 1998 to 2013 using the Nationwide Inpatient Sample (NIS) data. NIS is a stratified random sample of all U.S. community hospitals and is the largest inpatient database with information on all inpatient care regardless of insurance status. Prior studies have demonstrated a positive predictive value (PPV) for a diagnosis of epilepsy of 98.9% for ICD-9 code 345.xx, and a PPV of 84% for 780.39. Prevalence was calculated per 100,000 U.S. population. U.S. population data was obtained from U.S. census bureau.

RESULTS: Hospitalizations for uncontrolled epilepsy increased by 34% from 205,351 in 1998 to 276,280 in 2013. Prevalence of epilepsy hospitalizations per 100,000 U.S. population increased by 17% from 74 to 87. The average charges per hospitalization increased almost three-fold from $9,514 in 1998 to $32,172 in 2013. Even when accounting for 42.9% cumulative rate of inflation from 1998 to 2013, the charges for epilepsy hospitalizations were more than twice as much in 2013 as they were in 1998. The total charges in 2013 for hospitalizations for epilepsy were more than 7.25 billion. The increase in prevalence of epilepsy hospitalizations was highest in 18-44 years age group from 52/100,000 in 1998 to 68/100,000 in 2013; a 32% increase in prevalence in this age group. In 45-64 years age group the prevalence of epilepsy hospitalizations increased from 80/100,000 in 1998 to 94/100,000 in 2013, an 18% increase. The prevalence of epilepsy hospitalizations decreased in elderly and extreme elderly age groups.

CONCLUSIONS: The charges for epilepsy hospitalizations have more than doubled from 1998 to 2013 (after adjusting for inflation). The total charges for epilepsy hospitalizations are more than 7.25 billion dollars annually. The overall prevalence of epilepsy hospitalizations has also increased, this increase was highest in 18-44 years age group. Increasing prevalence and economic impact of uncontrolled epilepsy hospitalizations necessitates more effective measures for prevention of seizures.

SPONSORSHIP: This project was funded by Acorda Therapeutics.

G41 Cost-Effectiveness of Eslicarbazepine Acetate Monotherapy in Partial-Onset Epilepsy
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BACKGROUND: Of the new patients with epilepsy diagnosed each year, approximately 1/3 will not achieve adequate seizure control
A Secondary Analysis of the COMPASS Trial

OBJECTIVE: To compare the cost-effectiveness of eslicarbazepine acetate to other branded AEDs used as monotherapy treatment of partial-onset seizures in adults.

METHODS: A decision-analytic Markov model was developed to compare the seizures avoided and costs (in 2015 dollars) from a commercial payer perspective over a 3-year time horizon. The model assumes all patients start treatment with a branded AED (i.e., eslicarbazepine acetate (ESL), lacosamide, or lamotrigine XR), or with historical control. Patients defined as responders have a 50% reduction in seizure frequency and continue to experience this reduction in seizure frequency until they discontinue treatment, at which time they revert to the baseline seizure rate. Effectiveness inputs (50% responder and all-cause withdrawal rates) were obtained from a network meta-analysis of published phase III monotherapy trials. AED cost was determined using U.S. wholesale acquisition cost and market share data as of August 31, 2015. Cost per seizure was calculated from recent research, and was estimated at $388. A probabilistic sensitivity analysis (PSA) was also conducted to test model robustness.

RESULTS: Over the time horizon, eslicarbazepine acetate resulted in the avoidance of 34.5 seizures at a savings of $3 per seizure avoided, or a total savings of $118 compared to historical control. Eslicarbazepine acetate demonstrated longer mean monotherapy treatment duration, and greater number of seizures avoided, compared with historical control and active comparators; overall cost was lower than lamotrigine XR and historical control. In the PSA, eslicarbazepine acetate was a cost-effective treatment option at a willingness-to-pay threshold of $1,000 per seizure avoided (78.4% probability).

CONCLUSIONS: Based on the result of this cost-effectiveness model, eslicarbazepine acetate monotherapy was the most effective of the comparators, and was a cost saving treatment option vs. both historical control and lamotrigine XR.

SPONSORSHIP: Sunovion Pharmaceuticals.

G43 Healthcare Resource Utilization and Costs of Chronic and Episodic Migraine

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BACKGROUND: Episodic (EM) and chronic migraine (CM) are distinguished primarily by the frequency of headache-days. Published literature from large epidemiological studies have found that individuals with CM have greater humanistic and economic burden than those with EM. However, previous studies have relied on self-reported survey data. Studies analyzing medical claims to evaluate resource utilization and cost associated with migraine remain limited.

OBJECTIVE: To estimate and compare all-cause and headache-related healthcare resource utilization and costs of newly diagnosed CM and EM patients.

METHODS: This was a retrospective analysis of medical and pharmacy claims from the Scott and White Health Plan. First documentation of CM or EM diagnosis from December 2011 to December 2013 was defined as the index date. Patients were required to be ≥18 years of age, and have continuous enrollment ≥6 months pre-index and 12 months post-index. All-cause and headache-related healthcare resource utilization and costs were assessed for CM and EM groups over a 12 month period.

RESULTS: A total of 283 CM and 3,603 EM eligible patients were included in the final analytical dataset. The average age in the CM and EM groups were comparable (47.6 vs. 46.3, P=0.145), but the CM group had a higher proportion of females (87% vs. 82%, P=0.046) and higher baseline comorbidity burden (Selim score 2.63 vs. 1.7, P<0.001). Patients with CM had significantly greater unadjusted mean standard deviation annual headache-related healthcare costs ($2,123 [$2,917]) and all-cause costs ($14,311 [$23,814]) than patients with EM (headache-related, $584 [$1,314]; all-cause, $8,793 [$16,942]) (P<0.001 for each). Headache-related expenditures constituted a larger proportion of total all-cause healthcare costs for CM (14.8% vs. $2,123 of $14,311) than EM (6.6% vs. $584 of $8,793). CM had higher headache-related outpatient visits (77% vs. 24%, P<0.001),
emergency room visits (8% vs. 4%, \( P = 0.004 \)), and prescriptions filled (91% vs. 74%, \( P < 0.001 \)) compared to EM. While the proportion of patients using any opioids was similar for CM (18% and) and EM (14% and) (\( P = 0.081 \)), the CM cohort had statistically significant higher mean annual 30-day fills than EM (3.32 ± 4.2 vs. 1.74 ± 2.8, \( P = 0.004 \)).

**CONCLUSIONS:** The results of this real-world study build on previous epidemiological study findings, demonstrating that all-cause and headache-related healthcare resource utilization and costs are significantly greater among individuals with CM than with EM.

**SPONSORSHIP:** Allergan.

**G45 Cost-Effectiveness of OnabotulinumtoxinA for Chronic Migraine Prophylaxis in Adults in the United States**

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**BACKGROUND:** Chronic migraine (CM) is a common and severe primary headache disorder that implies an established history of migraine and headache occurring on ≥15 days per month for ≥3 consecutive months (with ≥8 days per month involving headache typical of migraine). The debilitating symptoms of CM are associated with impaired physical, social, and occupational functioning and diminished mental health and overall health-related quality of life. CM thus accounts for disproportionately higher direct and indirect costs compared with migraine in general. OnabotulinumtoxinA (BOTOX, Allergan plc, Dublin, Ireland) is the only prophylactic therapy in the United States approved specifically for patients with CM, but limited information is available regarding the relative cost associated with its incremental reduction in headache frequency.

**OBJECTIVE:** To assess, from the U.S. societal perspective, the incremental cost-effectiveness of onabotulinumtoxinA for CM prophylaxis by calculating cost per headache day averted, accounting for direct and indirect costs over 12 months.

**METHODS:** This simple discrete decision analysis approach used a hypothetical cohort of 1,000 patients with CM to compare onabotulinumtoxinA treatment with placebo (i.e., saline injection) and best supportive care (i.e., continuation of previous regimen). Cost inputs were based on publicly available or published U.S. economic data and included medication and procedural costs, as well as direct and indirect management costs attributed to CM. Clinical inputs were derived from pooled results from the published phase 3 PREEMPT clinical trial program. Sensitivity analyses were performed across the range of clinical cost inputs.

**RESULTS:** The base-case incremental cost per headache day averted for onabotulinumtoxinA was $13 compared with best supportive care and $264 compared with placebo. Sensitivity analyses demonstrated consistent results and reduced incremental costs per headache day averted with increased headache-day frequency or increased management costs.

**CONCLUSIONS:** Compared with best supportive care and placebo, the estimated 12-month incremental cost per headache day averted for patients with CM receiving onabotulinumtoxinA treatment was consistently below $300 and less than the acquisition costs for a single treatment cycle. These results and the value-for-money of onabotulinumtoxinA treatment can be further interpreted by payers, patients, and providers in terms of their respective willingness-to-pay preferences and the potential budgetary impact.

**SPONSORSHIP:** Allergan.

**G46 A Comparative Assessment of Intravenous Immunoglobulin (IVIG) Therapy in the Treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

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**BACKGROUND:** Real-world data comparing treatment patterns and costs associated with available therapeutic options are extremely limited. This study identified newly diagnosed CIDP patients who were initially treated with IVIG. Patients were followed for 2 years to assess their need for alternative treatment options, switching to other IVIG therapies, and associated costs from the healthcare plan perspective.

**CONCLUSIONS:**
OBJECTIVE: To compare CIDP-related treatment patterns and costs of care across IVIG therapies from the healthcare plan perspective.

METHODS: Patients with CIDP in the PharMetrics Plus 150+ million member claims database between 1/1/10 and 6/30/12 were identified. Patients having at least 1 diagnosis code of CIDP and evidence of starting IVIG therapy were included in the study. Patients were required to be ≥ 18 years of age at diagnosis and have continuous eligibility for medical and pharmacy benefits at least 1 year prior to and 2 years after their initial diagnosis. Patients receiving other CIDP treatments prior to their index IVIG therapy were excluded. Patients were placed into cohorts based on their index IVIG product.

RESULTS: There were 326 patients meeting all inclusion criteria: mean age of 55.6, mean Charlson comorbidity index score 1.6, and 62% male. The most prescribed IVIG products were Gammagard Liquid (36%), Gamunex-C (34%), and then Carimune (10%) and Privigen (9%). Over the 2-year follow-up period, patients receiving Privigen were least likely to be prescribed a concomitant CIDP treatment (40%), followed by Gamunex-C (48%), Carimune (52%), and Gammagard Liquid (52%). Patients receiving Gammagard Liquid were least likely to be switched to another IVIG (8%), followed by Gamunex-C (25%), Privigen (30%), and Carimune (42%). Two-year follow-up CIDP-specific costs were lowest for Carimune ($105,658), followed by Gamunex-C ($129,290), Privigen ($134,070), and Gammagard Liquid ($168,858).

CONCLUSIONS: This real-world comparison of IVIG utilization in CIDP patients indicated that there are substantial differences in costs, switching rates, and use of concomitant CIDP therapy across commercially available IVIG products. These contrasting costs may be related to manufacturing differences between products, thereby affecting the tolerability, efficacy, and occurrence of adverse events.

SPONSORSHIP: Grifols SSNA.

G48 Health Care Resource Utilization and Costs Among Patients Diagnosed with Sporadic Inclusion Body Myositis in the U.S. Medicare Population

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BACKGROUND: Sporadic inclusion body myositis (sIBM) is a rare form of progressive inflammatory myositis diagnosed among adults aged >50 years, and there is no established treatment for the condition. There are no studies highlighting the economic burden of sIBM in the U.S. Medicare population.

OBJECTIVE: To compare the economic and clinical burden between patients with and without sIBM using Medicare data.

METHODS: A retrospective study was conducted using data from the 5% U.S. Medicare claims data random sample January 1, 2009-December 31, 2013. Bootstrapping was performed to simulate results of 100% Medicare from the 5% random Medicare sample. Patients were included in the study if they had at least 2 outpatient sIBM diagnoses (International Classification of Diseases, 9th Revision, Clinical Modification code 359.71) on different dates ≥7 days apart, or at least 1 inpatient or emergency room (ER) sIBM diagnosis during the identification period (January 1, 2010-December 31, 2011). Patients were required to be ≥65 years, have at least 12 months of continuous health plan enrollment pre-and post-index date, and no diagnosis for congenital hereditary or hereditary progressive muscular dystrophy. Using a ratio of 1:5, hard matching was performed to identify patients without a sIBM diagnosis during the study period. Each patient without a sIBM diagnosis was matched to a sIBM patient of identical age, gender, race, region, and index year. Generalized linear models (GLM) were used to compare the adjusted health care costs and resource utilization between the two cohorts.

RESULTS: After applying the patient selection criteria and using a ratio of 1:5, there were 656 patients in the sIBM cohort and 3,280 patients in the control cohort. After adjusting for baseline demographics and characteristics, patients in the sIBM cohort had higher health care utilization, including inpatient stays (30.72% vs. 7.13%; P value < 0.0001) and outpatient visits (92.36% vs. 51.46%; P value < 0.0001), resulting in significantly higher inpatient ($4,366 vs. $1,150; P value = 0.02), outpatient ($3,303 vs. $1,758; P value = 0.002), and total health care costs ($15,131 vs. $6,542, P value < 0.001), compared to those in the control cohort.

CONCLUSIONS: The economic burden and health care resource utilization were significantly higher for patients with versus without a sIBM diagnosis.

SPONSORSHIP: Novartis Pharmaceuticals.

G49 Association of Rescue Medication Use with Clinical Outcomes and Health Care Costs in Patients with Seizure Clusters

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BACKGROUND: Seizure clusters (SCs) are multiple, distinct seizures that occur over a 24-hour period. Rescue medications are taken as needed to stop SCs; however limited data exist on the impact of inconsistent use of rescue medications on the clinical and economic outcomes associated with SC.

OBJECTIVE: To evaluate the association between use of rescue medications and the effects on clinical outcomes, healthcare resource utilization, and costs in epilepsy patients experiencing SCs.

METHODS: An online, retrospective chart review of epilepsy patients with SCs was conducted among 186 U.S.-based neurologists. Adults (≥18 years of age) who were diagnosed with SCs at least 12 months prior to chart abstraction and experienced ≥1 SC during the same period were eligible. Patient data over a 12-month period were collected by neurologists using a web-based form. Patients with at least one prescription of rescue medication were grouped by their use pattern: those who used for all clusters (Always Users), those who did not use for at least one episode (Sometimes Users), and those who never used (Never Users). Adherence was defined as use of a prescribed rescue medication to treat a SC, as reported in the chart abstraction form.

RESULTS: 500 complete patient charts were collected; the mean age was 41 years, and 293 (59%) were male. 363 (73%) Always Users, 80 (16%) Sometimes Users, and 57 (11%) Never Users were identified. On average, the number of SCs experienced by these 3 groups was: 2.4 ± 10.7, 3.9 ± 4.4, and 1.5 ± 2.1, respectively. Sometimes Users were more likely to progress to status epilepticus (SE; 29% vs. 15%, P < 0.01), had more seizure-related emergency department (ED) visits (70% vs. 48%, P < 0.01) and inpatient (IP) admissions (54% vs. 30%, P < 0.01), and greater costs ($26,753 vs. $13,265, P < 0.01) compared to Always Users. Never Users experienced significantly fewer SCs than Always Users. Despite the difference in the number of SCs, Never Users and Always Users were comparable in progression to SE (18% vs. 15%, P = 0.68), ED visits (58% vs. 48%, P = 0.16), IP admissions (42% vs. 30%, P = 0.06), and costs ($11,213 vs. $13,265, P = 0.84).
**CONCLUSIONS:** In this study, patients with an increased frequency of SC and who were non-adherent to rescue medication had more adverse clinical outcomes (SE), greater healthcare resource use (ED, IP), and costs. These findings suggest that patient adherence to rescue medication may be associated with improved clinical outcomes and healthcare resource use.

**SPONSORSHIP:** Acorda Therapeutics.

**G50 Impact of a Prior Authorization Program on an Extended Release Opioid Market Share and Pharmacy Costs: A Comparison Among Two National Commercial Payers**

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**BACKGROUND:** Payers utilize formulary management tactics such as prior-authorization (PA) attempting to control healthcare costs and ensure appropriate prescription (Rx) utilization. However, such tactics inherently result in patient access barriers. Unintended consequences have been associated with such restrictions including delayed treatment, negative impact on patients’ health status, and mixed economic results. Limited knowledge exists from the payer perspective concerning the impact of a PA on extended-release/long-acting opioid (ER/LAO) market share and total pharmacy resource utilization or cost.

**OBJECTIVE:** To model the impact of an oxycodone hydrochloride extended-release (OER) PA implemented in a national commercial plan on 1/1/2014 on ER/LAO market share and pharmacy costs alongside a national plan without such restriction.

**METHODS:** A retrospective matched cohort study analyzed IMS commercial pharmacy and medical claims data for adult patients with an ER/LAO claim between 7/1/13 and 12/31/13 (pre-period) in 2 large national plans: one adding an OER PA restriction and one with no such restriction. Study groups were matched by age, gender, geography, comorbidity index, cancer diagnosis (yes/no) and new ER/LAO user (yes/no) and followed through 9/30/2014. The per-patient per-month (PPPM) Rx costs were calculated using a budget impact model (BIM) including: (1) output from the retrospective analysis, (2) a PA administrative cost of $40, and (3) loss of OER rebates in the plan with PA.

**RESULTS:** A total of 1,560 matched ER/LAO user patients were identified, mean age of 49.1, 43.0% male, 4.0% with a cancer diagnosis. The modeled PPPM Rx cost for ER/LAO decreased by 0.57% in the plan imposing a PA and by 1.90% in the plan with no PA. Among the 520 matched OER users in the PA plan, 47.5% and 56.0% continued OER within the first 2 months and 9 months following the PA, respectively, potentially representing members who already met the requirements of the PA. In the pre-matched sample, OER market share declined by 6.8% in the PA plan and 1.3% in the non-PA plan within 9 months. For the PA plan, the ER/LAO market share increased 4.0% for morphine extended-release generics and 1.8% for fentanyl generics at 9 months.

**CONCLUSIONS:** Implementation of a PA for OER resulted in less cost savings to the health plan than the plan with no PA requirement. For the plan imposing the PA, savings from the minimal market share impact were offset by the assumed administrative costs and rebate loss, resulting in cost neutrality.

**SPONSORSHIP:** Shire.

**H01 Satisfaction and Adherence with Current Treatment Options for Dry Eye Disease: Analysis of Data from the United States National Health and Wellness Survey**

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**BACKGROUND:** Dry eye disease (DED) affects millions of Americans, significantly impacting their vision and health-related quality of life. Treatments include ocular lubricants, ophthalamic cyclosporine, and off-label use of other therapies.

**OBJECTIVE:** To evaluate satisfaction and adherence with current treatment options for DED in the United States (U.S.).

**METHODS:** Data were analyzed from participants (≥ 18 y) in the 2013 U.S. National Health and Wellness Survey who reported a diagnosis of DED. Treatment satisfaction and adherence were evaluated on 3-level scales (low, medium, and high). Multivariate models were used to test differences across treatment types (artificial tears, ophthalamic cyclosporine, other therapy [eg, topical steroids, doxycycline, omega-3]) and DED severity levels (mild, moderate, severe), controlling for age, sex, insurance type and other significant covariates.

**RESULTS:** The analysis included 4,746 participants with diagnosed DED (mean age 58.1 y [SD 15.5], 63% women): N = 3,074 taking artificial tears, N = 542 ophthalamic cyclosporine, N = 224 other therapy, and N = 906 no treatment. Rates for high, medium, and low satisfaction were: artificial tears (47%, 33%, 17%); ophthalamic cyclosporine (48%, 30%, 21%); and other therapy (54%, 34%, 13%). In multivariate analysis, treatment satisfaction was significantly different across treatment types (P = 0.0046) and DED severity levels (P < 0.0001). Participants using ophthalamic cyclosporine were more likely to have either low or high (vs. medium) satisfaction than those on artificial tears (P = 0.0080 and P = 0.0054 for medium/low and high/medium comparisons, respectively). Treatment satisfaction tended to decline with increasing symptom severity. Adherence was high in 31% and medium in 33% of cyclosporine users, compared to 22% high and 38% medium in other therapy users. However, differences in adherence across treatment groups were not statistically significant after adjustment. Participants with severe DED were more likely to have high or medium (vs low) adherence compared to those with mild DED (P = 0.0114 and P = 0.0195, respectively).

**CONCLUSIONS:** In this diagnosed DED population, the majority reported medium to high treatment satisfaction. Satisfaction was highest with other therapy compared to ophthalamic cyclosporine and artificial tears. Compared to artificial tears, ophthalamic cyclosporine users were either highly satisfied or highly dissatisfied with treatment, which may indicate effectiveness variations in participant subgroups. Participants with more severe DED symptoms had higher adherence but lower satisfaction with treatment.

**SPONSORSHIP:** Shire.

**H02 Impact of Ophthalmic Antihistamines Formulary Coverage in a Medicaid Pediatric Accountable Care Organization (ACO)**

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**BACKGROUND:** Ophthalmic antihistamines are indicated for allergic conjunctivitis, which occurs frequently in pediatric patients with a...
history of allergic rhinitis, eczema and asthma. Ketotifen,azelastine and olopatadine (Pataday and Patanol) are approved for use in children with allergic conjunctivitis. Limited head to head trials compare these medications to show superiority therefore, cost should be a lead consideration when choosing therapy. Partners For Kids (PFK), a pediatric Accountable Care Organization (ACO) recommended its five, contracted Medicaid managed care plans to cover ketotifen with no restrictions, step therapy for azelastine after ketotifen trial, and prior authorization (PA) for Pataday and Patanol. At the time of recommendation, restrictions differed across all plans. One of five plans accepted recommendation with the exception of PA on Pataday. PFK disseminated a prescribing guidance tool to all PFK providers advising on ophthalmic antihistamine prescribing with ketotifen as first line therapy, followed by azelastine and then olopatadine (Pataday or Patanol).

**OBJECTIVE:** Measure impact of PFK’s ophthalmic antihistamine prescribing guidance tool on cost and prescribing patterns; Measure impact of change in formulary coverage of ophthalmic antihistamines on cost and prescribing patterns.

**METHODS:** Prescription claims data for ketotifen, azelastine, Pataday and Patanol were extracted from PFK’s database for all five contracted plans between June 1, 2013 and May 31, 2015. Claims data was characterized by count of prescription claims, count of prescription claims change as a percentage from previous year, and paid per member per month (PMPM). These metrics were stratified by year (June 2013 to May 2014; June 2014 to May 2015).

**RESULTS:** Prescription claims analyses noted an increase in paid PMPM for ketotifen and azelastine, $0.005 and $0.002, respectively. While a decrease in paid PMPM was seen for Pataday by $0.011 and for Patanol by $0.032. The trend in paid PMPM correlated with the number of prescriptions and percentage change year over year. The calculated 12 month cost saving impact of PFK’s recommended formulary change to one plan was $65,600. The overall cost savings totaled $113,250 comparing baseline total paid to 12 months post-implemention of formulary coverage change and prescribing guidance tool.

**CONCLUSIONS:** Our findings demonstrate utilization management of ophthalmic antihistamines using step therapy and PA combined with prescriber education was effective in impacting cost and prescribing patterns in a Medicaid pediatric ACO.

**SPONSORSHIP:** None.

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**H03 Real-World Treatment Patterns and Costs of Ranibizumab and Aflibercept for Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema in the United States**

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**BACKGROUND:** Ranibizumab (RBZ) and aflibercept (AFL) are anti-vascular endothelial growth factor (anti-VEGF) therapies approved in the U.S. for the treatment of neovascular age-related macular degeneration (AMD) and diabetic macular edema (DME). Given differences in dosing guidelines between RBZ and AFL, real-world data can shed light on actual treatment patterns and associated costs.

**OBJECTIVE:** To compare real-world treatment patterns, specifically, intravitreal injection frequency (IF) and cost (IC) of RBZ and AFL, for AMD (12 months [12M]), 24 months [24M]) and DME (12M) in treatment-naive (TN) and previously-treated (PT) patients.

**METHODS:** This retrospective U.S. claims study included TN or PT patients (>18 years) who initiated RBZ or AFL treatment (index date [ID] 11-18-2011 to 7-31-2015 for AMD; and 8-10-2012 to 7-31-2015 for DME), with continuous eligibility for 12M prior to and 12-24M following ID without switching to another anti-VEGF agent. IF and IC for RBZ vs. AFL were compared over 12M and 24M in AMD patients, and 12M in DME patients using multivariate regression models (reference-RBZ) adjusted for patient demographics and clinical characteristics.

**RESULTS:** Over 12M, TN AMD patients receiving RBZ (N = 2,260) and AFL (N = 1,256) had comparable IF (adjusted incidence rate ratio [IRR] = 0.99, P = 0.558) and marginally lower IC with AFL vs. RBZ (adjusted cost ratio [CR] = 0.93, P = 0.008). Over 24M, IF and IC were similar with RBZ (N = 1,018) and AFL (N = 482) in TN patients (IRR = 1.06, P = 0.168; CR = 0.99, P = 0.832). PT AMD patients receiving RBZ (12M N = 873; 24M N = 344) or AFL (12M N = 1,990; 24M N = 847) had comparable IF (12M IRR = 0.99, P = 0.984; 24M IRR = 1.00, P = 0.926) and IC (12M CR = 0.97, P = 0.393; 24M CR = 1.03, P = 0.629). In DME patients over 12M, IF was similar between treatments in TN (RBZ [N = 591]; AFL [N = 371]) and PT (RBZ [N = 312]; AFL [N = 26]) patients (TN IRR = 0.83, P = 0.19; PT IRR = 0.90, P = 0.58). Significant differences in IC, in favor of RBZ, were seen in TN and PT patients over 12M (TN CR = 1.32, P = 0.04; PT CR = 1.56, P = 0.018).

**CONCLUSIONS:** In AMD patients over 12M, IF was similar for RBZ and AFL in TN and PT patients. IC was marginally lower with AFL than RBZ in TN patients over 12M, and similar in PT patients; over 24M, IF and IC were similar between RBZ and AFL in TN and PT patients. In DME patients, significant differences were noted in IC between treatments in TN and PT patients over 12M (all P < 0.05) but not in IF. This suggests RBZ was the less costly treatment for DME over 12M with similar IF, although further study is required to determine if this trend is maintained over 24M.

**SPONSORSHIP:** Genentech.

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**H04 Health Care Resource Utilization Associated with Tympanostomy Tube Placement in Pediatric Populations**

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**BACKGROUND:** Otitis media (OM) with effusion (OME) occurs in 90% of children by age 4. Chronic OME may lead to hearing loss; speech, language, and learning difficulties; decreased quality of life; and increased health care utilization. Tympanostomy tube (TT) placement is an established treatment for chronic OME and current standard of practice is to apply topical antibiotics during and after surgery to prevent otorhea, the most common post-TT complication. Otolaryngology clinical practice guidelines recommend topical antibiotics, not oral, to treat otorhea at any time in children with TTs. OM is a significant pediatric health burden, associated with over $4B USD in costs.

**OBJECTIVE:** To characterize resource utilization (antibiotic prescriptions [RX]) in children post-TT placement through Day 30 (D30). Differences between Medicaid-enrolled (MC) and commercially insured (CO) populations were evaluated.

**METHODS:** Pediatric patients (≥17 years) with TT surgery between 1/1/2010 and 12/31/2013 were included from insurance claims databases. Medical and pharmacy claims within 30 days post-TT surgery were evaluated.

**RESULTS:** Within 3 days of TT surgery, 23.1% of patients (N = 368,847; MC = 128,472, CO = 240,375) filled a topical RX. From D4 through D30, 10.5% and 14% of patients filled a topical and oral RX, respectively; with significant differences between MC and CO cohorts (11.8% vs. 17.8% vs. 9.7% and 12.1%, respectively, P < 0.0001). Over 30 days, 53.5% (29.6%) patients (MC = 36,122, CO = 72,883) visited the emergency department (ED) or physician office with an ear-related condition. Differences between Medicaid-enrolled (MC = 128,472, CO = 240,375) filled a topical RX. From D4 through D30, 10.5% and 14% of patients filled a topical and oral RX, respectively; with significant differences between MC and CO cohorts (11.8% vs. 17.8% vs. 9.7% and 12.1%, respectively, P < 0.0001). Over 30 days, 53.5% (29.6%) patients (MC = 36,122, CO = 72,883) visited the emergency department (ED) or physician office with an ear-related condition.
diagnoisis (e.g., otorrhea, OM, otalgia); of these, 8.2% and 8.9% had a
topical and oral RX, respectively; with significant differences between
MC and CO patients (9.7% and 10.9% vs. 7.4% and 8.0%, respectively,
P<0.0001). Following ED visits, 24.6% of patients filled a topical and
53.0% an oral RX.

CONCLUSIONS: This study suggests that ~77% of patients may not
have received antibiotic prophylaxis after TT surgery, contrary to
standard of care. Physicians report giving the bottle of topical antibi-
otic used during surgery, thus a RX is not filled post-TT. While MC
patients are more likely given oral antibiotics than CO, oral antibiot-
ics are inappropriate prescribed and overused in general, indicating
that physicians may be unaware of clinical guidelines recommend-
ing topical over oral antibiotics for TT otorrhea. Finally, antibiotic
use through D30 may indicate failure of topical drop prophylaxis in
preventing otorrhea. Fayers should consider educational and manage-
ment strategies to ensure appropriate antibiotic use and evidence-base
pediatric care.

SPONSORSHIP: Otonomy.

100-199 Diseases of the Circulatory System
(e.g., Atrial Fibrillation, ACS, Pulmonary Hypertension)

105 Drivers of Statin Intolerance in Claims Data as Defined by
a Regional Managed Care and Clinical Expert Panel
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BACKGROUND: Lipid lowering therapy with statins is recommended
by major guidelines to reduce cardiovascular (CV) risk. While stud-
ies demonstrate the safety and efficacy of statins, some patients may
experience symptoms leading to discontinuation and placing them at
an increased risk for CV events and increased healthcare costs.

OBJECTIVE: To understand managed care and provider perceptions
of what drives and may be used to identify statin intolerance (SI) in
claims data.

METHODS: A panel of experts within a regional healthcare system was
convened in November 2015. The panel consisted of three physicians
and two pharmacists with expertise in cardiology, internal medicine,
and formulary management. The panel was presented with general
information on statins, guidelines for statin usage, existing SI defini-
tions, and published claims-based algorithms in other disease states.
The panel was asked to identify key variables and relationships associ-
ated with SI in their patient populations.

RESULTS: The panel recommended a systematic process to identify
potential SI events using a year of follow up. The process differed
based on statin use prior to start of follow up: ≥ 6 months (established
statin users), < 6 months (recent statin starters), and no statin fills in
the previous year (new statin users). The recommendations identified
potential SI events by any of the following: (1) medical claim for rhab-
domyolysis, (2) medical claim for muscle weakness, (3) an outpatient
medical claim for creatinine kinase assay, (4) fills for ≥ 2 different
statins, (5) a decrease in statin dose, (6) discontinuation (D/C) of a
statin (no statin refills for ≥ 6 months from the last expected fill date)
after exhibiting ≥ 80% adherence (established statin users only), or (7)
D/C of a statin with a subsequent fill for a non-statin lipid lowering
agent. The process did not classify events as SI if statin dose decreases
or D/C may have been the result of severe drug-drug interactions or
as part of response-guided therapy due to low-density lipoprotein
cholesterol changes.

CONCLUSIONS: This panel outlined a systematic approach using
claims data to identify potential patients with SI. The next phase in
this research is to apply this approach in a managed care setting and
compare the results to another published SI algorithm (concurrent
validity). Implementation of these approaches may identify opportuni-
ties for managed care to re-engage patients with alternative CV therapy
to reduce their subsequent risk of CV events.

SPONSORSHIP: This project was funded by Regeneron and Sanofi U.S.

106 Reevaluating the Value of Ezetimibe in the U.S. for Patients
with History of CVD Based on the IMPROVE-IT Results
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BACKGROUND: The results of the IMPROVE-IT study have shown
that addition of ezetimibe (EZ) to ongoing statin therapy provides
additional clinical benefit with respect to CVD outcomes. This trial
justifies the practice of adding EZ to statin therapy in high risk car-
diovascular disease (CVD) patients, which prior to IMPROVE-IT, the
long term value of EZ add-on to statin therapy had been questioned.

OBJECTIVE: To assess the economic value of EZ in patients with CVD
in the U.S. healthcare system accounting for the impending change in
cost due to patent expiry.

METHODS: We developed a Markov model with annual cycles to
project the long term cost and benefits of EZ add-on to statin therapy
in patients with a history of CVD and LDL-C values ≥ 70 mg/dL.
Baseline risk of CVD events were derived from the placebo arm of the
IMPROVE-IT study and risk reduction in CVD events upon the rela-
tionship between LDL changes and reduction in CV events from CTT
meta-analysis. Health state cost, utilities values were taken from recent
literature assessments of statins in the U.S. and Non-CVD death rates
were based on U.S. mortality statistics. An appropriate cohort of statin
patients was identified from the IMS Pharmetrics and EMR databases.
We conducted an evaluation where the price of EZ was fixed at the
current wholesale acquisition cost (WAC) for the first year and the
price of EZ was reduced by 90% after one year of therapy.

RESULTS: We identified 548 statin patients in the IMS database
between the ages of 35-75 with a history of CVD and LDL-C values ≥ 70 mg/dL.
Patients had a mean age of 58 years, baseline LDL-C of 94.6 mg/dL,
55.5% were male and 35.6% of had diabetes. Based on a reduction in
current WAC price ($7.74) of 90% after 1 year our analysis resulted in
an additional $1,363 in cost and a gain of 0.17 in quality adjusted life
years (QALY), for an additional $8,150 per QALY gained. Incremental
reduction in event cost due to the addition of EZ offset almost 80% of
the incremental total drug cost of statin plus EZ.

CONCLUSIONS: With the positive result of IMPROVE-IT and impend-
ing ezetimibe patent expiry, these results suggest that initiating add-
on therapy with EZ is a clinical and cost-effective option for CVD
patients treated with statins.

SPONSORSHIP: Merck & Co

107 Modeling Health Outcomes Associated with Add-on
Vorapaxar Treatment to Standard Care Antiplatelet
Therapy for Prevention of Atherothrombotic Events in
Patients with a Recent MI or PAD
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BACKGROUND: Vorapaxar, a thrombin receptor antagonist, is indi-
cated for use in patients free of cerebrovascular disease with a history

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OBJECTIVE: To estimate long-term health benefits and risks of vorapaxar as an add-on treatment to standard care antiplatelet therapy (VOR+SC), consisting of aspirin and/or clopidogrel, among a population of patients derived from the qualifying MI and qualifying PAD cohort of TRA 2°P.

METHODS: A Markov model was developed, in which patients can transition among health states and are also at risk of experiencing non-transition related revascularization and non-fatal bleeding events. Risk equations were developed from individual patient-level data from TRA 2°P to predict long-term CV outcomes. Additional sources, which ranged from other clinical trials and U.S.-based observational studies, informed the inputs for short-term CV risk, the risk of non-CV death, and health-related quality of life. Survival and quality-adjusted life-years (QALYs) were extrapolated over a patient’s lifetime and discounted at a rate of 3% per year.

RESULTS: Over a lifetime horizon, VOR+SC relative to SC only was associated with 183 fewer MIs, strokes, and CV deaths, while leading to an increase of 28 major bleeding events within a population of 7,530 patients with recent MI and/or PAD. This was accompanied by an increase in life expectancy and health benefits, as the VOR+SC arm yielded an average of 19.89 undiscounted LYS and 9.55 discounted QALYs, compared to 19.57 undiscounted LYS and 9.39 QALYs in the SC only arm. Scenario analyses demonstrated that these results were robust to variation in key model parameters. For recent MI patients in particular, add-on vorapaxar provides the greatest incremental benefit upon treatment initiation at hospital discharge. Additional analyses showed that add-on vorapaxar provides consistent incremental benefits in subgroups of diabetes patients and multivascular disease patients.

CONCLUSIONS: This model leveraged TRA 2°P-based risk equations to make long-term projections of CV events. Based on this analysis, prescribing vorapaxar in addition to aspirin and/or clopidogrel for patients at high ischemic risk is expected to provide long-term health benefits.

SPONSORSHIP: This work was sponsored and funded by Merck & Co.

SPONSORSHIP: Bristol-Myers Squibb and Pfizer.

109 A Significant Economic Opportunity Using Unique Prescriptive Analytics to Improve Medication Adherence

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PROBLEM DESCRIPTION: Medicare Advantage (MA) plans invest considerable financial resources to improve quality measures related to medication adherence. Beyond deployment of interventions to modify behavior, plans are turning to analytic tools that enable more cost effective targeting of members for their programs. Typically, adherence programs target members who possess (or who are predicted to have) a proportion of days covered (PDC) value of 70-85%. However, when using this traditional targeting approach, a significant “blind spot” emerges, due to a fifth of highly adherent members (85-100% PDC) falling to non-adherence without intervention. This unanticipated PDC volatility at the individual level limits the opportunity to improve population adherence, and results in additional healthcare costs associated with managing non-adherent members.

GOAL: To identify adherent members who comprise the blind spot, quantify the impact of their fall to non-adherence, and detect the economic opportunity if these at-risk members maintain their adherence.

PROGRAM DESCRIPTION: Commercial and Medicare Advantage members on statins, RAS antagonists, and diabetes medications are assessed to ascertain total medical allowed amounts from a large national managed care claims database are also assessed to ascertain total healthcare costs of adherence vs. non-adherence.

OBSERVATIONS: In 673,000 Medicare members on statins, there was a $3,400 annual total healthcare cost savings associated with managing adherent vs. non-adherent members. In a separate analysis of 1.3 million Medicare members taking statin medications, 32% (n = 282,000) of the highly adherent population (85-100% PDC) were
identifying at risk to fall from adherence using the DAI 2.0. Without intervention, 174,000 (62%) actually fell to a PDC<80% in the subsequent year. The resultant financial opportunity for avoiding this fall to non-adherence is nearly $600 million. Similar economic opportunities exist when evaluating the RAS antagonist and diabetes drug categories, in both the Medicare and commercial population.

FINDINGS/RECOMMENDATIONS: Targeting highly adherent members, who are at significant risk to fall to non-adherence for intervention, can minimize the blind spot that emerges with traditional member targeting. This unique approach creates a greater opportunity for improvement in population adherence, and can reduce overall health care costs associated with managing unanticipated non-adherence.

SPONSORSHIP: Optum.

112 The Impact of a Pharmacy Pay-for-Performance Program on Medication Adherence in a Medicare Population

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BACKGROUND: The Medicare Five-Star Quality Rating System was developed by CMS to measure the quality of care provided by the health plans and to improve the quality of care for beneficiaries. Adherence is a key measure in the Patient Safety Part D Star domain. Healthfirst has implemented a pilot incentive program with community pharmacies to improve medication adherence for members enrolled in Medicare Advantage plans.

OBJECTIVE: To evaluate the overall performance and improvement of a community pharmacy incentive program on medication adherence and star ratings.

METHODS: Pharmacies in the Healthfirst network qualified for this program if they were located in New York City and exceeded 200 patients measured across the 3 adherence measures (diabetes, hypertension, and cholesterol). Adherence rates were calculated using the proportion of days covered with a rolling 6-month measurement period. Pharmacies received a commitment bonus for enrolling and viewing their baseline performance scores in EquiPPM for April through September 2014. Performance scores were updated and shared monthly with pharmacies along with patient outlier lists to improve performance. Pharmacies were eligible for a performance bonus and were communicated an additional opportunity for an improvement bonus in July 2013. The improvement in adherence for eligible pharmacies from baseline to the April 2015 through September 2015 measurement period was compared to non-qualifying pharmacies and broken out by pharmacy type.

RESULTS: A total of 133 pharmacies met eligibility requirements. 123 pharmacies agreed to participate and received the commitment bonus; 120 pharmacies (91 independent) remained in the pharmacy network and completed the program through September 2015. Qualifying independent pharmacies performance improved from baseline for each measure (1.15% for diabetes, 1.34% for cholesterol, and 1.54% improvement for hypertension). Chain pharmacy performance decreased for both cholesterol (-0.39%) and diabetes (-0.50%) measures but improved slightly for hypertension (0.24%). Non-qualifying pharmacies improved slightly during the same period (0.94% for diabetes, 0.88% for cholesterol, and 1.44% improvement for hypertension).

CONCLUSIONS: There was modest improvement in adherence performance within qualifying independent pharmacies as compared to no change or modest reductions in performance for chain pharmacies participating in the incentive program. Additional programs with refined eligibility requirements will be implemented and analyzed to determine the impact of incentive programs on pharmacy performance.

SPONSORSHIP: Healthfirst.

113 Improving Part D Stars Scores with a High-Touch, Patient-Centric Model Using Intensive Care Coordination in a Medicare Dual-Special Needs Population with Low Health Literacy

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BACKGROUND: Medication nonadherence contributes to poor health outcomes and is a primary driver of avoidable medical expense. Medication adherence is a central feature of healthcare reform, linking medication persistence to quality performance reimbursement through STAR measures.

OBJECTIVE: To describe a pioneering effort to improve Part D Star ratings for medication adherence through a high-touch coaching model with intensive care coordination in a dual-eligible special needs population (d-SNP) with low health literacy.

METHODS: An in-house program was established mid-2013 as an extension of MTM services. Patients were identified for intervention by Acumen report data based on percent days covered (PDC) criteria of 70-85% for RAS-Antagonists, Statins, and oral diabetes medications and were screened for the presence of a behavioral health diagnosis. Monthly intervention calls were made by pharmacists using high-touch, patient-centric coaching to identify and resolve barriers to adherence. Patient evaluation was completed in each encounter to understand unique barriers and develop strategies to resolve them. In-house care-coordination with other care teams was emphasized, promoting follow-up and follow-through to resolution by a multi-disciplinary team.

RESULTS: 1,500 patients were identified for intervention monthly; 67.9% had a behavioral health diagnosis. In 2013, 685 patients received coaching, increasing to 5,315 patients in 2014. Of 3,477 patients, barriers to adherence were: knowledge of medication indication (65.1%), forgetfulness (41.6%), forgetting to refill (16%), transportation (11%), cost (11%), and side effects (3%). To address patients’ logistical and financial barriers, pharmacists offered 90-day supplies, education on a transportation benefit, and facilitation of refill synchronization. Since program implementation, an increase in Star Ratings medication adherence scores was observed for 2014 and 2015 reporting years. The average rate of patients with PDC>80% increased significantly in all 3 medication adherence metrics among the 8 plans reporting these two years (Diabetes: +3.4%, P=0.005; RAS: +2.3%, P=0.019; Statins: +2.1%, P=0.055). Among these 8 plans, there was an average increase in Part D Summary Star ratings score of 0.35 stars from reporting year 2015 to 2016 (measurement year 2013-2014). This improvement is significantly driven by average increases across the 8 plans of 1 star for diabetes, 1.5 stars for RAS, and 0.63 stars for Statins.

CONCLUSIONS: A high-touch intervention impacted behavior and improved medication adherence in a d-SNP population.

SPONSORSHIP: Molina Healthcare.

115 Pulmonary Arterial Hypertension (PAH) Episodes of Care: Survival Analysis of PAH Patients Based on World Health Organization (WHO) Functional Class (FC)

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BACKGROUND: Pulmonary arterial hypertension (PAH) is a rare disease where patients experience increased pulmonary vascular resistance (PVR) and pulmonary arterial pressure that can lead to right heart failure and potentially death. The WHO pulmonary...
hypertension classification system categorizes PAH by increasing disease severity into 4 functional classes (FC); FCI-FCIV. Progression along the FC hierarchy is correlated with reduced functionality. Previous research has examined survival outcomes for PAH patients. This study used provider-reported FC to examine the survival rates of those PAH patients classified as FCII-FCIV.

**OBJECTIVE:** To examine the survival rates of PAH patients and how various factors (e.g., age, FC, etc.) impact their risk of mortality.

**METHODS:** Medicare and commercial patients who received treatment with an endothelin-receptor antagonist (ERA), phosphodiesterase type-5 inhibitor (PDE5i) or prostacyclin (PGI2) and reported a medical claim with ICD-9-CM 416.0, 416.8 or 416.9 or a medical claim indicating right heart catheterization were identified from 2009-2013. The date of initial therapy served as the index date. Provider-reported data from prior authorization forms required for advanced PAH therapies were examined for reported FC. Patients with a deceased date (all-cause) were identified and time to death was computed. A multivariable Cox Proportional Hazard model was used to examine the relationship of FC and survival while controlling for age, gender, race, geographical region, Elixhauser comorbidity score, and PAH index treatment.

**RESULTS:** WHO-FC was found for 437 patients (FCII = 99; FCIII = 282; FCIV = 56). FCIV recorded a greater number of deceased patients with an endothelin-receptor antagonist (ERA), phosphodiesterase type-5 inhibitor (PDE5i) or prostacyclin (PGI2) and reported a medical claim with ICD-9-CM 416.0, 416.8 or 416.9 or a medical claim indicating right heart catheterization were identified from 2009-2013. The date of initial therapy served as the index date. Provider-reported data from prior authorization forms required for advanced PAH therapies were examined for reported FC. Patients with a deceased date (all-cause) were identified and time to death was computed. A multivariable Cox Proportional Hazard model was used to examine the relationship of FC and survival while controlling for age, gender, race, geographical region, Elixhauser comorbidity score, and PAH index treatment.

**CONCLUSIONS:** PAH patients in FCII were associated with a lower risk of mortality. Research has shown that an increase in severity is associated with significantly higher medical costs. Previous studies found that FC improvement is possible and FCII is the treatment goal. Associated with significantly higher medical costs. Previous studies PAH patients in FCII were associated with a lower

**OBJECTIVE:** To evaluate projected cost consequences of initial Co-Tx with AMB+TAD among treatment-naïve WHO Group 1 Functional Class (FC) II/III PAH patients compared to initial single-agent therapy.

**METHODS:** An economic model was developed to estimate costs of PAH over a 3-year period in a hypothetical cohort of 100 treatment-naïve WHO Group 1 FC. II/III patients (source population = 15.6M) assumed to initiate first-line AMB+TAD or first-line AMB or TAD. Costs included PAH-related drugs and encounters (hospitalizations, ambulatory visits). Patients initiating single-agent AMB or TAD were assumed to remain on both drugs. Model parameters were estimated using AMBITION, published literature, and sources on file; model structure, assumptions, and inputs were validated by a panel of PAH experts.

**RESULTS:** In year 1, PMPM costs would be higher with AMB+TAD (vs. first-line single-agent therapy) by $0.0244, in year 2, however, annual PMPM cost differential would decrease substantially (to $0.0059), and by year 3, AMB+TAD would yield lower PMPM costs (-$0.0005) due to fewer encounters. Corresponding overall cost differentials would be $4.6M, $1.1M, and -$0.009M. Initial use of AMB+TAD—in lieu of single-agent therapy with delayed Co-Tx—would prevent 1 PAH-related hospitalization for every 11 patients treated during the 3-year period.

**CONCLUSIONS:** Initial therapy with AMB+TAD in PAH patients with WHO FC II/III symptomatology would be expected to reduce costs of PAH-related encounters compared to first-line single-agent therapy; while PAH-related drug costs would be higher initially, the impact on PMPM cost would be negligible. By year 3, expected annual total costs would be lower with AMB+TAD (i.e., it may be cost saving).

**SPONSORSHIP:** Gilead Sciences.

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**I16 Cost of First-Line Treatment of Pulmonary Arterial Hypertension with Ambrisentan Plus Tadalafil**

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**BACKGROUND:** Pulmonary arterial hypertension (PAH) is a progressive disease that requires complex clinical management. Failure of first-line single-agent therapy and the need for emergency care (often hospitalization) among newly diagnosed PAH patients is common. Accordingly, more aggressive approaches to PAH treatment have been suggested, and earlier use of combination therapy (Co-Tx) with ambrisentan plus tadalafil (AMB+TAD) is now recommended in guidelines. In the AMBITION study, Co-Tx with AMB+TAD in treatment-naïve PAH patients reduced the risk of hospitalization for worsening PAH (by 63%) and increased exercise ability (by 23 m) versus AMB or TAD alone, suggesting early initiation of AMB+TAD improves disease outcomes and thus may reduce PAH-related costs.

**OBJECTIVE:** To evaluate projected cost consequences of initial Co-Tx with AMB+TAD among treatment-naïve WHO Group 1 Functional Class (FC) II/III PAH patients compared to initial single-agent therapy.

**METHODS:** An economic model was developed to estimate costs of PAH over a 3-year period in a hypothetical cohort of 100 treatment-naïve WHO Group 1 FC. II/III patients (source population = 15.6M) assumed to initiate first-line AMB+TAD or first-line AMB or TAD. Costs included PAH-related drugs and encounters (hospitalizations, ambulatory visits). Patients initiating single-agent AMB or TAD were assumed to remain on both drugs. Model parameters were estimated using AMBITION, published literature, and sources on file; model structure, assumptions, and inputs were validated by a panel of PAH experts.

**RESULTS:** In year 1, PMPM costs would be higher with AMB+TAD (vs. first-line single-agent therapy) by $0.0244, in year 2, however, annual PMPM cost differential would decrease substantially (to $0.0059), and by year 3, AMB+TAD would yield lower PMPM costs (-$0.0005) due to fewer encounters. Corresponding overall cost differentials would be $4.6M, $1.1M, and -$0.009M. Initial use of AMB+TAD—in lieu of single-agent therapy with delayed Co-Tx—would prevent 1 PAH-related hospitalization for every 11 patients treated during the 3-year period.

**CONCLUSIONS:** Initial therapy with AMB+TAD in PAH patients with WHO FC II/III symptomatology would be expected to reduce costs of PAH-related encounters compared to first-line single-agent therapy; while PAH-related drug costs would be higher initially, the impact on PMPM cost would be negligible. By year 3, expected annual total costs would be lower with AMB+TAD (i.e., it may be cost saving).

**SPONSORSHIP:** Gilead Sciences.

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**I20 Predictors of All-Cause Healthcare Costs Among Patients with Newly Diagnosed Non-valvular Atrial Fibrillation Initiated on Dabigatran Versus Warfarin**

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1Boehringer Ingelheim; 2Optum Insight

**BACKGROUND:** Retrospective studies comparing dabigatran with warfarin suggest total all-cause costs are similar because medical cost savings offset higher pharmacy costs of dabigatran. These studies report matched all-cause costs for overall samples but do not examine whether subgroups of patients may incur lower costs when initiated on dabigatran versus warfarin.

**OBJECTIVE:** To identify predictors of total all-cause healthcare costs based on patient characteristics among patients with non-valvular atrial fibrillation (NVAF) on dabigatran or warfarin.

**METHODS:** This retrospective study, using administrative claims data, included patients with newly diagnosed NVAF and no prior oral anticoagulant use. The first observed claim for dabigatran or warfarin during 10/1/2010-11/30/2012 was defined as the index date. Those with at least 1 month of data following the index date were included in the analysis and followed until end of the study period (11/30/2013). Follow-up was a maximum of 1-year post-index date. Baseline Episode Risk Group (ERG) risk score was used to define severity levels I-V, with higher level indicating greater risk of healthcare use. Using stepwise regression, a predictive model was developed to assess the impact of a priori defined variables including ERG severity level, treatment (dabigatran or warfarin) and their interaction, on all-cause costs during follow-up.
RESULTS: Cohorts included 4,150 dabigatran and 11,032 warfarin-treated patients. Compared with the dabigatran cohort, the warfarin cohort was older (72.5 vs. 67.3 years) and had higher Charlson comorbidity score (2.0 vs. 1.4) (both \( P < 0.001 \)). The following interactions with cohort were statistically significant predictors of all-cause healthcare costs: ERG severity level (\( P = 0.017 \)), geographic region (\( P = 0.047 \)), and health plan type (\( P = 0.034 \)). At ERG severity levels I-VI, associated cost ratios comparing dabigatran versus warfarin were: 0.96 (\( P = 0.53 \)), 1.14 (\( P = 0.03 \)), 1.08 (\( P = 0.38 \)), 0.78 (\( P = 0.02 \)), 0.88 (\( P = 0.33 \)), and 0.92 (\( P = 0.44 \)), respectively. When ERG severity levels were combined, the cost ratios for dabigatran versus warfarin were 1.05 (\( P = 0.23 \)) and 0.86 (\( P = 0.03 \)) for levels I-III and level IV-VI, respectively.

CONCLUSIONS: ERG severity level could be used to identify patient subgroups for the estimation of all-cause healthcare costs among patients with NVAF initiated on dabigatran or warfarin.

SPONSORSHIP: Novartis Pharmaceuticals.

1A U.S. Budget Impact Analysis of ENTRESTO (Sacubitril/Valsartan) Versus Renin-Angiotensin-Aldosterone System Inhibition Only, for Heart Failure Patients with Reduced Ejection Fraction

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BACKGROUND: Based on the results of the PARADIGM-HF trial, the angiotensin receptor neprilysin inhibitor ENTRESTO (sacubitril/valsartan, Novartis Pharma AG, Basel, Switzerland) reduced all-cause mortality and hospitalizations when compared to its use in place of enalapril in heart failure patients with reduced ejection fraction (HF-REF).

OBJECTIVE: To examine the U.S. budget impact of replacing enalapril with ENTRESTO in a managed care setting.

METHODS: Using a hospital-level microsimulation model, we estimated U.S. healthcare expenditures, differential costs, and cost-effectiveness over 2 years for a sharp difference in patients treated with enteral or oral formulations of sacubitril/valsartan. Patient-level and provider-level data were used to simulate patients with HF-REF and an income of $40,000. Patients who could not be discharged to home were simulated in an inpatient setting.

RESULTS: Estimates indicate that use of ENTRESTO is more costly and less effective than use of enalapril. The incremental cost vs. effectiveness ratio (ICER) for use of ENTRESTO was $29,000 per QALY gained. The ICER ranges from $43,000 to $95,000 per QALY gained depending on the prevalence of patients with HF-REF.

CONCLUSIONS: The results of this analysis suggest that ENTRESTO is more costly and less effective than enalapril. Further research is needed to better understand the cost-effectiveness of this treatment.

SPONSORSHIP: None.
OBJECTIVE: To estimate the potential budget impact of ENTRESTO adoption from a U.S. private payer perspective.

METHODS: A budget impact model was constructed from a U.S. private payer perspective with a one to three-year time horizon. Beginning with a hypothetical health plan with one million members, the eligible population for ENTRESTO based on FDA-approved prescribing information (HF/LVF NYHA class II-IV) was identified from published data. Risks of total all-cause mortality and hospitalizations were taken from the PARADIGM-HF trial. Hospital costs combined Medicare and private insurance rates; medication costs included the wholesale acquisition cost (WAC) for ENTRESTO and representative angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB). Current ACEI/ARB prescribing trends were obtained from a 2012/13 retrospective database analysis and for the purposes of this model, it was assumed that an incremental 10% of eligible patients were prescribed ENTRESTO each year (equal share taken from current ACEI and ARB prescribing). Results were reported for the projected number of lives saved, hospitalizations avoided and net cost per-member-per month (PMPM).

RESULTS: Using a hypothetical one million member plan, this analysis estimated 360 patients would receive treatment with ENTRESTO in year one, resulting in a projection of 16% (n = 5) lower deaths and 15.6% (n = 24) all-cause hospitalizations avoided compared to treatment with ACEI/ARB, at a cost PMPM of $0.09. By year 3, 1,128 patients were expected to be treated with ENTRESTO, with a projection of 16 fewer deaths and 76 all-cause hospitalizations avoided ($0.29 PMPM).

CONCLUSIONS: For eligible patients, this analysis highlights that ENTRESTO use may reduce the projected occurrence of all-cause mortality and hospitalization compared to treatment with ACEI or ARB, at an acceptable estimated budget impact of nine cents ($0.09) PMPM in the first year.

SPONSORSHIP: This study was funded by Novartis Pharmaceuticals.

Cost Per Point Reduction in LDL-C for Patients Treated with Evolocumab 140 mg or Alirocumab 75/150 mg Within Employer-Sponsored Insurance Plans

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BACKGROUND: The PCSK9 inhibitors evolocumab and alirocumab are prescribed in addition to maximally tolerated statins to adults with clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) that require additional lowering of LDL-C. There is lack of head to head comparative economic and clinical data on these agents.

OBJECTIVE: To estimate cost per 1 mg/dL reduction in LDL-C with evolocumab 140 mg and alirocumab 75/150 mg in a clinical ASCVD or HeFH population over a 1-year period.

METHODS: Patients with clinical ASCVD or HeFH using statin therapy and having LDL-C levels > 100 mg/dl were identified in the Truven MarketScan Database from Jan 1, 2012 to Jan 1, 2014. An economic model using Monte Carlo simulations was developed to estimate cost per 1 mg/dL reduction in LDL-C. Efficacy was based on percent LDL-C reduction from published Navarrese meta-analysis (2015) of PCSK9i trial data: evolocumab 140 mg = 63.46%, alirocumab 75 mg = 52.63% and alirocumab 150 mg = 56.15%. Drug costs were based on Wholesale Acquisition Cost (WAC): evolocumab 140 mg = $1,085 per 4-week period, alirocumab 75/150 mg = $1,120 per 4 weeks. The model applies the percentage reduction in LDL-C to simulate the absolute LDL-C reduction achieved in this patient population. The ratio of LDL-C reduction obtained from the Monte Carlo simulation to the WAC price yielded the cost per 1 mg/dL reduction.

RESULTS: A total of 7,682 patients with ASCVD or HeFH were identified (44% female, mean age 62 years). Of those, 28.9% had LDL-C ≥100 mg/dL (mean 134.0 mg/dL [SD = 35.7]). When the LDL-C reduction from Navarrese meta-analysis was applied, the cost per 1mg/dL reduction was $207.02 and alirocumab 150 mg was $194.04. The cost per 1 mg/dL reduction for alirocumab is nearly 15-20% higher than evolocumab based on an mean absolute LDL-C reduction of 85.0 mg/dL with evolocumab, 70.5 mg/dL with alirocumab 75 mg and 75.2 mg/dL with alirocumab 150 mg from a starting baseline LDL-C of 134.0 mg/dL.
CONCLUSIONS: Given the ACC guidelines and variability in treatment goals for specific populations, assessing the cost per LDL-C point reduction offers an alternate approach to assessing value. The findings suggest that evolocumab 140 mg provides greater value (greater LDL-C reduction at lower cost) versus alirocumab 75/150 mg.

SPONSORSHIP: This research was funded by Amgen.

Cost Per Effectively Treated Patient with Evolocumab 140 mg and Alirocumab 75/150 mg


BACKGROUND: Evolocumab 140 mg and alirocumab 75/150 mg are PCSK9 inhibitors recently approved by the FDA along with diet and maximally tolerated statin therapy in adults with clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia who require additional lowering of LDL-C. Lack of head to head data makes it difficult to compare efficacy of these medications.

OBJECTIVE: To estimate the cost per effectively treated patient with evolocumab 140 mg and alirocumab 75/150 mg in patients with clinical ASCVD and baseline LDL-C ≥ 100 mg/dL while on statins over a 1-year period from a population level perspective.

METHODS: An economic model was developed using patients with ASCVD with LDL-C ≥ 100 mg/dL. Monte Carlo simulations were used to estimate the number of “effectively treated” patients defined based on ACC/AHA criteria: achieving a 50% reduction in LDL-C, a LDL-C < 70 mg/dL, or a composite of either endpoint. Baseline LDL-C in the model was the lowest LDL-C value following a clinical ASCVD event and statin initiation obtained from commercial and Medicare Advantage health plan enrollees in the Optum Research database. Reduction in LDL-C from baseline was modelled using efficacy estimates for evolocumab 140 mg, alirocumab 75/150 mg from the published Navarese Meta-analysis (2015) of 24 PCSK9i trials and >10,000 patients. Costs were based on Wholesale Acquisition Cost (WAC) in December, 2015. The ratio of the number of effectively treated patients from the model and annual WAC for the entire population yielded the cost per effectively treated patient.

RESULTS: A total of 15,944 patients with clinical ASCVD and high LDL-C were identified in the Optum Research database. The majority were female (58.4%), mean age 64.5 years, and mean baseline LDL-C 125.2 mg/dL. The mean percentage reduction in LDL-C in the Navarese meta-analysis was 63.46% for evolocumab 140 mg, 52.63% for alirocumab 75 mg and 56.15% for alirocumab 150 mg. Annual WAC was $14,138 for evolocumab 140 mg, $14,600 for alirocumab 75/150 mg. The cost per effectively treated patient defined as a 50% reduction in LDL-C was $18,027 for evolocumab 140 mg, $24,236 for alirocumab 75 mg and $21,961 for alirocumab 150 mg. Results were consistent across all definitions of effectively treated.

CONCLUSIONS: The cost per effectively treated patient regardless of definition using absolute LDL-C goals of < 70 mg/dL, ≥ 50% reduction in LDL-C, or a composite of either suggests that evolocumab 140 mg produces a more consistent and better economic outcome when compared to alirocumab 75/150 mg over 1-year.

SPONSORSHIP: This research was funded by Amgen.

Adherence to Treatment in Hemophilia: A Comparison of Conventional and Prolonged Half-Life Therapies

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BACKGROUND: Adherence to prophylactic therapy is key to successful prevention of bleeds in severe hemophilia. Prophylactic treatment with long-acting recombinant factor VIII Fc fusion protein (rFVIIIFc) and recombinant factor IX Fc fusion protein (rFIXFc) has been shown in clinical trials to decrease the frequency of infusions, while maintaining control of bleeding in subjects with severe hemophilia A and B, respectively.

OBJECTIVE: To assess real-world adherence rates for FVIII and FIX therapies, including both conventional and prolonged half-life therapies. A secondary objective was to explore adherence rates according to patient subgroups such as age and infusion frequency.

METHODS: A retrospective analysis was conducted using aggregate Specialty Pharmacy Provider (SPP) records in the United States from November 2013 through September 2015. Patients were considered eligible for the analysis if they received at least one shipment of FVIII or FIX for a prophylactic treatment regimen and had a minimum of 60 days of supplied therapy. Patients were excluded from the analysis if they were being treated episodically, for immune tolerance induction, or pharmacy records did not specify a prescribed infusion dose. Adherence was assessed by medication possession ratio (MPR). MPR per patient per calendar year was calculated from SPP records as: (Total days of supplied)/(Last fill date–[first fill date]+[last days of supplies]). Patients were categorized according to age and infusion frequency. Median MPRs were then computed and compared via Wilcoxon Rank-Sum statistic.

RESULTS: There were 2,805 patients receiving FVIII therapy and 596 patients receiving FIX therapy that were included in the analysis. The median MPR for rFVIIIFc was significantly higher than conventional FVIII therapies, (86% compared to 80% respectively, P < 0.0001). The median MPR for rFIXFc was also significantly higher than conventional FIX therapies, (85% compared to 77% respectively, P = 0.0005). A higher percentage of patients with a MPR ≥ 80% was observed among rFVIIIFc (61%) and rFIXFc (59%) compared to conventional FVIII (50%) and FIX (46%) therapies, respectively.

CONCLUSIONS: This is the first analysis of real-world data evaluating adherence to prolonged half-life therapies in hemophilia. Both rFVIIIFc and rFIXFc demonstrated statistically significant improvements in adherence compared to conventional factor therapies.

SPONSORSHIP: This research was funded by Biogen.

Analysis of Treatment Patterns in High Utilizers of Conventional FVIII Therapy

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BACKGROUND: The nature of hemophilia along with the absence of consensus treatment guidelines detailing best practices are considerations that contribute to significant pharmacy expenditures associated with managing hemophilia. Payer strategies for containing hemophilia costs are often focused on logistics related to minimizing waste, access to treatments, and establishing guidelines for drug distribution. Wide variation exists in hemophilia treatment patterns, evaluating high utilizers may provide an opportunity to optimize patient use of factor therapies.
RESULTS: The analysis included 2,888 hemophilia A patients that received at least one shipment of conventional FVIII with a median age of 20 (range: 1-86) and median weight of 68 kg (range: 3-176 kg). The 721 patients in the top quartile of factor utilization had a median age of 25 (range: 2-71) and median weight of 79 kg (range: 10-176 kg). Dosing frequency in these high utilizers ranged from as needed (PRN) to every thirty days, with three times a week and every other day as the most common dosing intervals, representing 46.2% and 33.3% of patients respectively. The median weekly prescribed dose across all regimens was 124.8 IU/kg. The top quartile of patients accounted for 63% of all units dispensed during this time frame. Additionally, the top 10% of patients accounted for 37% of all units.

CONCLUSIONS: Patients in the top quartile of factor utilization have relatively short infusion intervals and higher weekly prescribed doses. These high utilizing patients also contribute to a substantial portion of the total units of FVIII dispensed and are likely to influence pharmacy expenditures associated with managing hemophilia.

SPONSORSHIP: This research was funded by Biogen.

Cost of Care Among Pediatric Hemophilia Patients with and without Central Venous Access Devices Treated in U.S. Hospitals

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BACKGROUND: Central venous access devices (CVADs) facilitate repeated or urgent treatments for hemophilia patients. However, CVADs may increase the risk for infection and thrombosis, potentially increasing costs for care.

OBJECTIVE: To compare total inpatient and hospital outpatient costs for the pediatric hemophilia population with and without CVADs.

METHODS: This retrospective study of the U.S. Premier Healthcare Database included hemophilia patients from 548 hospitals aged ≤ 18 years who were discharged during 2006-2014. We identified hemophilia patients using primary or secondary ICD-9 diagnosis codes 286.0x or 286.1x, and CVAD exposure using billing information. We exact matched 1:1 CVAD to non-CVAD exposed patients by age, Factor-VIII or Factor-IX therapy, number of hospital encounters and hospitalization for infection in previous year, and U.S. census region categories. The ‘index visit’ was the first database encounter with a CVAD procedure for the CVAD cases, or any single matched encounter for controls. We compared inflation-adjusted total hospital costs (2014 $USD) for the index visit for CVAD cases and controls using generalized estimating equations. We adjusted models for Factor VIII therapy (yes/no) for outpatients and number prior hospital encounters for inpatients because stratification by admission status introduced imbalance in these variables between cases/controls.

RESULTS: We identified 4,793 pediatric hemophilia patients. Of these, 197 (4.1%) had CVAD exposure according to our criteria. The matched sample with cost data available included 321 patients (161 CVAD cases and 160 controls) with mean age 5 years, primarily male (93%), white (56%), treated in urban hospitals (91%) in the south U.S. region (58%), and had Medicaid as the primary payer (50%). The total cost for the inpatient index visit was median $17,954 and mean $32,907 ($SD $107,320). The total cost for the outpatient index visit median $343 and mean $1,416 (SD $3,432). Adjusted mean costs were higher for CVAD cases vs. controls for both inpatients ($59,371, 95% CI $42,682-$682,584 vs. $33,381, 95% CI $20,579-$54,148, P = 0.03) and outpatients ($3,166, 95% CI $2,059-$4,866 vs. $1,485, 95% CI $1,090-$2,022; P = 0.002).

CONCLUSIONS: Using real-world hospital data, total hospitalization costs for pediatric hemophilia patients with CVADs were approximately two times higher compared to those without CVADs. The results of this study may inform further research efforts to understand the costs and benefits of novel treatment alternatives for young hemophilia patients requiring CVADs.

SPONSORSHIP: This study was funded by Biogen.

A Systematic Review on the Health and Safety of Electronic Cigarettes

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BACKGROUND: The growth in sales and use of electronic cigarettes has skyrocketed in the past decade. With limited research and conclusions on its health, safety, and efficacy, we undertook a systematic review of published studies of electronic cigarettes.

OBJECTIVE: To summarize the available scientific research concerning electronic cigarettes with a focus on public health and safety of electronic cigarette usage; in addition, its implications in pharmacy practice will be elucidated.

METHODS: A systematic review and analysis of articles in PubMed was completed. Inclusion criteria of articles about electronic cigarettes and health included search for all articles containing “electronic cigarettes”, “e-cigs”, or “vaping” in the title, abstract, or body. Articles published in non-European or non-United States of America countries were excluded.

RESULTS: We identified 83 articles about electronic cigarettes. These articles and their conclusions were then divided into four general categories about electronic cigarette chemical profiles, use in smoking cessation, health effects, and usage. From these conclusions we identified certain themes pertaining to the health and safety of electronic cigarette usage. The health of electronic cigarette usage is defined by its use in smoking cessation and health risks. We found evidence for the usage of electronic cigarettes in smoking cessation with minor short-term adverse effect. The safety of electronic cigarette usage is defined by the composition of electronic cigarettes, the e-liquid, and vapor. We found discrepancies between e-liquid labeling and contents and the presence of heavy metals in electronic cigarette vapor among other chemicals.

CONCLUSIONS: Electronic cigarettes are drug delivery devices now regulated by the FDA. The presence of electronic cigarette usage is a growing trend in America especially in younger populations. New FDA regulations limits marking for therapeutic purposes but previous advertisements about the benefits of electronic cigarette has permeated the general populace. As pharmacist and public health advocates, it is
important to clarify the information surrounding electronic cigarettes and make recommendation on their use.

SPONSORSHIP: None.

**J05 Impact of AATT Patient Management Program on Health Outcomes and Medical Costs**

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BACKGROUND: Prolastin Direct (PD) provides augmentation therapy services for patients with alpha-1 antitrypsin deficiency (AATT) along with a comprehensive disease management (DM) program that has been shown to improve health-related QoL and reduce healthcare utilization.

OBJECTIVE: To evaluate the economic impact of a DM program by comparing healthcare utilization and costs between patients in the PD program with patients receiving augmentation therapy outside of the PD program.

METHODS: ICD-9-CM COPD diagnosed (491.x, 492.x, 496) patients treated with an alpha-1 proteinase inhibitor (A1PI); (CPT J0256, J0257, S9346 or product-specific NDCs) from 2008-14 were identified in the Optum Research and Impact Databases. Using A1PI brand as a proxy for DM exposure, the PD cohort comprised patients treated with Prolastin/Prolastin-C identified by product-specific NDCs or supplier codes. Patients treated with other A1PI brands were assigned to the comparator cohort; those with indeterminate A1PI brand were excluded. COPD-related services were identified by diagnosis codes and treatments. Healthcare utilization and costs (adjusted to 2013$) were compared between cohorts.

RESULTS: A total of 445 patients met inclusion criteria (213 PD and 232 comparator). Baseline demographics were similar with 51% male, mean age of 55.5 ± 10.1 years. Average length of follow up was 2.3 ± 1.8 (range 0.1-6.2) years with mean annual augmentation therapy costs of $120,457 ± 73,186 across both cohorts. Mean total and COPD-related annual costs were lower in the PD cohort ($142,406 vs. $167,935 and $45,589 vs. $65,296) (P<0.020). Using a covariate-adjusted GLM (gamma distribution with a log link) to account for skewness, total annual cost differences were statistically significant (P=0.020). The PD cohort was associated with several outcomes which may explain these cost differences, including significantly fewer annual inpatient visits (0.3 vs. 0.6), shorter lengths of stay (2.0 vs. 3.5), fewer severe COPD-related exacerbations (0.2 vs. 0.4), and lower infusion costs ($113,502 vs. $126,843). (All P<0.05).

CONCLUSIONS: Patients enrolled in the Prolastin Direct program had lower average annual healthcare utilization resulting in lower total and COPD-related costs versus patients receiving other augmentation therapy services. This analysis suggests that incorporation of comprehensive disease management programs may result in reduced healthcare utilization and lower healthcare costs for AATT patients treated with an alpha-1 proteinase inhibitor.

SPONSORSHIP: Optum was contracted by Grifols SSNA to conduct this research.

**J06 Predictors of Readmission Rates After COPD-Related Hospital or Emergency Department Visits**

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) is a progressive illness affecting 6.3% of the U.S. population and is one of six medical conditions Medicare measures for 30-day unplanned readmission and death in their Hospital Readmission Reduction Program. Evaluation of appropriate therapy after a COPD exacerbation is included in the NCQA HEDIS measures. This quality measure focuses on appropriate use of systemic corticosteroids (PCe-C) and inhaled bronchodilators (PCe-D) after an acute COPD exacerbation. There is limited evidence evaluating factors such as COPD HEDIS quality measures and their association with hospital readmission.

OBJECTIVE: To determine the factors associated with six-month readmission rates after COPD-related hospital or emergency department visit.

METHODS: A retrospective, observational, event-based analysis was conducted to identify COPD-related hospital and ED visits between 2007 and 2013 from a Central Texas health plan. The index date was defined as date of admission. Pre-index characteristics, such as demographics, comorbidities, healthcare resource utilization, and COPD-related medication use were collected. Patients enrolled for at six months post-index were assessed using generalized estimating equations to determine what factors are associated with readmission within 6 months. These factors include the pre-index and index variables, as well as receipt of PCE-D and/or PCE-C.

RESULTS: A total of 344 admissions were identified, 60 (17%) of these admission had a subsequent COPD-related readmission and 135 (39%) had an all-cause readmission within 6-month post-discharge. Older patients were more likely to have a COPD-related readmission (RR = 1.07, 95% CI 1.01-1.13, P=0.03). Patients on a pre-index maintenance medication were less likely to have an all-cause readmission (RR=0.49, 95% CI 0.30-0.79, P<0.01). Finally, patients with higher pre-index medical and pharmacy costs were more likely to have all-cause 6-month readmission (RR=1.01, 95% CI 1.00-1.02, P=0.01).

CONCLUSIONS: COPD-related readmission was more likely for older patients, while all-cause readmission was more likely for patients who were not on maintenance medication and those with higher pre-index healthcare costs.

SPONSORSHIP: This study was funded by GSK (HO-14-15081).

**J08 The Relative Burden of Community-Acquired Pneumonia Hospitalizations Compared to Other Serious Conditions in the Older Population**

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BACKGROUND: The risk of community-acquired pneumonia (CAP) increases with age and significantly impacts morbidity and mortality in the elderly population. However, the burden of illness and cost of preventing CAP has not been compared to other serious disease states.

OBJECTIVE: To compare the burden of CAP hospitalizations to myocardial infarction (MI), stroke, and osteoporotic fractures (OF) in a Medicare Advantage insurance plan.

METHODS: This retrospective analysis compared hospitalizations for CAP, MI, stroke, and OF in adults aged 65-89 years enrolled in a national Medicare Advantage insurance plan during 2013-2014. Individuals who were not hospitalized in 2013 for one of these conditions and had no evidence of long-term care in 2013 were included. Hospitalizations for each condition in 2014 were described by incidence rates, length of stay, percent with a readmission or death within 30 days, and total costs. Use of preventive measures in 2013 included vaccinations for CAP and preventive medications for MI, stroke, and OF.
RESULTS: A total of 1,585,022 individuals with a mean age of 74.2 years were included. The rate of CAP-related hospitalizations was the highest among all conditions at 1,262 per 100,000 person-years compared to 673 for MI, 610 for stroke, and 706 for OF (all P < 0.01). The readmission rate for CAP was slightly lower than MI (12.7% vs. 13.3%, P = 0.043) but higher than stroke (10.0%) and OF (10.8%), both P < 0.01. The 30-day case fatality rate was highest for CAP (15.1%) compared to MI (11.3%), stroke (11.8%), and OF (6.4%); P < 0.01 for all. Total direct hospitalization costs were $266 million (M) for CAP, $203.7M for MI, $131M for stroke, and $165M for OF. Expenditures for preventive vaccinations for CAP were $32M, including $8.7M for pneumococcal vaccines and 23.2M for flu vaccines. Comparatively, the cost of preventive medications for MI and stroke reached $373M and OF totaled $43M.

CONCLUSIONS: Although CAP had a higher burden of hospitalization and total costs than MI, stroke, and OF in the elderly population, utilization of prevention efforts for CAP was much lower. Prioritization of CAP prevention is needed to substantially reduce the burden of CAP.

SPONSORSHIP: Pfizer funded this study.

J10 Trends in Palivizumab Utilization Within Medicaid and Commercial Populations
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BACKGROUND: Palivizumab is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in high-risk children. Previous studies of palivizumab utilization have examined populations submitted for prior authorization but have not examined utilization within insured populations as a whole.

OBJECTIVE: To describe palivizumab utilization trends and characterize high-risk infants who received palivizumab within Medicaid and commercial populations.

METHODS: Infants born July 1, 2003-June 30, 2013 were identified in the Multistate Medicaid (MED) or MarketScan Commercial (COM) databases. Infants were required to have 18 months of continuous enrollment and pharmacy benefits after birth. DRG and ICD-9-CM codes were used to identify infants with chronic lung disease of prematurity (CLDP), congenital heart disease (CHD), and those born preterm without CLD or CHD. Palivizumab use in the outpatient setting was identified by the presence of ±1 prescription drug claim with a NDC code or medical claim for palivizumab administration (CPT or HCPCS code).

RESULTS: Palivizumab utilization rates among all infants averaged 2.6% (MED) and 2.8% (COM) during the study period and decreased over time to 1.9% for MED and COM infants in 2012-2013. Utilization decreased among all infant groups from 2003-2004 to 2012-2013 with the greatest proportional decline among infants 35-36 weeks gestational age (wGA). Overall utilization was highest among infants with CLDP (82%) and <29 wGA (78%), followed by 29-30 wGA (62%-64%), 31-32 wGA (45%-48%), CHD (28%), 33-34 wGA (20%-23%), and 35-36 wGA (3%). Most MED and COM infants were admitted to the neonatal intensive care unit at birth (92%) and diagnosed with respiratory distress or apnea during the birth hospitalization (78%). Utilization by month was consistent across infant groups for both MED and COM with most doses being administered during the commonly defined RSV season of November to March (8% Oct, 13% Nov, 17% Dec, 19% Jan, 18% Feb, 17% Mar, and 5% Apr). Approximately half of MED and COM infants with CLDP, CHD, and those <29 wGA who did not receive palivizumab were discharged from their birth hospitalization between March and June.

CONCLUSIONS: Palivizumab use is low relative to the number of infants born each year, has declined in recent years in both MED and COM infants, and could be improved within high-risk infant subgroups recommended for immunoprophylaxis, particularly those discharged multiple months prior to the RSV season.

SPONSORSHIP: AstraZeneca.

J13 Initial Diagnosis and Treatment Patterns by Healthcare Setting Among Chronic Obstructive Pulmonary Disease (COPD) Patients in the United States
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BACKGROUND: COPD remains undiagnosed in a majority of patients until they progress towards the later stages of the disease where they are more likely to have exacerbations that may lead to hospitalizations. Appropriate treatment, including long-acting bronchodilators, following exacerbation may prevent future exacerbations. However, undertreatment is a major gap in COPD care. Evaluating rates of diagnosis and evaluating treatment patterns by healthcare setting may provide insight to the degree of under-diagnosis and under-treatment.

OBJECTIVE: To determine the healthcare setting of initial COPD diagnosis and descriptively assess COPD treatment patterns post-diagnosis.

METHODS: A retrospective observational analysis of administrative claims data was conducted. Managed care enrollees ≥40 years old with a COPD diagnosis (≥1 medical claim with a COPD ICD-9-CM diagnosis code) occurring between 1/1/2011 and 12/31/2012 were selected. The index date was defined as the earliest COPD diagnosis. Continuous health plan enrollment was required in the 12-month period prior to and following the index date, defined as pre- and post-diagnosis period respectively. Only ‘new’ COPD patients were included i.e., no COPD diagnosis was allowed in the pre-diagnosis period. Patients were placed into one of the two study groups depending upon the place of service of the index COPD diagnosis: (1) Inpatient or ED (IP/ED) and (2) physician office or other outpatient (PO/OP) setting. Treatment patterns were assessed in the post-diagnosis period based on the occurrence of ≥1 prescription claim for a COPD treatment. Proportions of patients receiving various COPD treatments were reported.

RESULTS: The study population consisted of 66,927 COPD patients. Of these, 14.5% were diagnosed in an IP/ED setting. About 40% of the study population did not receive a prescription for any type of COPD treatment. Only 25% received a prescription for a long-acting bronchodilator. A greater proportion of patients in the IP/ED group received a COPD treatment of any type compared to those in the PO/OP group (59.4% vs. 54.6%, respectively). There were no differences in the proportions of patients receiving a long-acting bronchodilator by healthcare setting of initial COPD diagnosis.

CONCLUSIONS: This study showed that a sizable proportion of patients are first diagnosed with COPD in an IP/ED setting. This study also highlights that under-treatment is prevalent in COPD, with most patients not receiving a long-acting bronchodilator therapy including those first diagnosed with COPD in an IP/ED setting.

SPONSORSHIP: Boehringer Ingelheim Pharmaceuticals.
**J15 Incidence and Predictors of Hospital Readmission Among Patients with Chronic Obstructive Pulmonary Disease in the Department of Veterans Affairs**


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**OBJECTIVE:** To describes 30- and 60-day all-cause and 30-day chronic obstructive pulmonary disease (COPD)-related readmission and factors associated with all-cause readmission for adults with COPD in the Department of Veterans Affairs (VA).

**METHODS:** A retrospective cohort analysis was conducted using data from the national VA VINCI database of COPD patients hospitalized for COPD (indicated by primary discharge diagnosis) between 1/1/2004 and 7/1/2014 with ≥1 year baseline data. Readmission incidence was calculated as number of index hospitalizations with a subsequent hospitalization within 30 or 60 days after discharge divided by total number of index hospitalizations. Multivariate logistic regression was used to determine predictors of the first readmission including demographics, care site measures, history of hospitalizations, smoking, comorbidities, index hospital length of stay, ICU stay, and discharge disposition.

**RESULTS:** Overall, 89,502 COPD patients had an index hospitalization during the study period. All-cause 30-day readmission was 17.3% and 60-day readmission was 26.7%. COPD-related 30-day readmission was 7.8%. Of the 11,977 COPD patients with readmission within 30 days of first COPD hospitalization, mean age was 70.6 years and 97% were men. Top primary discharge diagnoses for the first readmission were COPD-related (34.3%) and pneumonia (3.9%), with the remaining distributed among multiple conditions (the most common being heart failure, 5.8%). An initial regression model showed that previous hospitalizations (OR: 1.39 for 1 hospitalization to 3.24 for 5 or more hospitalizations, p < 0.001), moderate/severe liver disease (OR: 1.44, P = 0.003), paraplegia (OR: 1.41, P < 0.001), pulmonary hypertension (OR: 1.32, P = 0.016), substance abuse (OR: 1.28, P < 0.001) and heart failure (OR: 1.25, P < 0.001) were the strongest significant independent predictors of all-cause 30-day readmission among COPD patients in the VA.

**CONCLUSIONS:** COPD readmission incidence in the VA is consistent with that identified by Medicare and resulted from multiple causes. Initial investigation showed that the risk of 30-day all-cause readmission among COPD patients was associated with multiple chronic difficult-to-manage comorbid conditions. Since hospital readmissions have been targeted under the Affordable Care Act for cost control, characterizing readmission risk factors will help in understanding the potential for lowering the rate among COPD patients.

**SPONSORSHIP:** AstraZeneca.

**J16 Severe and Acute Inhaler Use in Chronic Obstructive Pulmonary Disease**


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**BACKGROUND:** The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommends maintenance inhaler use based on disease severity but there is limited guidance for acute inhaler use.

**OBJECTIVE:** To examine the relationship between chronic obstructive pulmonary disease (COPD) severity and acute inhaler use, alone or in conjunction with maintenance medications.

**METHODS:** We identified Medicare fee-for-service beneficiaries diagnosed with COPD using a 5% sample of administrative claims data from the 2006-2012 Chronic Condition Data Warehouse. Beneficiaries were followed for two years. Individuals with at least 1 COPD-related inpatient visit, COPD-related emergency department visit, or supplemental oxygen use claim during the first six months of follow-up were categorized with moderate-severe COPD; otherwise, subjects were classified with mild COPD. Maintenance inhalers were identified as inhaled corticosteroids, long-acting beta agonists, long-acting anticholinergics, and short-acting anticholinergics used as monotherapy or in combination with other classes. Acute inhalers were identified as short-acting beta agonists used as monotherapy. The severity cohorts were compared on patient characteristics, maintenance inhaler use, and acute inhaler use. Acute and maintenance inhaler use per year were categorized into six groups (>0 to <2, >2 to ≤4, >4 to ≤6, >6 to ≤8, >8 to ≤10, and >10 to ≤12).

**RESULTS:** We identified 25,268 beneficiaries with COPD who met inclusion criteria; of these beneficiaries, 20,536 had mild COPD and 4,732 had moderate-severe COPD. Beneficiaries had an average age of 67.1 years and were predominately white females. For acute inhaler use per year, there was a bimodal distribution for both cohorts, with highest peak use at the >0 to ≤2 and >2 to ≤4 acute inhalers per year, and a second peak use at the >10 to ≤12 acute inhalers per year. Differences in median (interquartile range) acute inhaler use per year between mild (4.2 [3.9]) and moderate-severe (4.6 [6.4]) COPD cohorts was statistically significant (P < 0.001). Similar findings were found for maintenance inhalers.

**CONCLUSIONS:** The bimodal distribution for acute inhalers may indicate a group of patients with suboptimal use and a group with overuse of acute inhalers. The higher use of acute inhalers for moderate-severe COPD patients may indicate suboptimal use of and/or adherence to maintenance inhalers, overuse of acute inhalers, and/or insufficient control of COPD. Thus, it may be important for clinicians to be sensitive to patients’ COPD inhaler use patterns.

**SPONSORSHIP:** University of Maryland School of Pharmacy, Baltimore, MD.
RESULTS: For omalizumab, the expected per-year NNT to prevent an exacerbation comprised 1.04 (1/0.957) for all enrolled patients or 0.73 (1/1.375) for only patients treated with LABA. The expected NNT comprised 11.9 (1/0.084) for asthma-related hospitalizations and 8.9 (1/0.113) for asthma-related hospitalizations or ER visits.

CONCLUSIONS: With the contemporary definition of an asthma exacerbation and background therapy, clinicians would expect to treat approximately 1 patient with severe uncontrolled asthma for a year with omalizumab to prevent one asthma exacerbation. In patients with severe uncontrolled asthma, clinicians would expect to treat approximately 12 such patients with omalizumab for a year each to prevent a hospitalization or approximately 9 such patients for each year each to prevent a hospitalization or an ER visit.

SPONSORSHIP: Genentech.

J18 Associations Between Asthma Control and Economic Outcomes Among Patients with Allergic Asthma Treated with Inhaled Corticosteroids and Long-Acting Beta Agonists Combination Therapy

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BACKGROUND: Inhaled corticosteroids (ICS) used in combination with long-acting beta agonists (LABA) are recommended for individuals with moderate/severe persistent asthma. However, there is limited real-world research examining the unmet needs in asthma control and its association with economic outcomes among patients on this treatment regimen.

OBJECTIVE: To examine associations between asthma control and economic outcomes among patients with allergic asthma treated with ICS and LABA combination therapy.

METHODS: Data from the 2011-2013 U.S. National Health and Wellness Survey, a nationally representative, self-administered, internet-based survey of adults, were used to identify those with allergic asthma currently treated with ICS and LABA combination therapy (N=1,923). Allergic asthma was defined by a self-reported physician diagnosis of asthma and at least one of the following allergic comorbid conditions: chronic hives, nasal allergies, hay fever, atopic dermatitis, dermatitis, eczema, or skin allergies. Patients were grouped by asthma control using the Asthma Control Test (ACT; scores ≤ 15 = very poorly controlled [n = 563; 29.3%], 16-19 = not well-controlled [n = 482; 25.1%] and 20-25 = well-controlled asthma [n = 878; 45.7%]). Outcomes included Work Productivity and Activity Impairment Questionnaire: General Health Version 4.0 (WPAI-GH), healthcare resource use (HRU), physician visits, emergency room (ER) visits, and hospitalizations, and estimated annual indirect and direct costs. Generalized linear models, controlling for covariates (i.e., demographics and health characteristics), examined whether outcomes differed by asthma control.

RESULTS: Patient mean age was 49.8 years (SD = 15.4); 66.3% were female and 75.9% were white. Very poorly controlled relative to not well-controlled and well-controlled asthma patients had greater overall work impairment (adjusted means = 36.41% vs. 24.74% and 17.69%) and activity impairment (50.77% vs. 38.58% and 28.34%) and higher numbers of ER visits (0.60 vs. 0.37 and 0.31) and hospitalizations (0.23 vs. 0.16 and 0.10), all P<0.05. Very poorly controlled compared with well-controlled patients had higher numbers of physician visits (8.45 vs. 6.94), P<0.001. Very poorly controlled patients compared with well-controlled patients incurred higher indirect and direct costs ($13,024 vs. $5,895; $31,279 vs. $21,047, respectively, all P<0.001).

CONCLUSIONS: Findings suggest improving asthma control among allergic asthma patients on ICS and LABA could potentially reduce work productivity loss, activity impairment, HRU, and associated costs.

SPONSORSHIP: Novartis Pharmaceuticals.

J19 Factors Affecting Prescription Drug Coverage Gap Among COPD Patients: Analysis of Time to Coverage Gap

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BACKGROUND: Global Initiative for Chronic Obstructive Lung Disease guidelines recommended maintenance of medications to reduce symptom and decrease severity in COPD. More increase severity in COPD. More than a third of these patients in Medicare enter the coverage gap (e.g. Donut Hole) every year which increases the cost burden to the patient. It is important to understand which Medicare beneficiaries are more likely to fall into the gap to assist health maintenance organizations with identifying patients that can benefit from medication therapy management services and/or counseling regarding drug utilization.

OBJECTIVE: To identify characteristics among COPD patients that (1) do not fall into the coverage gap, (2) fall into the coverage gap, and (3) fall into the coverage gap and reach the catastrophic coverage. Further, factors associated with time to reach coverage gap were evaluated.

METHODS: A retrospective cross-sectional cohort study was conducted using the Cigna-HealthSpring Medicare Advantage database, which captures members in south east Texas. Subjects age ≥ 65 years with ≥ 1 ICD-9 code for COPD (491.XX, 492.XX, 496.XX), between January 1, 2011 and December 31, 2013. Three cohorts were identified: (1) no gap, (2) coverage gap and (3) gap with catastrophic coverage based on their pharmacy outpatient spending. Multinomial logistic regression was performed to identify patient and plan characteristics associated with reaching the coverage gap. A Cox proportional hazards model assessed factors related to time to reaching the coverage gap.

RESULTS: A total of 3,142 COPD patients were identified with 79% in no gap, 10% in gap and 11% in gap with catastrophic coverage. Patients’ age and CMS risk score were significant factors associated with both, entering coverage gap and gap with catastrophic coverage. COPD patients with age above 85 years had a lower risk of being in coverage gap and catastrophic coverage compared to those less than 70 years. CMS risk score was the only factor to predict time to reach coverage gap. A higher CMS risk score indicated 24% more likelihood to have a shorter duration of time to reach coverage gap.

CONCLUSIONS: Patients with great disease burden and possibly great severity (greater CMS risk score) are more likely to enter the coverage gap and may enter the gap sooner than those with lower severity.
SPONSORSHIP: This study was partially sponsored by University of Houston, Cigna-HealthSpring, and GlaxoSmithKline.

J20 Impact of Non-adherence to Inhaled Corticosteroid/Long-Acting β2-Agonist (ICS/LABA) Therapy on Health Care Costs in Patients with Chronic Obstructive Pulmonary Disease (COPD)

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BACKGROUND: Poor adherence to COPD medications is well documented.

OBJECTIVE: To evaluate the impact of non-adherence to ICS/LABA therapy on health care costs in patients with COPD.

METHODS: In this study (NCT#02446041), COPD patients (≥ 40 years) naive to ICS/LABA who initiated budesonide/formoterol (160/4.5 μg) or fluticasone/salmeterol (250/50 μg) combination therapy during 03/01/2009-1/31/2014 were identified from the HealthCore Integrated Research Database and followed for 12 months. First prescription fill was considered the index date. Patients with cancer or chronic oral corticosteroid (OCS) use (≥ 180 days) were excluded. Patients were stratified into four cohorts based on adherence to the index therapy, measured by the proportion of days covered (PDC): adherent (AD) cohort (PDC ≥ 0.8), mildly non-adherent (NAD) (0.5 ≤ PDC < 0.8), moderately NAD (0.3 ≤ PDC < 0.5), and highly NAD (PDC < 0.3). Each NAD group was matched to the AD group independently 1-to-1 on demographic and pre-index clinical characteristics using propensity scores. All-cause and COPD-related (medical claims for a COPD diagnosis and pharmacy claims for COPD medication) health care costs (adjusted to 2014 U.S. dollars) were estimated.

RESULTS: Overall, 13,657 eligible patients with COPD initiated ICS/LABA and 1,898 (13.9%) were adherent over 1 year. Matching resulted in 1,572 patients per group for comparison #1 (AD vs. mildly NAD), 1,604 per group for comparison #2 (AD vs. moderately NAD), and 1,755 per group for comparison #3 (AD vs. highly NAD). Cohorts were well balanced on age (mean, 67 years), gender (51%-53% female), prior COPD-related medication use, prior health care utilization, and comorbid conditions. During the 1-year follow-up, AD patients incurred significantly lower mean all-cause health care costs than NAD patients for all comparisons (comparison #1: $22,671 vs. $25,545, P < 0.01; #2: $22,508 vs. $24,303, P < 0.01; #3: $22,460 vs. $25,148, P < 0.01), mainly driven by lower hospitalization costs despite higher pharmacy costs. COPD-related medical costs were lower but COPD-related pharmacy costs were higher in AD patients, resulting in significantly higher mean total COPD-related health care costs for AD patients (comparison #1: $8,149 vs. $7,053, P < 0.01; #2: $7,997 vs. $6,623, P < 0.01; #3: $8,080 vs. $5,644, P < 0.01).

CONCLUSIONS: This study showed an association between poor adherence to ICS/LABA therapy and a statistically significant increase in all-cause health care costs. Improving adherence may provide an opportunity to reduce the overall economic burden among patients with COPD.

SPONSORSHIP: AstraZeneca.

J21 Chronic Obstructive Pulmonary Disease Medication Adherence and Hospital Use

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BACKGROUND: Chronic obstructive pulmonary disease (COPD) is one of the most common lung diseases. There is no cure for COPD but it can be managed with COPD maintenance medications. Prior studies have reported that high COPD medication adherence was associated with lower hospitalization rates. However, those studies used cross sectional designs or used suboptimal adherence measures.

OBJECTIVE: To examine adherence to COPD maintenance medications and association with all-cause hospitalizations and with all-cause hospital days among Medicare beneficiaries with COPD using a longitudinal design.

METHODS: A retrospective cohort study was conducted using 2007 to 2010 Medicare Current Beneficiary Survey (MCBS) data linked with Medicare claims. The MCBS is a continuous survey of a representative sample of the U.S. Medicare population. COPD medication adherence was assessed during six months following an index date, defined as the date of first COPD maintenance medication fill following diagnosis of COPD in the interval from July 1, 2007 through December 31, 2009. Hospitalization was assessed during a six-month period following the COPD medication assessment period. Medication adherence was measured using proportion of days covered (PDC). Beneficiaries with a PDC of 0.80 or higher were considered adherent and beneficiaries with a PDC less than 0.80 were classified as nonadherent. Logistic regressions were used to examine association between medication adherence and all-cause hospitalization risk, adjusted for demographic and clinical covariates. A zero-inflated negative binomial model was used to examine association between medication adherence and all-cause hospital days, adjusted for demographic and clinical covariates.

RESULTS: Among 383 beneficiaries who met study criteria, 44 percent were 75 years or older, 59 percent were female, and 84 percent were White. Approximately 45 percent of the sample was adherent (95% CI = 39.9%-50.0%). No significant association was found between medication adherence and risk of having a hospitalization (Odds ratio = 0.881, P = 0.697). However, medication adherence was associated with 1.35 lower hospital days among adherent beneficiaries as compared to nonadherent beneficiaries (Standard error = 0.023).

CONCLUSIONS: Adherence to COPD medication medications was low, with less than one-half of Medicare beneficiaries being adherent to their COPD medications. Medication adherence was associated with lower all-cause hospital days after adjusting for demographic and clinical covariates.

SPONSORSHIP: No funding was received for this work.

J23 Costs and Length of Stay in Hospitalized Patients with Idiopathic Pulmonary Fibrosis: Analysis of the National Inpatient Sample

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BACKGROUND: IPF patients are frequently hospitalized.

OBJECTIVE: To provide a more detailed view of the economic impact of IPF and identify factors associated with cost and length of stay (LOS), we studied IPF patients admitted to short-stay hospitals in the U.S.

METHODS: We conducted a retrospective cohort study using the National Inpatient Sample (NIS), the largest publicly available all-payer U.S. inpatient database that contains claims data from >7 million hospital stays/year. We included all hospitalizations 2009-2011 with claims for IPF (ICD-9-CM code 516.3, 516.31) and a principal diagnosis of respiratory disease (ICD-9-CM 492-519). Lung transplant admissions were excluded. Variables were weighted to represent national
Ulcerative colitis (UC) is associated with a considerable burden of illness.

**OBJECTIVE:** To examine treatment patterns, dosing, and cost of tumor necrosis factor (anti-TNF) drugs used to treat Crohn's disease (CD) can impact prescription and reimbursement decisions.

**RESULTS:** The study population consisted of 295 patients: mean age 50.9, 51% female and the majority (62%) were located in the Southern U.S. at index. 50 (17%) patients received ADA treatment and 245 (83%) received IFX at index, with 78% patients on TNFi monotherapy (no ≥31 days of overlapping azathioprine or 6-mercaptopurine). Treatment discontinuation was observed in 26 (52%) ADA and 111 (46%) IFX patients during the 12-month post-index period. In these patients, mean time to discontinuation of ADA and IFX was 19 and 22 weeks, respectively. Of those that discontinued, 12 (46%) ADA and 76 (68%) IFX patients did not restart index TNFi or initiate another TNFi therapy. Similar rates of therapy switching were observed between ADA- and IFX-treated patients with respective mean times to switch of 18 and 30 weeks. Mean TNFi medication costs amounted to $29,193 out of a mean total UC-related healthcare cost of $41,618 per UC member, in the 12 months post-index.

**CONCLUSIONS:** This study shows that approximately half of ADA and IFX patients discontinued therapy after 12 months of follow up. Approximately half of ADA patients and the majority of IFX patients did not restart or switch therapies. Mean TNFi medication costs accounted for over half of total UC-related healthcare costs. This study indicates a need for further investigation of patient treatment patterns and outcomes following discontinuation of TNFi therapy.

**SPONSORSHIP:** This study was sponsored by the Humana-Pfizer Research Collaboration and funded by Pfizer.

**K03 Impact of Site of Care on the Drug and Administration Costs of Certolizumab Pegol Versus Infliximab in Crohn’s Disease**

**BACKGROUND:** Utilization patterns and administration costs of anti-tumor necrosis factor (anti-TNF) drugs used to treat Crohn's disease (CD) is of interest. This analysis compared certolizumab pegol (CZP) to infliximab (IFX) in terms of drug and administration costs by site of care for CD patients (pts) receiving subcutaneous certolizumab pegol (CZP) or intravenous infliximab (IFX).

**OBJECTIVE:** To assess the total annual healthcare costs and individual treatment costs by site of care for CD patients (pts) receiving subcutaneous certolizumab pegol (CZP) or intravenous infliximab (IFX).

**METHODS:** Medical and pharmacy claims data (2008-2012) were derived from the Truven MarketScan database of commercially insured pts. Inclusion criteria: CD diagnosis, starting treatment with CZP or IFX (7/1/2008-12/31/2010), age ≥18 years, ≥30 months of medical insurance eligibility. Exclusion criteria: pregnancy, diagnosis code for rheumatic disease or cancer, off-label anti-TNF use, overlapping anti-TNF use for ≥30 days. Annual healthcare service costs for each anti-TNF group were calculated per pt-year (PY). Mean cost per treatment was calculated based on site of care: office, home, outpatient hospital and pharmacy fill. Statistical differences in treatment costs between groups were assessed via the Mann-Whitney U test.

**RESULTS:** A total of 272 pts were treated with CZP (total exposure: 374 PY) and 1,069 were treated with IFX (total exposure: 1,800 PY). Total annual healthcare costs per PY were $40,534 for CZP and $47,420 for IFX. Mean costs per cost center for CZP pts were $3,454 in office, $4,147 in outpatient hospital and $24,685 in pharmacy fills; mean costs per cost center for IFX pts were $18,379 in office, $19,158 in outpatient hospital and $4,182 in pharmacy fills. Mean cost per treatment administration was $2,031 for CZP and $4,636 for IFX (P<0.01). Costs incurred per site of care were (mean cost [n=treatment administrations]) office: $1,749 (n=476) for CZP and $3,816 for IFX.
visits ($10,941 vs. $7,049; $P<0.01). CZP pts incurred $2,147 ($n = 2,867) per pharmacy fill for self-administered treatments, IFX must be administered by a healthcare professional.

**CONCLUSIONS:** IFX treatment was consistently more expensive than CZP, and pts incurred greater annual healthcare costs. The most expensive cost center for IFX and CZP was outpatient hospital and pharmacy fills, respectively.

**SPONSORSHIP:** This study was funded by UCB Pharma.

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**K04 Healthcare Resource Utilization and Direct Medical Costs Among Patients with Irritable Bowel Syndrome with Diarrhea**

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**BACKGROUND:** Irritable bowel syndrome (IBS) affects 10-15% of U.S. adults, with the diarrhea subtype (IBS-D) estimated to account for one-third of cases. IBS is associated with a significant economic burden; however, information on the economic burden of IBS-D is limited.

**OBJECTIVE:** To assess healthcare resource utilization (HRU) and direct costs associated with IBS-D among a sample of the U.S. population.

**METHODS:** Adult respondents were identified from the 2012 U.S. National Health and Wellness Survey, a self-administered, internet-based survey. IBS-D patients were defined as those who reported a prior IBS-D diagnosis, or reported symptoms consistent with Rome II criteria for IBS-D. Controls included respondents who did not report diagnoses of IBS or inflammatory bowel disease or meet Rome II criteria for IBS-D. HRU was assessed as number of health provider visits, emergency room (ER) visits, and hospitalizations reported by respondents in the previous 6 months. Reported HRU was doubled to estimate annual HRU. Annual direct costs were calculated by applying unit costs derived from the 2012 Medical Expenditure Panel Survey database to annual HRU estimates. Multivariable generalized linear models compared IBS-D patients vs. controls, adjusting for age, gender, ethnicity, income, education, body mass index, smoking status, alcohol use, exercise activity, and Charlson Comorbidity Index.

**RESULTS:** A total of 66,491 respondents were included (1,102 IBS-D patients; 65,389 controls). After controlling for demographic and health characteristics, IBS-D patients had significantly greater mean annual numbers of physician office visits (9.70 vs. 6.19), gastroenterologist visits (0.54 vs. 0.09), ER visits (0.51 vs. 0.29; all $P<0.01), and hospitalizations (0.28 vs. 0.18; $P=0.02) compared with controls. Direct costs were $5,862 higher per patient/year for IBS-D patients vs. controls ($16,801 vs. $10,939; $P<0.001). The majority of these costs for IBS-D patients and controls were attributable to physician office visits ($10,941 vs. $7,049; $P<0.001), followed by hospitalizations ($4,312 vs. $2,957; $P=NS) and ER visits ($781 vs. $444; $P=0.001).

**CONCLUSIONS:** IBS-D patients utilized significantly greater healthcare resources and incurred significantly higher direct healthcare costs compared with controls, even after adjusting for potential confounders. The substantial economic burden of IBS-D highlights the need for treatments to effectively alleviate and manage IBS-D symptoms.

**SPONSORSHIP:** Allergan.

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**K05 Factors Influencing Treatment Choice Among Patients with Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C): Results from the CONTOR Study**

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**BACKGROUND:** CIC and IBS-C are symptom-based conditions often treated with prescription and over-the-counter medications. Understanding factors that impact patients’ treatment preferences may help healthcare providers better optimize patient care.

**OBJECTIVE:** To describe patient-reported factors influencing constipation treatment choice among CIC and IBS-C patients participating in the CONTOR study.

**METHODS:** Fully insured patients ≥18 years old were identified from a large, geographically-diverse U.S. health plan based on claims from 12/2012-4/2014. Identification criteria included: ≥1 medical claim for constipation (564.0x), IBS (564.1x), or abdominal pain (789.0x) plus ≥1 pharmacy claim for a stool softener/laxative, or ≥1 pharmacy claim for linaclotide or lubiprostone. Patients who participated in the study completed a self-administered survey that included both an assessment of symptom severity via the Patient Assessment of Constipation Symptoms (PAC-SYM) and patient-reported factors impacting choice of constipation therapy. Respondents were stratified by symptom severity based on median PAC-SYM score.

**RESULTS:** Of 9,590 patients invited to participate, 1,136 eligible patients responded and are included in this analysis. Respondent demographics did not differ significantly from non-respondent demographics. The majority of respondents were female (94%), mean age (SD) was 47 (12) years. A higher proportion of patients rated symptom relief as being “very important”: alleviates symptoms (96%); relieves bowel symptoms (90%); consistent symptom relief over time (88%); relieves abdominal bloating (76%) & abdominal pain (74%), while a smaller proportion rated side effects (type of side effects [84%] and likelihood of side effects [59%]) and cost (health insurance pays for part of treatment [65%] and overall cost [48%]) as very important when choosing a constipation treatment. Among patients with more severe symptoms, symptom relief was more often rated as “very important” versus those with less severe symptoms: relieve bowel symptoms (93% vs. 87%); relieve abdominal bloating (81% vs. 70%) and abdominal pain (78% vs. 69%); predictability of bowel movements (51% vs. 40%) (all $P<0.001).

**CONCLUSIONS:** Symptom relief is the most important factor for CIC/IBS-C patients when choosing how to treat their condition, more so than side effects or cost.

**SPONSORSHIP:** Forest Laboratories, an Allergan affiliate, and Ironwood Pharmaceuticals.
clinical study to evaluate the efficacy and safety of OCA. 198 patients completed the DB phase of the study and 193 enrolled in a long term safety extension (LTSE) phase. Exposure to OCA during the DB phase resulted in statistically significant liver biochemistry improvements and OCA was generally well tolerated.

**OBJECTIVE:** To assess the long-term safety and tolerability of OCA.

**METHODS:** All patients enrolled in the LTSE first met the inclusion criteria for the DB study, which included PBC diagnosis, ALP ≥ 1.67x ULN and/or total bilirubin > ULN to <2x ULN, stable UDCA or unable to tolerate UDCA. During the DB phase, patients were randomized to placebo, OCA 5 mg titrating to 10 mg after 6 months based on tolerability/clinical response, or OCA 10 mg. In the LTSE, all patients started at OCA 5 mg with the option to increase by 5 mg every 3 months. An interim safety analysis was conducted during the LTSE period.

**RESULTS:** Long-term OCA treatment demonstrated durability of therapeutic response and safety for more than 2 years, no new safety signals emerged during the LTSE. The overall incidence of new adverse events (AEs) during the LTSE was lower for patients who received OCA during the DB phase, suggesting improved tolerability. Pruritus was the most common AE. As with the overall AE rate, the incidence of pruritus was lower during the LTSE phase (DB: 56% OCA titration, 68% OCA 10 mg; LTSE: 19% OCA 5 mg, 36% OCA 10 mg). The use of an OCA titration strategy improved study retention: 0% PBO, 1% OCA titration, and 10% OCA 10 mg patients discontinued due to pruritus in the DB phase and 2% patients withdrew due to pruritus in the LTSE. After more than 2 years of OCA treatment, LDL remained comparable to baseline, while the decrease observed in HDL during the DB remained unchanged in the LTSE. During the LTSE, the overall SAE incidence was low (11% OCA 5 mg, 8% OCA 10 mg), none were related to OCA and there continued to be no trend in the types of SAEs that were observed.

**CONCLUSIONS:** Continued treatment with OCA for over 2 years was safe and generally well tolerated, with trends for improved tolerability.

**SPONSORSHIP:** Intercept Pharmaceuticals.

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**K12**

**The Need for Improved Liver Literacy in the U.S. Population**

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**Intercept Pharmaceuticals**

**BACKGROUND:** Liver health is critical to a person’s overall health, yet most Americans possess only a basic understanding of this vital organ. Americans do not currently prioritize or understand the importance of liver health.

**OBJECTIVE:** To assess the level of awareness, knowledge, attitudes and behaviors surrounding liver health and liver disease in the general U.S. population.

**METHODS:** We conducted online surveys from 1/6/15-1/12/15 in the GfK Knowledge Panel, a stratified probability sample representative of the population of U.S. households. To correct for technology & income bias, households without a computer/internet were provided hardware/internet access to participate. We selected 511 respondents using random probability address-based sampling. Final data were weighted by age, region, race/ethnicity, education, and income according to the 3/14 U.S. Census Current Population Survey. Margin of error was ±3.4%.

**RESULTS:** The vast majority of participants were aware of tests and values for blood pressure (91%), blood sugar (81%), cholesterol (79%), and BMI (69%), and were much more likely to discuss these with their physician. In contrast, 81% of respondents do not perceive themselves to be at risk for liver disease, and most said they do not think about or discuss it with friends and family (71%), or their physician (76%). In fact, 42% had some belief that a person can live without a liver. While 72% of participants report having had routine bloodwork, only 34% were aware that liver health was assessed as a part of these tests; few admit discussing liver test results with their physician. Respondents reported greater likelihood of thinking and worrying about other diseases (weight, heart, breast, mental, prostate, colon and kidney) than liver. 59% reported more stigma associated with liver cirrhosis than with kidney disease, heart disease, cancer (colon, breast, prostate, or lung), diabetes, or reproductive health problems.

**CONCLUSIONS:** In a representative U.S. sample, awareness and concern about liver disease ranked low compared to other diseases. Participants report low levels of interaction with physicians about liver disease compared to other diseases, and were much less familiar with measures of liver health than (for example) cardiovascular.
Massive public health campaigns in cardiovascular health have raised awareness and increased monitoring, screening & treatment. With increasing non-viral liver diseases, such as non-alcoholic fatty liver and steatohepatitis, these data point to a need for broad public health educational campaigns in liver disease.

SPONSORSHIP: Intercept Pharmaceuticals.

K13 The Classification and Regression Tree Approach to Predicting Patient-Specific Factors Associated with Discussing Biologic Treatment with a Health Care Provider in Crohn’s Disease Patients

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BACKGROUND: Patient (pt) and physician shared decision making discussions are important in understanding pts’ preference and openness to biologics.

OBJECTIVE: To identify pt-specific predictors associated with having a discussion with a physician about biologics.

METHODS: Crohn’s Disease (CD) pts (N = 123) were identified through the Sample Czar nonprofit-focused panel or All Global online consumer panel. Patients completed a self-administered web-based questionnaire assessing demographic, health characteristics and behaviors related to inflammatory bowel disease (IBD) treatment (Tx). Patients were U.S., aged ≥ 18, with no prior biologic use. Classification and regression tree (CART) analysis was used to identify pt-specific predictors associated with having a discussion with a physician about biologics. CART is based on binary recursive partitioning of the data and was employed to determine variable importance, starting with all CD pts, and thereafter, all newly defined subgroups, to determine at every step of the analysis, the threshold of each variable that yielded the most significant division into two subgroups, most likely to differentiate between those having a biologic conversation vs. those that didn’t. Cross validation technique was used to prune and optimize the regression tree.

RESULTS: 46 of 123 pts with CD reported having a biologics discussion with their gastroenterologist. Ten variables of importance, including frequency of resource use, symptoms, number of symptoms, number of years since diagnosis (Dx) and Tx duration, satisfaction with current Tx and adherence levels, were computed in CART after considering all primary and surrogate splits. CART threshold analysis identified at least one hospitalization in the last 6 months as the most important predictor. If not hospitalized in last 6 months, those pts treated with mesalamine < 53 months, who were less than extremely satisfied with current Tx and had a diagnosis > 3 yrs were most predictive. If ≤ 3 yrs since Dx, those with less than full adherence were most predictive.

CONCLUSIONS: Among many pt-specific factors, having an inpatient visit in the last 6 months, having been diagnosed with CD for more than 3 years, and non-adherence to prior IBD tx are most positively predictive of having a discussion with a physician about biologics.

SPONSORSHIP: Janssen Scientific Affairs supported this research.

L00-L99 Diseases of the Skin and Subcutaneous Tissue (e.g., Psoriasis, Pressure Ulcers)

L01 Estimation of Annual Indirect Costs Associated with Moderate-to-Severe Plaque Psoriasis in the United States

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BACKGROUND: There are limited data on indirect costs due to loss of work productivity (missed work time and impairment while working) among U.S. patients with moderate-to-severe plaque psoriasis. Costs of productivity loss are estimated to account for 32% of the total burden of psoriasis.

OBJECTIVE: To estimate the indirect costs of psoriasis by treatment-based disease improvement via Psoriasis Activity Severity Index (PASI) score change from an employer’s perspective.
METHODS: Psoriasis Work Productivity and Activity Impairment Questionnaire (WPAI) from baseline to week 16 from a phase 3b study (CLEAR) comparing the efficacy and safety of secukinumab vs. ustekinumab were analyzed. Both treatment arms were pooled for the analysis and stratified by 4 levels of PASI score change from baseline to 16 weeks: less than 50% improvement (PASI < 50), 50%-74% improvement (PASI 50-74), 75%-89% improvement (PASI 75-89), and at least 90% improvement (PASI ≥ 90). Percentage of work time missed and impairment while working captured by WPAI from baseline to week 16 for all trial subjects employed at baseline were used to estimate the percentage of overall work impairment due to psoriasis. Applying the national averages for full- and part-time employment, hours worked per week, and hourly wages from the U.S. Department of Labor, we estimated the annual indirect costs due to loss of work productivity by level of PASI score change.

RESULTS: Overall work impairment due to psoriasis decreased with greater skin clearance (22.8% for PASI < 50, 13.3% for PASI 50-74, 6.4% for PASI 75-89, and 4.9% for PASI ≥ 90), with the majority of impairment being related to productivity loss at work (presenteeism) rather than missed work time (absenteeism). The productive work time missed due to psoriasis symptoms decreased with increasing psoriasis clearance: 8.2 hours/week and 427.4 hours/year for patients with PASI < 50 (poorly controlled psoriasis), 4.8 hours/week and 230.3 hours/year for PASI 50-74, 2.3 hours/week and 120.2 hours/year for PASI 75-89, and 1.8 hours/week and 92.5 hours/year for PASI ≥ 90. The annual indirect costs due to work productivity loss per employed psoriasis individual were estimated to be $10,147 for a person with PASI < 50, $5,941 for PASI 50-74, $2,852 for PASI 75-89, and $2,196 for PASI ≥ 90, respectively.

CONCLUSIONS: Among U.S. working patients with moderate-to-severe psoriasis, those achieving PASI improvement ≥ 90 were associated with a prominent increase in workplace productivity and reduction in annual indirect costs.

SPONSORSHIP: Novartis Pharmaceuticals.

L03 Cost-Effectiveness of Adding Clostridial Collagenase Ointment to Standard of Care in Individuals with Stage IV Pressure Ulcers Carter M1, Waycaster C2, Gilligan A1, Schaum K2. 1143 Salsbury Ave, Cody, WY 82414; mcarter@strategic-solutions-inc.com; 307.587.5352

BACKGROUND: Stage IV pressure ulcers are an epidemic among bed-bound populations, with a reported prevalence as high as 26% among hospitalized patients, 43% among nursing home patients, and 39% among patients with spinal cord injuries. Every year, billions of dollars are spent on the treatment of pressure ulcers and associated morbidities, representing a significant portion of health care resources. Appropriate cost-effective treatment modalities are therefore of the utmost importance.

OBJECTIVE: To determine the cost-effectiveness of adding clostridial collagenase ointment (CCO) to standard of care (SOC) for stage IV pressure ulcers (PU) treated in the hospital outpatient department wound clinic setting of care.

METHODS: A 3-state Markov model with a cycle length of 4 weeks was chosen to estimate the costs and clinical consequences of the adjunctive use of CCO. The time horizon for the economic analysis was 2-years. The Markov PU health states were unhealed, healed, and dead. Healing rates used in the economic analysis were derived from an examination of stage IV PU closure rates observed in the U.S. Wound Registry (USWR). The clinical analysis of USWR data revealed that the proportion of stage IV PU closed at 1 year and 2 years was double for PU treated with CCO compared to those treated with SOC. Mortality rates were modeled using the age structure of the two comparative cohorts using national census data. Unit costs included outpatient visits at hospital-based wound care clinics, dressing changes, debridement, and offloading. Costs were based on 2015 Medicare reimbursement rates with the exception of commercial costs for supplementary offloading devices. Costs and effectiveness were discounted at 3% for the second year. The model was calibrated in stages using a dependent validity method to ensure that final results were within prescribed limits when compared against USWR parameters. A sensitivity analysis was performed to assess model uncertainty.

L02 Number Needed to Treat and Cost Per Responder to Achieve PASI-90 for the Novel Treatments of Moderate-to-Severe Psoriasis in the United States Armstrong A1, Betts K2, Li J, Sundaram M3. 1 N Waukegan Rd, North Chicago, IL 60064; abstracts01@jmed.com; 847.937.1215

BACKGROUND: Novel treatments for moderate to severe psoriasis, biologics and apremilast, have demonstrated significant clinical benefits in relieving symptoms. With improvements in efficacy and quality of life, the use of a higher standard such as a 90% reduction in the Psoriasis Area and Severity Index (PASI-90) is increasingly of interest in therapeutic paradigms.

OBJECTIVE: To compare the clinical benefits of these novel treatments in psoriasis, this study estimated the number needed to treat (NNT) to achieve one additional PASI-90 responder with novel psoriasis treatments and evaluated the incremental drug cost per PASI-90 responder for biologic treatments relative to apremilast.

METHODS: Phase 3 randomized controlled trials of novel treatments in patients with moderate to severe psoriasis were identified through a targeted literature review. A Bayesian network meta-analysis was conducted to estimate the relative PASI-90 response with each treatment during the trial period (10 weeks for infliximab; 12 weeks for etanercept, ustekinumab, and secukinumab; and 16 weeks for adalimumab and apremilast). The NNT was estimated as the reciprocal of the difference in estimated PASI-90 response rates between biologic treatment and apremilast during the trial period. Apremilast was selected as the reference point because of its lower price and efficacy. The incremental cost per PASI-90 responder of each biologic was estimated for one year. Drug costs, including acquisition and administration costs, were assessed in 2015 USD.

RESULTS: A total of 17 Phase 3 trials were identified. Compared with apremilast, the NNT to achieve one additional PASI-90 response during the trial period was 2.17 (95% credible interval: 1.90-2.50) for secukinumab 300 mg; 2.56 (2.11-3.17) for infliximab; 3.05 (2.43-3.85) for adalimumab; 3.31 (2.68-4.14) for secukinumab 150 mg; 3.57 (2.92-4.52) for ustekinumab; and 9.02 (6.13-14.35) for etanercept. The one-year incremental cost per PASI-90 responder relative to apremilast was $24,893 ($20,748-$31,164) for infliximab; $54,402 ($43,910-$69,549) for adalimumab; $68,492 ($60,448-$79,199) for secukinumab 300 mg; $92,583 ($76,740-$118,700) for ustekinumab; $103,775 ($85,126-$131,354) for secukinumab 150 mg; and $218,096 ($154,944-$363,252) for etanercept.

CONCLUSIONS: Infliximab and adalimumab had the lowest incremental costs per PASI-90 responder among the biologic treatments compared with apremilast.

SPONSORSHIP: AbbVie.
RESULTS: The base-case cost-effectiveness analysis revealed that the use of CCO saved an estimated $6,445 per patient and added an additional 17.2 ulcer-free weeks over the 2-year period. Sensitivity analyses showed that results remained robust within the values tested.

CONCLUSIONS: The addition of enzymatic debridement with CCO to SOC in outpatients with stage IV pressure ulcers results in both cost savings and improved clinical benefits.

SPONSORSHIP: This research was sponsored by Smith & Nephew.

L04 The Comparative Effectiveness of Adding Klostridial Collagenase Ointment to Standard of Care in Individuals with Stage IV Pressure Ulcers

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BACKGROUND: The management and treatment of pressure ulcers (PU) poses substantial clinical and economic challenges for health care systems. Debridement is critical to wound bed preparation in treating chronic wounds such as PU. The immediate goal of debridement is the removal of debris and nonviable tissue as a means to the end goal of the wound epithelialization. Sharp debridement is generally considered the “gold standard” method for wound debridement. However, multiple studies have suggested that sharp debridement may work well in adjunct with other treatment approaches, such as skin substitutes, growth factors, or other methods of debridement (i.e., enzymatic).

OBJECTIVE: To assess the comparative effectiveness of adjunctive enzymatic debridement with clostridial collagenase ointment (CCO) plus sharp debridement compared to sharp debridement alone (SD) for the management of stage IV pressure ulcers (PU) in the hospital outpatient department wound care clinic setting.

METHODS: Electronic medical records on PU were extracted from the U.S. Wound Registry from 2007-2013 and used for the comparative effectiveness analysis. A propensity score matching method was used to adjust for selection bias and to test for treatment effects between the CCO and SD cohorts.

RESULTS: Using sharp debridement current procedural terminology codes and propensity score matching 337 CCO and 336 SD stage IV PU were identified and used in the analysis. After matching, both groups were statistically similar with respect to patient age, PU surface area and PU age. The average patient ages were 66 years (±19) in the CCO group and 64 (±19) in the SD group. The average stage IV PU wound sizes were 16 cm² (±23) in the CCO group versus 18 cm² (±29) in the SD group. The average stage IV PU ages were 355 days (±412) in the CCO group versus 501 (±743) days in the SD group. The proportion of wounds closed at 1 year or 2 years was 2 times greater in the CCO group compared to the SD group (0.05). Kaplan-Meier analysis showed that the average time to stage IV PU closure was significantly faster in the CCO group at 456 days versus 589 days in the SD group (P < 0.0001).

CONCLUSIONS: CCO as an adjunct therapy coupled with sharp debridement yielded better clinical outcomes and facilitated faster closure rates for stage IV PU relative to sharp debridement alone. Healthcare providers should consider CCO an effective adjunctive therapy to sharp debridement when treating PU in the hospital outpatient department setting.

SPONSORSHIP: This research was sponsored by Smith & Nephew.

L05 Long-term Safety of crisaborole topical ointment 2% in children and adults with mild-to-moderate atopic dermatitis

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BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory skin disease often requiring long-term topical treatment. Unfortunately, topical therapies have not changed over the past 15 years and are associated with potential safety concerns. To address the need for a more targeted and safe long-term treatment, crisaborole topical ointment, 2% (Anacor Pharmaceuticals, Inc., Palo Alto, CA), a novel nonsteroidal, topical, anti-inflammatory phosphodiesterase 4 (PDE4) inhibitor, has been investigated for the treatment of AD.

OBJECTIVE: To assess the long-term safety results of patients as young as 2 years of age with mild-to-moderate AD enrolled in an open-label extension study.

METHODS: A multicenter, open-label, long-term, 48-week safety study was conducted in patients who opted to continue treatment after completing a 28-day Phase 3 pivotal study (NCT02118766/NCT02118792). Patients were assessed for AD severity every 4 weeks using the Investigator’s Static Global Assessment (ISGA) scale and were treated with 4-week cycles of crisaborole as needed. Each On-Treatment Period was initiated by the investigator based on severity of AD (ISGA ≥ 2 [Mild]). Safety measures included assessment of local tolerability, adverse events (AEs), serious adverse events (SAEs), clinical laboratory results, vital signs, and physical examinations.

RESULTS: The study enrolled 517 patients, who had a mean age of 11.7 years. During the open-label extension and the pivotal studies, 65% of patients reported at least 1 treatment-emergent adverse event (TEAE), most of which were mild (51.2%) or moderate (44.6%) in severity and considered unrelated to treatment (93.1%). Treatment-related AEs occurred in 10.2% of patients; the most frequently reported events were atopic dermatitis (3.1%), application site pain (burning/stinging, 2.3%), and application site infection (1.2%). Of 9 treatment-emergent SAEs (7 of which occurred in the extension study), none were considered treatment related. During the long-term study, 33 patients (6.4%) interrupted or discontinued treatment because of TEAEs, although only 9 patients (1.7%) discontinued the study because of TEAEs. No safety signals were identified from review of the clinical laboratory and vital sign results. There were no cutaneous adverse reactions such as application site atrophy, telangiectasia, or hypopigmentation reported. The safety profile of crisaborole was similar across age groups.

CONCLUSIONS: Crisaborole Topical Ointment, 2%, has a favorable safety profile for the long-term treatment of patients with mild-to-moderate AD aged 2 years or older.

SPONSORSHIP: Anacor Pharmaceuticals.

L06 Crisaborole Topical Ointment 2%, a Novel, Nonsteroidal, Topical, Anti-Inflammatory, Phosphodiesterase Inhibitor, in 2 Phase 3 Studies in Children and Adults with Mild-to-Moderate Atopic Dermatitis

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BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory skin disease often requiring long-term topical treatment. Unfortunately, topical therapies have not changed over the past 15 years and are associated with potential safety concerns. To address the need for a more targeted and safe long-term treatment, crisaborole topical ointment, 2% (Anacor Pharmaceuticals, Inc., Palo Alto, CA), a novel nonsteroidal, topical, anti-inflammatory phosphodiesterase 4 (PDE4) inhibitor, has been investigated for the treatment of AD.

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METHODS: A multicenter, open-label, long-term, 48-week safety study was conducted in patients who opted to continue treatment after completing a 28-day Phase 3 pivotal study (NCT02118766/NCT02118792). Patients were assessed for AD severity every 4 weeks using the Investigator’s Static Global Assessment (ISGA) scale and were treated with 4-week cycles of crisaborole as needed. Each On-Treatment Period was initiated by the investigator based on severity of AD (ISGA ≥ 2 [Mild]). Safety measures included assessment of local tolerability, adverse events (AEs), serious adverse events (SAEs), clinical laboratory results, vital signs, and physical examinations.

RESULTS: The study enrolled 517 patients, who had a mean age of 11.7 years. During the open-label extension and the pivotal studies, 65% of patients reported at least 1 treatment-emergent adverse event (TEAE), most of which were mild (51.2%) or moderate (44.6%) in severity and considered unrelated to treatment (93.1%). Treatment-related AEs occurred in 10.2% of patients; the most frequently reported events were atopic dermatitis (3.1%), application site pain (burning/stinging, 2.3%), and application site infection (1.2%). Of 9 treatment-emergent SAEs (7 of which occurred in the extension study), none were considered treatment related. During the long-term study, 33 patients (6.4%) interrupted or discontinued treatment because of TEAEs, although only 9 patients (1.7%) discontinued the study because of TEAEs. No safety signals were identified from review of the clinical laboratory and vital sign results. There were no cutaneous adverse reactions such as application site atrophy, telangiectasia, or hypopigmentation reported. The safety profile of crisaborole was similar across age groups.

CONCLUSIONS: Crisaborole Topical Ointment, 2%, has a favorable safety profile for the long-term treatment of patients with mild-to-moderate AD aged 2 years or older.

SPONSORSHIP: Anacor Pharmaceuticals.
BACKGROUND: Mild-to-moderate atopic dermatitis (AD) is the predominant presentation (up to 90%) of a complex chronic inflammatory skin disease with distressing signs and symptoms that occurs primarily in children and confers a significant burden upon patients, their caregivers, and the health care system. The most troublesome symptom, pruritus-induced scratching, can further damage the skin and promote secondary infection, leading to exacerbation of AD symptoms and worsening of disease severity, negatively impacting the patients’ quality of life. Topical therapies for AD have changed very little over the past 15 years, heavily relying on 2 broadly acting treatment categories (corticosteroids and calcineurin inhibitors) that constrain providers to weigh the need for relief versus safety concerns and are limited in treatment areas and length of application. There remains a need for a single, topical, nonsteroidal, anti-inflammatory agent that safely minimizes the symptoms and severity of AD for acute and maintenance therapy.

OBJECTIVE: To assess the safety and efficacy of the novel, nonsteroidal, topical, anti-inflammatory phosphodiesterase 4 (PDE4) inhibitor, crisaborole, in the treatment of mild-to-moderate AD.

METHODS: Patients ≥2 years old with mild-to-moderate AD were randomized 2:1 to receive crisaborole or vehicle twice daily with evaluation on Days 8, 15, 22, and 29. Primary and secondary efficacy endpoints analyzed AD disease severity with the Investigator’s Static Global Assessment (ISGA). Supportive efficacy endpoints examined time to improvement in pruritus, severity of pruritus, and signs of AD.

RESULTS: Studies 301 and 302 enrolled 503:256 and 513:250 crisaborole/vehicle patients, respectively. At Day 29, more crisaborole-treated patients achieved ISGA success than those treated with vehicle (301: 32.8% vs. 25.4%, P = 0.038; 302: 31.4% vs. 18.0%, P < 0.001) with a greater percentage of “almost clear/1” or “clear/0” ISGA scores (301: 51.7% vs. 40.6%, P = 0.005; 302: 48.5% vs. 29.7%, P = 0.001). Success in ISGA and Improvement in Pruritus were achieved earlier with crisaborole than vehicle (P < 0.001 vs. vehicle). A greater proportion of crisaborole-treated patients achieved success for all clinical signs of AD by Day 29. Treatment-related adverse events were infrequent, transient, and mild/moderate in severity.

CONCLUSIONS: Two Phase 3 studies show that crisaborole represents a novel, safe, and efficacious treatment for children and adults with mild-to-moderate AD.

SPONSORSHIP: Anacor Pharmaceuticals.

L07 Real-World Effectiveness of Anti-Tumor Necrosis Factor (anti-TNF) Switching in Psoriatic Arthritis: A Systematic Review of the Literature

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BACKGROUND: Refractory patients with moderate-to-severe psoriatic arthritis (PsA) are commonly managed by switching between anti-TNFs.

OBJECTIVE: To evaluate the effectiveness of switching between anti-TNFs using a systematic review of the literature.

METHODS: MEDLINE- and Embase-indexed English-language publications were systematically searched from 1995-May 2015 for studies assessing real-world effectiveness outcomes of anti-TNF cycling in PsA patients.

RESULTS: Among 1,086 unique citations identified, 48 were retrieved, and 38 studies and meeting abstracts were included. In 7 studies, 2,932 patients were tested for the association between consecutive treatment lines and effectiveness, of which 2 studies significant differences between lines of anti-TNF therapy. Effectiveness measures varied widely. Only 7 of 18 measures were common across studies: ACR 20, 50, and 70, CRP, DAS28, PASI, and drug survival. In the NOR-DMARD multi-center study, significant improvement for ACR 70 (23.7% vs. 12.5%, P = 0.04) and mean change in CRP (P = 0.001) was observed for 1st-line relative to 2nd-line therapy. Likewise, in a Danish registry (DANBIO), response defined as ACR 20, 50, 70, and mean DAS28 scores were significantly improved with 1st-line vs. 2nd-line anti-TNF use. In an Italian hospital cohort, PASI 50 and 75 responses at Week 24 were also comparatively higher in the 1st line compared to 2nd line. Drug survival declined from initial anti-TNF to the 2nd and 3rd line in the DANBIO study (P < 0.0001), and from 1st line to 2nd line in a Norwegian clinical study (P < 0.001), but no drug survival loss was observed in a 12-year French cohort. When later lines were tested, no differences in CRP or PASI mean change were detected between 2nd- and 3rd-line anti-TNFs, in a second Italian hospital study. In the only study with multivariate regression testing for predictors of response, DANBIO patients were less likely to respond (ACR 20 or 50) to the second anti-TNF course if safety rather than lack of effect caused them to switch (odds ratio [OR] 0.04, P = 0.003 and OR 0.03, P = 0.03, respectively).

CONCLUSIONS: Effectiveness of anti-TNFs in 2nd-line and later has been reported in few real-world studies of PsA patients. Subsequent treatment lines may be associated with less response in some measures. Comparisons across studies are hampered by a lack of shared outcomes and studies that test for differences by treatment line. More research is needed to quantify the effectiveness of sequential anti-TNF lines in this progressive population and to compare these effects with response to drugs with a different mechanism of action.

SPONSORSHIP: Novartis Pharmaceuticals.

L08 Treatment Patterns, Healthcare Resource Utilization, and Costs Associated with Psoriatic Arthritis Among Humana Commercial and Medicare Member Populations

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BACKGROUND: The chronic inflammatory disease psoriatic arthritis (PsA) reduces quality of life and imposes an economic burden. PsA outcomes have improved with biologic therapy. Greenberg et al. (2015) analyzed MarketScan Research databases of U.S. commercial and Medicare Supplemental plans and reported 61% of PsA patients (pts) used biologics and 52% used non-biologic disease-modifying antirheumatic drugs (nbDMARDs).

OBJECTIVE: To examine patient characteristics, treatment (tx) patterns, healthcare resource utilization (HCRU) and costs in Humana Medicare Advantage with Prescription Drug Plan (MAPD) and Commercial Plan (CP) members with PsA. HCRU and costs were compared between tumor necrosis factor inhibitor (TNFi) and non-TNFi-treated pts.

METHODS: A retrospective cohort study using payment claims data from pts with ≥2 diagnoses of PsA ≥30 days apart. Index event was the first PsA diagnosis January 1, 2008-December 31, 2013. Pts were 18-89 yrs at index with continuous enrollment in MAPD or CP ≥12 months (mo) pre- and ≥12 mo post-index. Pts initiating TNFi 0-6 mo post-index were compared to non-TNFi-treated pts. HCRU and costs were evaluated using generalized linear models adjusted for age, gender, Elixhauser.

RESULTS: The study included 1,011 pts (60% MAPD, n = 610): mean age 58 yrs, 52% male, 64% in Southern USA. ECI was 5.9 vs. 1.8 for
MAPD vs. CP members. Post-index, MAPD and CP members received nBDMARDs (40% and 46%, respectively), TNFis (14% and 48%), NSAIDs (41% and 47%), and corticosteroids (33% and 32%). After excluding pts with TNFi tx pre-index, the mean time to initial TNFi tx was 77 days for MAPD and 63 days for CP. Of those initiating TNFi therapy, 79% of MAPD and 78% of CP members used monotherapy, 7% of MAPD and 14% of CP members switched TNFi tx, and 52% of MAPD and 33% of CP discontinued TNFi tx in year 1. All-cause HCRU (ER, inpatient, outpatient) events were higher in MAPD vs. CP at years 1 and 2. Adjusted PsA-related outpatient visits were greater for TNFi pts vs. non-TNFi-treated patients in MAPD (6.8 vs. 3.7, P < 0.001) and CP (5.8 vs. 4.0, P < 0.001). TNFi vs. non-TNFi adjusted PsA-related costs were $24,508 vs. $1,734 (P < 0.001) in MAPD and $28,667 vs. $2,480 (P < 0.001) in CP.

CONCLUSIONS: PsA-related outpatient visits were greater for TNFi pts vs. non-TNFi-treated patients. Many discontinued TNFi tx within a year; PsA-related costs were significantly higher for pts initiating TNFi therapy vs. non-TNFi. Compared to a U.S. insurance claims database our findings suggest that PsA may be undertreated.

SPONSORSHIP: Pfizer.

L09 The Relative Importance of Mode of Administration in Treatment Choices Among Patients with Psoriasis in the United States

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BACKGROUND: Recent studies evaluated patient perspectives around mode of administration relative to psoriasis treatment outcomes, in some cases showing that administration aspects can be as or more important than clinical outcomes. However, there is limited preference information that focuses on the tradeoffs that patients with psoriasis may be willing to accept between efficacy and mode of administration of treatments among several therapeutic modalities.

OBJECTIVE: To assess the relative importance of mode of administration among psoriasis patients in the United States (U.S.) by quantifying preferences for features of psoriasis treatments in that population.

METHODS: Patients in the U.S. with a self-reported physician diagnosis of psoriasis completed an online discrete-choice experiment survey consisting of eight choices between pairs of hypothetical medication profiles defined by treatment-related improvements in treatment efficacy, treatment adverse reactions, and treatment mode/frequency of administration. The profile pairs in the choice questions were prepared following an experimental design with known statistical properties. A random-parameters logit (RPL) regression model was used to analyze the preference data from the survey. Patient’s willingness to trade treatment efficacy for reduced treatment burden was calculated using results from the RPL model.

RESULTS: 397 psoriasis patients provided data for analysis. The mean self-assessed PASI score of patients was 8.9 (SD, 9.8). Improvements in treatment efficacy were more important than changes in the speed of onset and most increases in the chance of treatment side effects considered in the study. The maximum possible improvement in treatment efficacy offered in the study was not enough to match the improvements in well-being associated with some changes in mode of administration. For example, respondents were willing to accept a reduction in the percentage of patients who achieve clear or almost clear skin after treatment from approximately 70%-40% to avoid injections at home and use a topical treatment. Topical treatments were the most preferred option of administration followed by oral agents and IV infusion.

CONCLUSIONS: Psoriasis patients had well-defined preferences for changes in the attributes considered in the study. Some changes in mode of administration were more important than changes in treatment efficacy. This result supports observations from previous studies and highlights the importance of broad discussions between dermatologists and patients about psoriasis treatments and their administration features.

SPONSORSHIP: Leo Pharmaceuticals.

L10 Medication Utilization Patterns of Apremilast Among Patients with Psoriatic Arthritis

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BACKGROUND: The phosphodiesterase-4 (PDE-4) inhibitor apremilast was recently approved as a twice-daily oral formulation for the treatment of patients with psoriatic arthritis (PsA). Apremilast therapy is commonly initiated with a “starter” dose (provided as a free in-office sample or via specialty pharmacy prescription), followed by maintenance therapy available only via specialty pharmacy.

OBJECTIVE: To assess real-world apremilast utilization patterns (persistence and adherence) among patients with PsA, including the impact of providing in-office starter doses.

METHODS: A retrospective study was conducted using early view data from Truven MarketScan Commercial claims database (up to September 2015). Biologic-naive patients aged ≥18 years with a diagnosis of psoriatic arthritis (ICD-9 code 696.0) and ≥1 pharmacy claim for apremilast on or after diagnosis beginning March 21, 2014 (the FDA approval date for PsA) were included; the earliest apremilast claim was defined as the index date. Continuous coverage for ≥12 months before the index date and ≥6 months after the index date was required. Kaplan-Meier and chi-square analyses were used to compare medication persistence (time from initiation to discontinuation [defined as a gap in therapy of >28 days]) and adherence (proportion of days covered [PDC] during the follow-up period) between patients with an initial claim for a ‘Maintenance pack’ (signifying use of non-reimbursed/sample packs) vs. ‘Starter pack’ (signifying use of reimbursed from the first dose) over a 6-month follow-up period.

RESULTS: A total of 403 patients were included; mean age was 49 years and 227 (56%) were female. The initial claim was for a starter dose in 49 (12%) of patients vs. a maintenance pack in 354 (88%) of patients. Overall, 245 patients (60%) discontinued use during 6 months follow-up; among those, the median time to discontinuation was 65 days. Persistence was similar among patients initiating with a starter vs. a maintenance dose (median time to discontinuation 113 vs. 121 days); however, 21% of patients with an initial claim for a maintenance dose discontinued use by 30 days vs. 12% on starter pack. Mean PDC was 67% overall; adherence was similar among patients initiating with starter vs. maintenance doses.

CONCLUSIONS: This real-world claims analysis may suggest that a majority of biologic-naive PsA patients on apremilast initiated therapy with starter doses were potentially dispensed as free samples. Medication adherence and persistence to apremilast were generally suboptimal, whether initiated via free samples or pharmacy prescription.

SPONSORSHIP: This study was fully sponsored by AbbVie.

CONCLUSIONS: Psoriasis patients had well-defined preferences for changes in the attributes considered in the study. Some changes in mode of administration were more important than changes in treatment efficacy. This result supports observations from previous studies and highlights the importance of broad discussions between dermatologists and patients about psoriasis treatments and their administration features.

SPONSORSHIP: Leo Pharmaceuticals.
Healthcare Costs in Psoriasis Patients Newly Initiated on Apremilast or Biologic Therapies

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BACKGROUND: There are currently no comparative published data on the healthcare costs among patients with psoriasis (PsO) who have been treated with apremilast vs. biologic therapy in a real-world care setting.

OBJECTIVE: To compare healthcare costs among patients with PsO initiating apremilast or biologic agents from the U.S. managed care perspective.

METHODS: Adult patients with ≥2 diagnosis codes for PsO (ICD-10-L40) were selected from the MarketScan Commercial and Medicare Supplemental Databases (2014-2015). The first apremilast or biologic prescription date was defined as the index date and patients were required to be continuously enrolled for ≥6 months pre- and ≥3 months post-index. To ensure new patient starts, biologic users were required to be treatment-naïve to the index medication in the pre-index period, although prior use of a different biologic was not reason for exclusion. Healthcare costs were assessed in 2014 US$ and were defined as the sum of pharmacy and medical service costs such as inpatient, outpatient (including IV infusion procedures), emergency room, and all other services (e.g. laboratory, radiology, and other ancillary services). Results were expressed in cost per patient per month and reported separately for disease-specific PsO costs.

RESULTS: In total, 839 patients initiating apremilast and 1,981 initiating biologic therapies met the inclusion criteria. Mean enrollment time post-index was 5.4 months for apremilast and 8.3 months for biologics. Baseline demographic characteristics were balanced between the 2 cohorts with the exception of mean age (apremilast: 50.4 vs. biologics: 46.1; P < 0.001), gender (apremilast: 50.4% female vs. biologic: 44.2%, P = 0.002), and mean Charlson Comorbidity Index (apremilast: 0.6 vs. biologics: 0.4; P < 0.001). Mean monthly costs of patients initiating apremilast vs. biologics during the study period were as follows: all healthcare: $2,910 vs. $4,222 (P = 0.004); all PsO-related healthcare: $2,231 vs. $3,661 (P = 0.004), which included PsO-related pharmacy: $2,089 vs. $3,324 (P = 0.004); PsO-related inpatient: $54 vs. $5 (P = 0.024); PsO-related emergency room: $2 vs. $2 (P = 0.948); and PsO-related outpatient: $104 vs. $537 (P = 0.004).

CONCLUSIONS: Apremilast use was associated with lower healthcare costs compared to biologic use, with average savings of greater than $1,000 per patient per month. The difference can be attributed to lower PsO-related pharmacy and outpatient costs.

SPONSORSHIP: This research was funded by Celgene.

Prevalence and Systemic Treatment of Psoriasis and Psoriatic Arthritis Among Differently Insured Populations

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BACKGROUND: Psoriasis (PsO) is a chronic inflammatory skin disease, affecting 2.3% of U.S. population. About 20% of PsO patients have moderate to severe disease that requires systemic therapy. PsO patients may also develop psoriatic arthritis (PsA). Little is known about the differences in disease prevalence and utilization of systemic treatment among PsO/PsA patients enrolled in different types of health plans.

OBJECTIVE: To examine the prevalence of PsO/PsA and the use of systemic therapies among differently insured patients.

METHODS: Using administrative medical and pharmacy claims data, we identified people that had at least one medical claim with an ICD-9 code representing PsO or PsA in the primary or secondary diagnosis field from 1/1/2014-12/31/2014. We then determined the utilization of non-biologic and biologic disease-modifying anti-rheumatic drugs (DMARDs) among patients diagnosed with PsO only (without PsA) and patients with PsA (with or without PsO). Patients having a diagnosis of rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis, or Crohn’s disease were excluded from the utilization analysis since DMARDs are also used for treating these conditions.

RESULTS: Medicare plans had the highest claims-based prevalence for PsO (commercial: 0.47%; Medicare: 0.77%; Medicaid: 0.29%) and PsA (commercial: 0.10%; Medicare: 0.17%; Medicaid: 0.05%). PsA occurred in less than 10% of PsO patients. Depending on health plan type, 5-7% of PsO patients were treated with non-biologics. Treatment rate for biologics varied significantly by health plan type (commercial: 14.2%; Medicare: 4.0%; Medicaid: 4.4%). Compared to patients diagnosed with PsO alone, PsA patients were more likely to be treated with DMARDs. Medicare has the highest percentage of patients treated with non-biologics (commercial: 37.3%; Medicare: 41.8%; Medicaid: 33.1%) while commercial plans had the highest percentage of patients treated with biologics (commercial: 57.9%; Medicare: 22.0%; Medicaid: 32.9%). Methotrexate was the most commonly used non-biologic for treating PsO and PsA. Ustekinumab, adalimumab, and etanercept were the most commonly used biologics for treating PsO while adalimumab, etanercept, and infliximab were commonly used for treating PsA across different health plan types.
CONCLUSIONS: Utilization of systemic treatment among PsO/PsA patients varies by health plan type. The underlying causes for this difference (whether due to difference in disease severity or prescribing pattern, etc) need to be further examined.

SPONSORSHIP: This study was supported by OptumRx.

Economic Impact of Above-Label Dosing with Etanercept, Adalimumab, or Ustekinumab in Patients with Moderate-to-Severe Psoriasis

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BACKGROUND: Some psoriasis patients are treated with above-label dosing of biologics, presenting cost implications for patients and payers.

OBJECTIVE: To assess patterns of above-label dosing and associated costs for etanercept (ETA), adalimumab (ADA), and ustekinumab (UST) among patients with moderate to severe psoriasis.

METHODS: Psoriasis patients enrolled in employer-sponsored health plans in the U.S. from January 2007 to March 2012 were identified from the MarketScan Commercial and Encounters database. Patients were required to have ≥1 confirmed diagnosis of psoriasis and ≥2 medication fills for ETA, ADA, or UST, and to have had continuous enrollment and prescription drug benefits for 12 months prior to and 18 months following the first biologic use in the maintenance period. Patients were excluded if they had psoriatic arthritis or other autoimmune diseases indicated for treatment with ETA, ADA, or UST. Extensive above-label use was defined as a dose at least 10% higher than indicated in the label for >6 months over a 12 month period during the maintenance period (on label doses for ETA, ADA and UST are 50 mg once weekly, 40 mg every other week, and 45 mg every 12 weeks for patients <100 kg [220 lb] or 90 mg for patients 100 kg [220 lb], respectively). The percent of patients with extensive above-label use, mean days of above-label use, and additional costs associated with extensive above-label use (above-label cost minus on-label cost) were examined for ETA, ADA, and UST.

RESULTS: This study identified 3,310 psoriasis patients on ETA (1,443), ADA (1,447), and UST (420). Extensive above-label use occurred in 20% of ETA patients (mean above-label use of 282 days), 2.6% of ADA patients (279 days), and 14.8% of UST patients (305 days). About two-thirds of patients with extensive above-label use were male, and the average age was around 50 years. These findings translate into excess daily costs per patient of $69 for ETA, $68 for ADA, and $64 for UST; the corresponding excess annual costs for each patient (mean values adjusted for year 2014) were $19,458, $18,972, and $19,520, respectively. Given the number of patients with above-label use per product, this results in an overall annual excess of $5,623,362 for ETA, $701,964 for ADA, and $1,210,240 for UST, respectively.

CONCLUSIONS: Psoriasis patients treated with ETA, ADA, and UST had extensive above-label use over the 12-month follow-up period, which subsequently leads to higher costs to payers.

SPONSORSHIP: Novartis Pharmaceuticals.

M00-M99 Diseases of the Musculoskeletal System and Connective Tissue (e.g., RA, OA, Osteoporosis, Gout, Dupuytren’s Contracture)

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BACKGROUND: The Swedish Farmacotherapy (SWFOT) trial and several other trials in rheumatoid arthritis (RA) demonstrated that in MTX incomplete responder patients (MTX-IR) clinical effectiveness of adding anti-TNF was only marginally better than stepping up to triple therapy (TT), which involves addition of two low cost oral disease modifying agents hydroxychloroquine and sulfasalazine. Because these therapies may be more effective in different subsets of patients, we asked if an objective multi-biomarker disease activity (MBDA) score can help identify these subsets.

OBJECTIVE: To evaluate whether the MBDA score could be used to predict optimal choice of second-line treatment for patients with inadequate response (IR) to MTX.

M02 The Multi-biomarker Disease Activity Score in Methotrexate Incomplete Responders Predicts Clinical Responses to Non-biological Versus Biological Therapy in Early RA

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BACKGROUND: Oral isotretinoin (OI) is an expensive drug with the specific indication for severe nodular acne unresponsive to conventional therapy. Previous research in 2002[1] demonstrated that prescribing of OI was not in accordance with the labeling. There is a lack of published literature describing current treatment patterns and costs of OI.

OBJECTIVE: To provide a description on current prescription patterns, drug and disease costs attributable to acne patients on OI.

METHODS: This was a retrospective study that used Humana’s claims database, covering over 18 million lives. The study period was from January 1, 2010 to December 31, 2014. Patients were identified if they were 10 to 64 years old, had a diagnosis of acne (ICD-9-CM-706.1) and received a prescription for OI during the study period. Assessed outcomes included total OI drug costs and acne related medical costs. Also examined were prescribing of oral antibiotics or topical retinoids in the 6 months prior to the patient’s first prescription for OI. Second course of OI therapy was queried in patients 10 to 24 years old.

RESULTS: A total of 10,960 patients were prescribed OI and were included for study. 76.8% were between 10 to 24 years old. OI drug costs rose from $4,272,352 in 2010 to $7,435,841 in 2014 and the average OI cost per patient increased from $1,497 to $2,102. Acne related medical costs for these patients were quite consistent averaging $485 per patient during this time frame. The prescribing of oral antibiotics and topical retinoids in the 6 months prior to OI was examined. 29.3% of the patients received a topical retinoid; 55.3% an oral antibiotic; 65.4% received an oral antibiotic or a topical acne product. Of the 2275 patients between the ages of 10 to 24 on OI, 28.1% received a second course.

CONCLUSIONS: OI is indicated for severe nodular acne in patients who are unresponsive to conventional therapy, including systemic antibiotics. The prescribing of conventional acne products prior to OI was similar to Chen’s study. There was an increase in the number of patients prescribed OI over the 5 years. Acne related medical costs were relatively constant at $485 per patient per year. Limitations include: unable to provide indication of oral antibiotic for acne, dosing duration of oral antibiotic and lack of disease severity.

SPONSORSHIP: Galderma Laboratories, Fort Worth, TX.

M03 Oral Isotretinoin Prescribing, Utilization, and Costs in a Managed Care Plan

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BACKGROUND: Oral isotretinoin (OI) is an expensive drug with the specific indication for severe nodular acne unresponsive to conventional therapy. Previous research in 2002[1] demonstrated that prescribing of OI was not in accordance with the labeling. There is a lack of published literature describing current treatment patterns and costs of OI.

OBJECTIVE: To provide a description on current prescription patterns, drug and disease costs attributable to acne patients on OI.

METHODS: This was a retrospective study that used Humana’s claims database, covering over 18 million lives. The study period was from January 1, 2010 to December 31, 2014. Patients were identified if they were 10 to 64 years old, had a diagnosis of acne (ICD-9-CM-706.1) and received a prescription for OI during the study period. Assessed outcomes included total OI drug costs and acne related medical costs. Also examined were prescribing of oral antibiotics or topical retinoids in the 6 months prior to the patient’s first prescription for OI. Second course of OI therapy was queried in patients 10 to 24 years old.

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CONCLUSIONS: OI is indicated for severe nodular acne in patients who are unresponsive to conventional therapy, including systemic antibiotics. The prescribing of conventional acne products prior to OI was similar to Chen’s study. There was an increase in the number of patients prescribed OI over the 5 years. Acne related medical costs were relatively constant at $485 per patient per year. Limitations include: unable to provide indication of oral antibiotic for acne, dosing duration of oral antibiotic and lack of disease severity.

SPONSORSHIP: Galderma Laboratories, Fort Worth, TX.

M04 The Multi-biomarker Disease Activity Score in Methotrexate Incomplete Responders Predicts Clinical Responses to Non-biological Versus Biological Therapy in Early RA

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BACKGROUND: The Swedish Farmacotherapy (SWFOT) trial and several other trials in rheumatoid arthritis (RA) demonstrated that in MTX incomplete responder patients (MTX-IR) clinical effectiveness of adding anti-TNF was only marginally better than stepping up to triple therapy (TT), which involves addition of two low cost oral disease modifying agents hydroxychloroquine and sulfasalazine. Because these therapies may be more effective in different subsets of patients, we asked if an objective multi-biomarker disease activity (MBDA) score can help identify these subsets.

OBJECTIVE: To evaluate whether the MBDA score could be used to predict optimal choice of second-line treatment for patients with inadequate response (IR) to MTX.
M05 Gout-Related Ambulatory Care Utilization and Patient Characteristics Predictive of Resource Use

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BACKGROUND: Gout is associated with high morbidity, and it imposes a substantial burden on the healthcare system.

OBJECTIVE: To describe ambulatory care use by U.S. patients with gouty arthritis (gout) using a nationally representative sample.

METHODS: Data from the 2009-2010 U.S. National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey were used to examine the ambulatory care burden for gout, characteristics of gout patients, associated types of providers, and prescribing pattern of urate-lowering therapies (ULT). A multistage probability design used geographic samples of primary sampling units (PSU), physician practices within PSU, and patient visits within practices. The first sampling stage included PSU representing U.S. geographic locations; the second stage used a probability sample of practicing physicians selected from master files of the American Medical Association and the American Osteopathic Association. Weighted analyses estimated the effects of age, sex, and comorbidities on association with gout and prescription of ULT.

RESULTS: Of the 1.24 billion annual U.S. ambulatory care visits, >13 million were associated with gout (>300% increase from 2002). Almost all (90%) gout-related visits occurred in freestanding ambulatory clinics, 10% occurred in a hospital clinic or emergency department. The majority of visits were by men, average age for men was lower than that for women (64 vs. 71 years). Among gout visits occurring at freestanding clinics, 55% were managed by primary care providers (PCPs) and 45% by specialists. Each year there were >9.25 million prescriptions for a ULT, 2.6 million for colchicine, 1.9 million for NSAIDs, and 425,000 for prednisone. In a multivariate model, positive/negative predictors of gout visits (odds ratio; 95% CI) included older age (0.95; 0.95-0.96), female sex (0.31; 0.25-0.39), private insurance (0.16; 0.13-0.20), chronic renal failure (4.40; 1.54-12.59), congestive heart failure (2.57; 1.20-5.51), asthma (0.13; 0.06-0.27), and depression (0.22; 0.12-0.40). Among those with gout, female sex (2.38; 1.22-4.62), chronic renal failure (4.38; 1.11-17.25), osteoporosis (6.77; 1.02-44.86), and arthritis (0.35; 0.16-0.77) were predictors of ULT use.

CONCLUSIONS: These findings support the increasing prevalence of gout. Raising awareness of the growing disease burden of gout and providing tailored education to both PCPs and specialists is crucial.
which should include information regarding comorbidities and predictors of treatment with ULT.

**SPONSORSHIP:** This study was sponsored by AstraZeneca.

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**M08 Real-World Experience with Tofacitinib Versus Certolizumab Pegol for the Treatment of Rheumatoid Arthritis in Biologic-Naïve Patients and After First Biologic Experience**

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**BACKGROUND:** Tofacitinib is an oral JAK inhibitor for the treatment of rheumatoid arthritis (RA). Limited data are available comparing tofacitinib with TNFi in biologic-naïve (BN) and biologic-experienced (BE) patients (pts) with RA.

**OBJECTIVE:** To compare pt characteristics, treatment patterns and healthcare costs in BN and BE pts receiving tofacitinib vs. the TNFi certolizumab pegol (CZP) in a U.S. claims database.

**METHODS:** This was a retrospective cohort analysis of healthcare claims in pts aged ≥ 18 years at index (date of first tofacitinib/biologic DMARD [bDMARD] use) with a RA diagnosis (ICD-9: 714.0x-714.4x; 714.81) receiving tofacitinib (identified first) or bDMARD in Truven Health MarketScan Research databases (November 2012-September 2014). Pts were continuously enrolled for ≥ 12 months pre-/post-index and had 1 (due to greater imbalance in number of tofacitinib and CZP pts with ≥ 2 bDMARDS) or no bDMARDS at any time pre-index. Monotherapy was defined as absence of conventional synthetic DMARDs within 90 days post-index. Treatment persistence (index medication refills without a 60-day gap after prior prescription days’ supply had run out), and adherence (proportion of days covered [PDC]), were evaluated. Twelve-month RA-related plan-/pt-paid costs were assessed based on DMARD use and RA-related visits pre-/post-index.

**RESULTS:** 340 BN (tofacitinib: n = 210; CZP: n = 130) and 449 BE (tofacitinib: n = 392; CZP: n = 57) pts met selection criteria. One CZP pt was excluded from cost analyses due to outlying data. More BE CZP pts (93.0%) had prior TNFi use vs. tofacitinib pts (73.0%) (P = 0.001). BN tofacitinib pts had higher mean pre-index RA-related total, pharmacy, and medical costs vs. CZP pts (all P < 0.05). A greater proportion of BN (P = 0.0019) and BE tofacitinib pts used monotherapy at index vs. CZP pts. A similar proportion of tofacitinib and CZP pts were persistent over 12 months in BN (39.5% vs. 36.2%) and BE (42.9% vs. 42.1%) cohorts. For pts receiving tofacitinib and CZP, respectively, 12-month post-index mean (SD) PDC was similar in BN (0.54 [0.30] vs. 0.53 [0.30]) and BE (0.56 [0.30] vs. 0.56 [0.31]) cohorts. The difference in 12-month post-index total RA-related costs was higher for CZP pts vs. tofacitinib pts in BN ($5,172; P = 0.0046) and BE ($4,533; P = 0.0182) cohorts.

**CONCLUSIONS:** In a U.S. claims database, a greater proportion of BN and BE pts starting tofacitinib vs. CZP used monotherapy with comparable persistence and adherence, and lower RA-related total costs, despite higher pre-index costs in BN pts. Further evaluation is warranted given the limited sample size in BE pts.

**SPONSORSHIP:** Pfizer.

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**M09 An Economic Evaluation of Tofacitinib (Xeljanz) Treatment After One or Two TNF Inhibitors in Rheumatoid Arthritis from the United States Perspective**

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**BACKGROUND:** Tofacitinib (TOFA) is an oral Janus kinase inhibitor for the treatment of rheumatoid arthritis (RA). Treatment cycling with biologic DMARDs, such as TNF inhibitors (TNFi), is common and results in reduced clinical efficacy.

**OBJECTIVE:** To evaluate and compare the economic impact of TOFA 5 mg BID treatment after one TNFi (adalimumab [ADA] or etanercept [ETN]) or two TNFi (ADA and ETN) in patients (pts) with moderate to severe RA who failed first-line methotrexate therapy, from the U.S. perspective.

**METHODS:** A decision-tree economic model was used to evaluate costs over 2 years (yrs). Treatment response was modeled as American College of Rheumatology (ACR) 20/50/70 response. ACR response rates at 6 month intervals were derived from U.S. prescribing information. Safety event rates were sourced from a meta-analysis. It was assumed that 75% of pts switched therapy after an adverse event (AE)/lack of response. Costs inputs included drug monitoring, drug administration, and treatment for minor/serious AEs. The population comprised all organization members (ie RA and non RA); RA pts receiving TNFi were estimated using epidemiologic data. Results were based on an organization size of 1 million. Economic endpoints were total costs, costs per member per month (PMPM), and costs per ACR20 responder.

**RESULTS:** 1,321 pts were treated and included in the analysis. Based on ACR20 switch criteria and 100% monotherapy rate for all treatments, total 2-yr costs were lower for TOFA after one TNFi (ADA→TOFA: $129,240,497; ETN→TOFA: $130,214,370) vs. two TNFi (ADA→ETN→TOFA: $133,731,160; ETN→ADA→TOFA: $136,665,292). Costs PMPM were lower for TOFA after one TNFi (ADA→TOFA: $5.39; ETN→TOFA: $5.43) vs. two TNFi (ADA→ETN→TOFA: $5.57; ETN→ADA→TOFA: $5.57). Costs per ACR20 responder were lowest for pts who received ETN→TOFA ($126,817) and highest for pts who received ADA→ETN→TOFA ($142,967). When monotherapy was adjusted to 50% for all treatments, similar trends were seen for 2-yr total costs (ADA→TOFA: $131,147,659; ETN→TOFA: $133,189,708; ETN→ADA→TOFA: $134,836,207), costs PMPM (ADA→TOFA: $5.46; ETN→TOFA: $5.49; ADA→ETN→TOFA: $5.63; ETN→ADA→TOFA: $5.62) and cost per ACR20 responder (ADA→TOFA: $132,966; ETN→TOFA: $123,735; ADA→ETN→TOFA: $137,077; ETN→ADA→TOFA: $127,002). Differences were noted even with rebates of up to 20% for ADA and ETN and 0% for TOFA. Similar trends were seen when ACR50 switch criteria were used.

**CONCLUSIONS:** A treatment strategy with TOFA after one TNFi is predicted to be a lower cost treatment option vs. TOFA following two TNFis.

**SPONSORSHIP:** Pfizer.

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**M11 Healthcare Resource Utilization and Costs Between Psoriatic Arthritis Patients with Moderate-to-Severe Psoriasis and Those with Minimal Skin Psoriasis in the U.S.**

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**BACKGROUND:** Psoriatic arthritis (PsA) is a chronic inflammatory disease that often exists with psoriasis (PsO). The severity of PsO among PsA patients varies, which may affect the economic burden in this population.

**OBJECTIVE:** To compare healthcare resource utilization (HRU) and costs between PsA patients with moderate-to-severe (mod-sev) PsO and those with minimal skin PsO.

**RESULTS:** Costs between PsA patients with moderate-to-severe (mod-sev) PsO and those with minimal skin PsO were total costs, costs per member per month (PMPM), and costs per ACR20 responder.
METHODS: Adults (18-64 years) with ≥ 2 claims for PsA (ICD-9-CM: 714.0) ≥ 30 days apart were selected from the MarketScan claims database (data period: 07/2009-06/2014). The index date was a randomly selected date after the first PsA claim. All patients were required to have ≥ 12-month continuous eligibility before (baseline period) and after (study period) the index date. Patients in the PsA+mod-sev PsO group were required to have ≥ 2 claims for PsO (ICD-9-CM: 714.0) that were ≥ 30 days apart, and ≤ 1 PsO claim and ≥ 1 systemic therapy/phototherapy in the data period. PsA patients were classified into the PsA+ minimal skin PsO group if they did not have any PsO claim or phototherapy in the data period, or had ≥ 1 PsO claim but no evidence of systemic therapy/phototherapy in the data period. HRU and costs were measured during the study period and compared between the two cohorts using Wilcoxon rank sum tests for continuous variables and Chi-square tests for categorical variables. All-cause total healthcare, drug and medical costs were compared using generalized linear models with robust variance estimates. The models controlled for demographics, insurance type, and individual non-PsA-associated comorbidities. Bonferroni correction was used to adjust for multiple comparisons.

RESULTS: A total of 10,495 patients with PsA+mod-sev PsO and 13,503 patients with PsA+minimal skin PsO were included in this study with comparable age and sex. Patients with PsA+mod-sev PsO had higher rates of chronic pulmonary disease and liver disease (excluding fatty liver). In addition, these patients had a significantly higher rate for emergency room [ER] visit (22.4% vs. 20.7%) and more frequent ER visits (mean: 0.38 vs. 0.36); almost all patients had ≥ 1 outpatient [OP] visit (100.0% vs. 98.8%) but those with PsA+mod-sev PsO had more frequent OP visits (mean: 20.99 vs. 17.37) (all P < 0.01). Patients with PsA+mod-sev PsO also incurred significantly higher total healthcare costs and drug cost (adjusted mean annual incremental cost: $10,925 and $10,398, respectively; P < 0.0001). CONCLUSIONS: PsA patients with mod-sev PsO incurred significantly higher HRU and costs than those with minimal skin PsO, highlighting the differential HRU and costs by PsO severity among PsA patients.

SPONSORSHIP: Novartis Pharmaceuticals.

M13 Increased Out-of-Pocket Costs and Limited Access to Specialists Are Associated with Lower Quality of Care for Patients with Rheumatoid Arthritis

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BACKGROUND: Rheumatoid arthritis (RA), an inflammatory disorder of the joints, affects 1.5 million Americans. Measures have been developed to monitor the quality of RA care offered by physicians. For example, Medicare’s Physician Quality Reporting System measures the share of patients with RA who use disease-modifying antirheumatic drugs (DMARDs). However, it is unclear how regional variation in patient cost sharing and access to specialists relates to the quality of RA care.

OBJECTIVE: To assess how geographic differences in patient out-of-pocket (OOP) costs and access to rheumatologists are associated with DMARD use among patients with RA.

METHODS: We used a large commercial claims database (2008-2014) to measure variation in patient DMARD use across metropolitan statistical areas (MSAs). Patients with RA were required to be U.S. residents aged ≥ 18 years. For each RA patient, we identified whether or not they visited a rheumatologist, as well as health care costs borne by payers and patients over a 12-month period. We fit a logistic regression model for the primary quality outcome—DMARD use—accounting for regional differences in patient age, gender and health status. A linear regression model was used to measure the relationship between average OOP costs and average DMARD use across MSAs. Using a t-test, we tested for differences in DMARD use across MSAs based on whether or not the patient had visited a rheumatologist.

RESULTS: Across 409 MSAs, 501,376 patients met the inclusion criteria. In the average MSA, 64.5% (SD: 10.4%, IQR: 59-72%) of RA patients used a DMARD, and 57.4% (SD: 16.4%, IQR: 47.0%-69.4%) visited a rheumatologist during the year. Annual per capita health care costs in the average MSA were $22,576 (SD: $4,326, IQR: $19,494-$22,355), of which pharmacy costs made up $5,776 (SD: $1,599, IQR: $4,833-$6,760). Patient OOP payments made up 9.5% (SD: 2.5%, IQR: 7.9%-10.8%) of all outpatient prescription drug expenses. In the average MSA, patients who visited a rheumatologist were more likely to receive a DMARD than those who did not (71.6% vs. 53.4%, P < 0.001). MSAs ranked in the 10th percentile of patient OOP cost had 6.6% (P < 0.01) less DMARD use than MSAs ranked in the 90th percentile.

SPONSORSHIP: This study was funded by UCB Pharma.
CONCLUSIONS: Patients living in MSAs with higher out-of-pocket costs and limited access to rheumatologists were more likely to experience lower quality of care as measured by DMARD use. Payers should consider whether alternative cost sharing structures—such as value-based insurance design—could improve quality without increasing costs or patient burden.

SPONSORSHIP: This study was funded by AbbVie.

M17 Real-World Treatment Patterns and Demographic, Clinical, and Economic Characteristics of Systemic Lupus Erythematosus (SLE) Patients Initiating Repository Corticotropin Injection Therapy

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BACKGROUND: Repository corticotropin injection (RCI; H.P. Acthar Gel) is FDA-approved to treat an exacerbation or as maintenance therapy in SLE.

OBJECTIVE: To describe profile of SLE patients initiating RCI.

METHODS: Patients aged ≥ 18 years with ≥ 2 diagnoses for SLE between 7/1/2006 and 4/30/2015 were identified from a nationally representative HealthCore Integrated Research Database. RCI patients were indexed on the 1st RCI, while others were indexed on the initiation of oral corticosteroid (prednisone-equivalent dose ≥ 20 mg/day for ≥ 2 months), cyclophosphamide, azathioprine or belimumab, or the 1st SLE-related inpatient admission after SLE diagnosis. Pre-index period was the continuously enrolled period between the SLE diagnosis and the index date. Baseline characteristics, actual real-world treatment patterns, and per patient per month (PPPM) costs, to account for variable length of follow-up) healthcare costs (allowed paid amount) were assessed using descriptive statistics.

RESULTS: Among 9,944 eligible SLE patients (mean age 53, 85% female and Deyo-Charlson Comorbidity Index [DCI] score 2.0 at index), 29 (0.3%) patients initiated RCI. RCI patients on average were 45 (SD, 12.9) years old and 90% were female. Most RCI patients were enrolled in a PPO (66%) and had a higher mean DCI score (2.6). Mean length of follow-up for RCI patients was 23 (SD, 22) and 24 (SD, 21) months for the pre- and post-index periods, respectively, during which RCI was filled 3.7 times (SD, 5.4) on average. Most commonly used medications during the pre-index period were corticosteroids (83%), anti-malarial drugs (59%), immunosuppressants (52%), and biologics (31%) whereas post-index were corticosteroids (83%), anti-malarial drugs (38%), NSAIDs (38%), and immunosuppressants (33%). RCI patients had less PPPM inpatient (0.075 vs. 0.061) and emergency department (ED) visits post-index as compared to the pre-index period, which resulted in lower PPPM medical costs ($5,869 vs. $3,742) (inpatient $3,192 vs. $799), ED ($163 vs. $841). However, overall post-index costs PPPM were higher ($6,774 vs. $11,167) largely due to pharmacy costs ($905 vs. $7,443).

CONCLUSIONS: RCI was initiated in a small portion of patients who tended to be younger and sicker than the comparable SLE population. Healthcare use (inpatient/ ED visits) and associated costs were lower following initiation of RCI, indicating potentially better disease control. These reductions in medical costs may partially offset the costs of the medication. Future research exploring impact of RCI on long-term outcomes is needed.

SPONSORSHIP: This study was funded by Mallinckrodt Pharmaceuticals.

M18 Clinical Characteristics and Disease Activity in Psoriatic Arthritis Patients with Dactylitis or Enthesitis in a Real-World Setting: Results from Corrona Registry

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BACKGROUND: Enthesitis, inflammation at the insertion sites of tendons and ligaments, and dactylitis, the diffuse swelling of digits, are important extra-articular manifestations of psoriatic arthritis (PsA) and are present in many patients.

OBJECTIVE: To characterize the demographic and clinical characteristics of PsA patients with dactylitis or enthesitis and evaluate the association with outcomes such as minimal disease activity (MDA) and functional status (Health Assessment Questionnaire [HAQ]) in a large national observational cohort of PsA and spondyloarthritis patients (Corrona).

METHODS: PsA patients ≥ 18 years enrolled in the Corrona registry were included in the study and baseline characteristics (disease activity and functionality measures) at registry enrollment assessed. Regression models adjusting for age, gender, race, BMI, disease duration, history of biologic use, conventional synthetic DMARD use, and prednisone use evaluated the associations of enthesitis and dactylitis status with MDA and HAQ (0-3).

RESULTS: 1,567 PsA patients were included in the analysis; 228 (14.6%) had dactylitis and 420 (26.8%) had enthesitis at enrollment. Adjusted multivariable analysis showed patients with dactylitis were more likely to not be in MDA vs. patients with no dactylitis and patients with enthesitis were more likely to have elevated disease activity, less likely to be in MDA, and more likely to have reduced functional status (as assessed by the HAQ) vs. patients with no enthesitis. Adjusted models showed a mean difference of 0.08 (95% CI = -0.02, 0.17) in HAQ in patients with dactylitis vs. patients with no dactylitis (reflecting poorer functional status), although this was not statistically significant. A significant difference of 0.16 (95% CI = 0.09, 0.24; P < 0.05) in HAQ was seen in patients with enthesitis vs. those who did not have enthesitis.

CONCLUSIONS: PsA patients with enthesitis or dactylitis are more likely to have elevated disease activity, less likely to be in MDA, and more likely to have reduced functional status (as assessed by the HAQ) than patients without these manifestations.

SPONSORSHIP: The design, study conduct, and financial support for this analysis were provided by Novartis Pharmaceuticals.

M19 Identifying Psoriatic Arthritis and Ankylosing Spondylitis Patients Responsible for the Highest Costs of Care in the Real World: Data from a Large U.S. Cohort

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Novartis Pharmaceuticals

BACKGROUND: Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are spondyloarthritidic conditions that can have an economic burden on patients.

OBJECTIVE: To investigate demographic and clinical characteristics, healthcare utilization patterns, biologic usage, and associated costs among patients with PsA or AS who had the highest costs vs. the general population.
METHODS: MarketScan Commercial and Medicare Supplemental Databases were used to stratify PsA and AS patients into 2 groups based on overall costs: ≥90% quantile (top 10% cost group) and <90% quantile (bottom 90%). Patients were aged ≥ 18 years with ≥ 2 diagnostic claims for PsA from October 1, 2011 to September 30, 2012 (first diagnosis = index date) and were continuously enrolled with medical and pharmacy benefits for 12 months before and after the index date. Baseline demographics, comorbidities, Eliahuexar comorbidity score (ECS), medical (hospitalizations, emergency room/office visits) and pharmacy costs were reported. The Wilcoxon rank-sum test was used for continuous variables, the chi-square test for categorical variables.

RESULTS: The study included 10,832 PsA patients and 4,288 AS patients. The PsA top 10% (N = 1,083) group was older (mean age 54.7 ± 10.8 y vs. 51.6 ± 11.9 y; P < 0.01) and had higher ECS scores (2.0 vs. 1.1; P < 0.01) vs. the bottom 90% group (N = 9,740) respectively. The high-cost group also had a higher rate of biologic use (83.4% vs. 58.7%; P < 0.01) vs. the bottom 90% cost group, respectively. In addition, mean all-cause medical costs were ~13 times higher ($30,591 ± $51,862 vs. $2,277 ± $4,138 respectively). Similarly, the AS top 10% cost group (n = 428) was older (mean age 54.7 ± 10.8 y vs. 48.7 ± 13.4 y; P < 0.01) and had higher ECS scores (2.0 ± 2.3 vs. 1.8 ± 1.5; P < 0.01) vs. the bottom 90% group (n = 3,860), respectively. They also had significantly higher biologic use (70.4% vs. 50.5%; P < 0.01) and oral disease-modifying agent (26.6% vs. 21.3%; P < 0.01) vs. the bottom 90% AS cost group, respectively. Mean all-cause medical costs for the AS top 10% group were 17 times higher vs. the bottom 90% group ($42,703 ± $78,942 vs. $2,491 ± $4,561, respectively); mean biologic costs were 2 times higher ($18,261 ± $16,048 vs. $10,373 ± $13,552, respectively).

CONCLUSIONS: Medical costs marked the largest difference between the high and lower cost groups of PsA and AS patients. This study highlights a high-cost subgroup of older patients with increased comorbidities that may require more individual medical and biologic treatment management.

SPONSORSHIP: Novartis Pharmaceuticals.

M20 Real-World Clinical Characteristics and Disease Outcomes in Psoriatic Arthritis Patients by Extent of Body Surface Area Affected by Psoriasis: Results from Corrona Registry

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BACKGROUND: Psoriatic Arthritis (PsA) is a chronic immune related condition affecting the joints. Well-established patient physician relationships are instrumental to obtaining the best patient outcomes.

OBJECTIVE: To assess the extent of misalignment in satisfaction with current PsA treatment between physicians and their PsA patients and compare demographic/clinical characteristics and drug treatment of aligned and misaligned cases.

METHODS: We analyzed the Adelphi 2011 and 2014 surveys of USA rheumatologists (Docs) and their PsA patients (Pats). Docs provided patient demographics, clinical details, comorbidities and satisfaction with PsA treatment. Pats reported satisfaction, completed the Work Productivity Activity Impairment (WPAI) and alternative HAQ-DI (excluding: pain and devices) questionnaires. Two cohorts were compared: aligned (doc and pat both satisfied with PsA treatment, or both dissatisfied), and misaligned (doc and pat reported satisfaction was different).

RESULTS: From 305 paired doc and pat records, 233 (76.4%) were ‘aligned’, and 72 (23.6%) ‘misaligned’. Both cohorts were similar in age (mean 50.0, 49.8) and sex (% female: 44.6, 45.8). Aligned cases had longer time since diagnosis (mean years: 6.4, 5.2) and more were receiving a biologic DMARD (% receiving: 62.9, 49.3). Misaligned cases were more symptomatic, with higher TJC (mean 5.6 vs. 2.9), SJC (mean: 3.7, 1.9), higher BSA >3% BSA affected: 64.2% vs. 55.1%), more PsA symptoms (mean: 6.8, 4.9). The most common comorbidities were hypertension (28.9%), elevated cholesterol (20.0%), depression (14.1%), and obesity (13.8%). A greater proportion of misaligned group had depression (20.8% vs. 12.0%) and anxiety (15.3% vs. 9.4%). WPAI results showed misaligned group were more impaired in overall work (mean: 38.7%, 21.4%), while at work (mean: 36.2%, 16.5%)

M21 Misalignment Between Physician and Patient Satisfaction with Current Psoriatic Arthritis Treatment

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BACKGROUND: Psoriatic Arthritis (PsA) is a chronic immune related condition affecting the joints. Well-established patient physician relationships are instrumental to obtaining the best patient outcomes.

OBJECTIVE: To assess the extent of misalignment in satisfaction with current PsA treatment between physicians and their PsA patients and compare demographic/clinical characteristics and drug treatment of aligned and misaligned cases.

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in daily activities (mean: 38.7%, 22.3%). Additionally disability was higher (mean alternative HAQ-DI score: 0.563, 0.369).

CONCLUSIONS: Missalignment between rheumatologists and their PsA patients in satisfaction with PsA treatment exists in almost a quarter of cases. In cases of misalignment, disease severity and patient reported outcomes were worse. The findings suggest greater alignment may result in improved outcomes; although further research is required to verify this hypothesis.

SPONSORSHIP: Novartis Pharmaceuticals.

M22 Satisfaction in Psoriatic Arthritis Patients Despite Active Joint Disease

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BACKGROUND: Psoriatic Arthritis (PsA) is a chronic immune-mediated condition affecting the joints, often with concomitant psoriasis. Across a number of immunological conditions high patient satisfaction is reported, despite patients having active disease.

OBJECTIVE: To compare the characteristics of PsA patients with active joint disease who are satisfied with their current treatment against those who are unsatisfied.

METHODS: We analyzed the Adelphi 2011/2014 PsA Disease Specific Programmes, surveys of USA rheumatologists and their PsA patients. Physicians provided patient demographics, disease characteristics and comorbidities. Patients reported their satisfaction with PsA control, and completed the Work Productivity Activity Impairment (WPAI) and alternative HAQ-DI (excluding aids and devices) questionnaires.

RESULTS: From 78 PsA patients with active joint disease, 54 (69.2%) were satisfied with their treatment and the remaining 24 (30.8%) disagreed.

CONCLUSIONS: The Medicaid pharmacy program covers most drugs available in the United States (U.S.). In spite of the importance of the program, information about the use of osteoporosis drugs in the Medicaid population is very limited.

OBJECTIVE: To describe secular trends in utilization, expenditures and market share of osteoporosis drugs in the Medicaid fee-for-service program in the period 1995-2014, to assess the impact of generic entry on the U.S. market of osteoporosis drugs; and to evaluate the impact of the implementation of Medicare Part D on the utilization of osteoporosis drugs in the Medicaid program.

METHODS: The Medicaid program national drug utilization and pharmacy reimbursement of osteoporosis drugs data were obtained from the Centers for Medicare and Medicaid Services. Descriptive analyses were performed for pharmacy reimbursement, utilization, and average reimbursement per 30 defined daily doses (DDDs).

RESULTS: The osteoporosis drug utilization increased from 30,000 DDDs in 1995 to 7.9 million DDDs in 2005. Following the implementation of Medicare Part D, osteoporosis drug utilization in Medicaid declined to 2.1 million DDDs in 2006. Generic market share ranged from 30.3% to 56.8% the first year after generic entry, 51.3% to 67.0% two years later, and 61.6% to 96.4% five years after generic alternatives entered the U.S. market.

CONCLUSIONS: The generic market share of osteoporosis drugs was relatively low in comparison with other insurance programs. Medicare Part D resulted in a reduction in the number of postmenopausal women using the Medicaid program and an important reduction in the utilization of osteoporosis drugs in the Medicaid program.

SPONSORSHIP: This study has no funding to declare.

M23 Medicaid Osteoporosis Drugs Utilization and Expenditures: The Effect of Generic Drugs Market Entry

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BACKGROUND: Despite Active Joint Disease

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OBJECTIVE: To examine demographic differences in 4 measures of oral BP exposure: discontinuation rate, adherence, persistence and non-persistence during the first 3 years following BP initiation.

METHODS: Among women aged ≥ 50 years initiating oral BP therapy during 2002-2007 with ≥3 years follow-up, adherence was calculated using the proportion of days covered, allowing stockpiling of drug for prescriptions/refills overlapping ≤ 30 days (d) supply. Persistence was quantified by BP treatment duration allowing a maximum gap of 30d or 60d between prescription/refills; non-persistence was quantified by the summative periods without BP outside the allowable gap. Measures were compared by age and race groups.

RESULTS: Among 48,390 women initiating oral BP, 26.7% discontinued during Year (Yr) 1 of follow-up, including 12.5% with only 1 filled prescription. For the 35,456 who received BP beyond Yr 1, only 14.7% discontinued during Yr 2. Discontinuation rates were significantly higher for women age ≥80 years (vs. 65-79 and 50-64 years) and lower for Asians vs. non-Hispanic (NH) whites. Of the 42,363 women with ≥2 BP prescriptions, the median adherence was 0.86 (interquartile range, IQR 0.47-0.98), with 56.2% achieving an adherence ≥ 80% in Year 1. For those treated in Yr 2 and Yr 3 of follow-up, the median adherence was 0.84 (IQR 0.46-0.97) and 0.85 (IQR 0.52-0.97), respectively. Adherence was slightly greater for Asians vs. NH whites.
During the 3 years of observation, the median BP treatment duration (sum of periods of persistence) was 2.16 (IQR 0.93-2.90) years with a maximum gap ≤30d between prescription/refills and 2.29 (IQR 0.96-3.00) years with a maximum gap ≤60d; 18,174 (42.9%) women had at least 1 period of non-persistence beyond the 60d allowable gap, with a median cumulative non-persistence period of 0.65 (IQR 0.30-1.25) years during follow-up.

CONCLUSIONS: Adherence was relatively stable for women treated beyond Yr 1, with persistence dependent on the allowable gap between prescriptions. Over 60% of women had evidence of BP therapy during Year 3 of follow up. Asian race was associated with lower discontinuation, better adherence and longer persistence. Discontinuation also varied by age. These findings suggest that subgroups of BP users may require different levels of support and monitoring to maximize the benefit of osteoporosis therapy.

SPONSORSHIP: National Institutes of Health (Grant #1R01AG047230) and Kaiser Permanente Northern California Community Benefit.

OPIOD ABUSE AND RISK MODEL IN MEDICARE BENEFICIARIES

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BACKGROUND: Opioid misuse and abuse are important and costly problems in the U.S.

OBJECTIVE: To determine prevalence and direct cost of patients at risk for opioid abuse (“at-risk abuse”) and accuracy of a model to predict the likelihood of subsequently being diagnosed with opioid abuse.

METHODS: Retrospective case-control study of Medicare claims data, including medical, pharmacy and enrollment information from 2010 to 2011. Subjects were Medicare beneficiaries ≥18 years of age, with an index date between 7/1/2010 and 6/30/2011, and ≥6 months continuous eligibility before and after index date identified as at-risk abuse (based on previously published risk factors including number of opioid prescriptions or diagnosis of other abuse, mental illness, or hepatitis) and matched controls (age, gender, disability, region). Prevalence and cost were based on 2010-2011. Costs were modeled using univariate generalized linear regression with gamma distribution and log link. The utility of a previously developed model for predicting opioid abuse was tested in the at-risk patients.

RESULTS: Total Medicare population was 53,765,609 and those without HMO coverage (population of interest) was 15,526,034. The prevalence of at-risk abuse was 17.4/1,000, and 33.0% were eligible based on disability. Total annual mean unadjusted costs (SD) were significantly higher for at-risk abusers ($36,224.00 [91,735.30]) than matched controls ($21,685.20 [74,003.83]); a difference of $14,538.80 (P<0.0001). Mean costs for at-risk abusers were higher than controls in all cost categories (inpatient, outpatient, ED visits, and drug costs). There was a strong predictive accuracy of the risk model; c-statistic = 0.874. Most variables in the model were predictive except ≥6 opioid classes consumed. Variables that were significant and the odds ratio (OR) was at least 1.5 included: 1-5 opioid classes consumed, mental illness, hepatitis, other substance abuse, ≥3 hospitalizations, ≥3 emergency department visits, and ≥1 outpatient visits. Overall, there was a significant interaction between age and gender. Males ≥65 years of age were less likely to develop abuse than females <65 years of age.

CONCLUSIONS: In 2010-2011, the prevalence of at-risk abuse was 117.4/1,000 persons and annual medical costs were significantly higher for at-risk abusers than controls. A model for predicting the likelihood of being diagnosed with abuse had strong predictive accuracy. Using claims data to identify those at-risk for abuse may be useful in mitigating opioid abuse and reducing associated costs in the Medicare population.

SPONSORSHIP: Pfizer.

N100-N99 Diseases of the Genitourinary System (e.g., ESRD)

N01 Contemporary Anemia Management in U.S. Hemodialysis Patients

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DaVita Clinical Research

BACKGROUND: Anemia is common in end-stage renal disease (ESRD) patients and the majority of ESRD patients on dialysis receive erythropoiesis-stimulating agents (ESA) and/or intravenous (IV) iron therapy. In 2011, following changes to Medicare reimbursement for dialysis services and concerns about the safety of using ESAs to target hemoglobin levels greater than 11 g/dl, there was a rapid decline in ESA utilization and a corresponding decrease in mean hemoglobin levels in this patient population.

OBJECTIVE: To assess contemporary anemia management practices among hemodialysis (HD) patients with respect to medication utilization and relevant laboratory measurements.

METHODS: We performed a retrospective, observational study of adult (≥18 years) patients receiving thrice weekly in-center HD at facilities of a large dialysis organization (LDO) during the period June 1, 2014 to May 31, 2015 (N = 148,690). All study data were derived from LDO electronic health records. Outcomes assessed were monthly use and dose of intravenous (IV) iron and ESA, as well as quarterly hemoglobin and serum ferritin concentrations.

RESULTS: The proportion of patients receiving IV iron in each month of the study period ranged from 68.6% to 71.7% (overall mean: 70.3%); ESA use ranged from 85.1% to 87.2% (overall mean: 86.5%). The mean cumulative monthly dose of IV iron among users ranged from 209 to 256 mg/month with an overall mean of 228 mg (median: 200 mg). ESA dose among users ranged from 3,704 to 4,062 U/treatment with an overall mean of 3,913 U/treatment (overall median: 2,384 U/treatment). No temporal trends in IV iron or ESA utilization were detected during this period. Mean quarterly hemoglobin and serum ferritin values over the study period were 10.8 g/dl (range 10.76-10.86 g/dL) and 742 ng/mL (range: 727-755 mg/mL), again, no temporal trends were observed.

CONCLUSIONS: Anemia management practices among HD patients appear to have stabilized, hemoglobin concentrations, serum ferritin levels, and utilization of anemia medications remained constant over the period June 2014 to May 2015 and were comparable to values reported at the end of 2012.

SPONSORSHIP: This study was supported by Keryx Biopharmaceuticals.
BACKGROUND: Older patients are at risk for hyperkalemia due to decreased aldosterone production, comorbid diseases, and K+-altering medications. Patronier is a nonabsorbed potassium binder that exchanges Ca²⁺ for K⁺ rather than Na⁺ that has been approved by the U.S. Food and Drug Administration.

OBJECTIVE: To evaluate the effects of patronier in a prespecified subgroup of patients ≥65 years old with chronic kidney disease and hyperkalemia on renin-angiotensin-aldosterone system inhibitors from the 2-part, single-blind, phase 3 patronier trial (OPAL-HK).

METHODS: Patients (n = 243) with baseline serum K⁺ (s-K⁺) levels ranging from 5.1 to <6.5 mEq/L received patronier (8.4 g daily dose for mild hyperkalemia, 16.8 g daily dose for moderate-to-severe hyperkalemia) in a 4-week treatment phase (part A). Subsequently, patients with central lab baseline s-K⁺ levels ranging from 5.5 (≤ ≤6.5 mEq/L (n = 107) were randomized to continue patronier or switch to placebo in an 8-week withdrawal phase (part B). Primary endpoints were change in s-K⁺ from baseline to week 4 in part A and between-group (patiromer vs. placebo) difference in change in s-K⁺ from part B baseline to part B week 4.

RESULTS: A total of 131 (54%) patients were ≥65 years old at baseline. Consistent with the overall patient population (-1.01 [0.03] mEq/L, P < 0.001), the mean (standard error) s-K⁺ for patients ≥65 years old decreased significantly from baseline at week 4 (-1.01 [0.03] mEq/L, P < 0.001). For the overall group and patients ≥65 years old, 76% and 73%, respectively, had s-K⁺ >3.8 to ≤5.1 mEq/L (secondary endpoint) at part A week 4. Compared with patronier, more placebo patients, both ≥65 years old and in the overall patient population (P < 0.001), developed recurrent hyperkalemia in part B. The between-group difference in median (95% confidence interval) change in s-K⁺ in patients ≥65 years old from baseline to week 4 of part B was 0.81 (0.49, 1.14; P < 0.001) and was 0.72 (0.46, 0.99, P < 0.001) in the overall patient population. Patronier was generally well tolerated, in all patients, mild-to-moderate constipation was the most common adverse event in part A (11%) and occurred in a numerically higher proportion of patients ≥65 years old (14.5%) compared with those <65 years old (6.3%).

CONCLUSIONS: Patronier significantly reduced s-K⁺ in patients ≥65 years and, when compared with placebo, maintained control of s-K⁺.

SPONSORSHIP: Funding for this study was provided by Relypsa.

N04 Chronic Diuretic Therapy Does Not Impair the Effectiveness of Patiromer in Hyperkalemic Patients with CKD

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BACKGROUND: Diuretics are frequently used to lower blood pressure, prevent or control volume overload, and reduce peripheral edema in advanced chronic kidney disease (CKD). Loop or thiazide diuretics, alone or in combination, can also be used to lower serum potassium (s-K⁺) in hyperkalemic patients but can induce intravascular volume depletion, hypotension, syncope, and/or gout, and may not be ideal for long-term hyperkalemia management. Thus, additional therapy may be required for treatment of patients with chronic or recurrent hyperkalemia on diuretic therapy with s-K⁺ binders.

OBJECTIVE: To evaluate the potassium-lowering effects of an FDA-approved medication, patronier, in hyperkalemic patients with CKD on chronic diuretic therapy vs. those not receiving diuretics, during the initial treatment phase of the 2-part OPAL-HK study.

METHODS: Patients (n = 243) on renin-angiotensin-aldosterone system inhibitors with baseline s-K⁺ levels ranging from 5.1 to <6.5 mEq/L received patronier (8.4 g daily dose for mild hyperkalemia, 16.8 g daily dose for moderate-to-severe hyperkalemia) for 4 weeks. For this post hoc analysis, change in s-K⁺ from baseline to week 4 was assessed in patients stratified by diuretic use (n = 132) and type. Patients receiving aldosterone antagonists alone were allocated to the no diuretic group.

RESULTS: The mean ± standard deviation age of all patients was 64.2 ± 10.5 years, 58% were male, and baseline clinical characteristics such as serum creatinine were similar across treatment groups. Mean ± (standard error of the mean) s-K⁺ decreased from baseline at week 4 in all diuretic subgroups: -1.01 ± 0.08 mEq/L (loop only),
vs. 37%, P showed similar adherence for MR or AM during the first 90 days of managing adherence at treatment initiation. Further research may identify opportunities for providers to assist atomeic disease. Adherent initiators had more therapy experience. P adherent resided in the South compared to AM adherent (61% vs. 43%, P (26% vs. 2%, based on claims data (5% vs. 16%, have dual eligibility (18% vs. 2%, P 20% vs. 8%, previously tried an OAB therapy (self-report: 45% vs. 31%,

**CONCLUSIONS:** The s-K+-lowering efficacy of patiromer in hyperkalemia patients was unaffected by concomitant diuretics.

**SPONSORSHIP:** Funding for this study was provided by Relypsa.

**N05 Medicare Beneficiaries Initiating Mirabegron Versus Anti-muscarinic Treatment for Overactive Bladder: Patient-Reported Adherence and Claims-Based Adherence Rates**

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**BACKGROUND:** Antimuscarinics (AM) and mirabegron (MR) are pharmacotherapy for overactive bladder (OAB). However, over half of patients never refill their initial prescription and adherence tends to be low. MR is a first in class beta-3 agonist for treatment of OAB that may have better adherence.

**OBJECTIVE:** To examine adherence during the first 90 days for patients initiating MR or AM and patient characteristics associated with adherence.

**METHODS:** This prospective observational study used real-time prescription (Rx) claims from the Humana Research Database to identify initiators (no Rx in previous 6 months) of MR or AM within 1 week of Rx. Medicare members initiated on MR or AM were recruited to participate in a longitudinal series of 3 phone surveys over 90 days. Patient reported Morisky Medication Adherence Scale (MMAS) was collected in surveys. Claims based measures were: patient demographics, clinical characteristics, days’ supply and proportion of days covered (PDC). Adherence was defined as PDC > 0.80. Descriptive and inferential statistical analyses were performed.

**RESULTS:** 1,897 MR and 2,444 AM patients were identified; 146 MR and 186 AM patients completed all 3 surveys, had continuous enrollment for at least 90 days, and a confirmatory Rx claim. Self-report and claims-based adherence at 90 days was similar between MR and AM initiators (MMAS: 3.7 vs. 3.6; PDC = 0.83). The correlation between MMAS and PDC was not significant. Compared to non-adherent members, adherent members more frequently reported having previously tried an OAB therapy (self-report: 45% vs. 31%, P = 0.019; claims: 20% vs. 8%, P > 0.006). Adherent MR initiators were more likely to have dual eligibility (18% vs. 2%, P = 0.013), and low income subsidy (26% vs. 2%, P = 0.001) compared to MR non-adherent. More AM non-adherent resided in the South compared to AM adherent (61% vs. 43%, P = 0.024) and were less likely to have previously tried an OAB therapy based on claims data (5% vs. 16%, P = 0.039) but not self-report (25% vs. 37%, P = 0.092).

**CONCLUSIONS:** Results from claims and self-report differed but both showed similar adherence for MR or AM during the first 90 days of treatment. Adherence was high compared to the literature, perhaps pointing to a more engaged Medicare patient population for this symptomatic disease. Adherent initiators had more therapy experience. Further research may identify opportunities for providers to assist managing adherence at treatment initiation.

**SPONSORSHIP:** This study was funded by Astellas Pharma Global Development as part of the Astellas-Humana Research Collaboration.

**N06 A Prospective Study of Medicare Beneficiaries Initiating Mirabegron Versus Anti-muscarinic Treatment: Patient-Reported Outcomes from the Overactive Bladder Satisfaction Scales (OAB-S)**

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**BACKGROUND:** Antimuscarinics (AM) are pharmacotherapy for overactive bladder (OAB), but are often associated with side effects. Mirabegron (MR) was introduced as a first in class beta-3 agonist, with fewer of the AM-related side effects.

**OBJECTIVE:** To understand differences between patients initiating MR or AM using a validated patient reported outcome instrument, the OAB-Satisfaction (OAB-S).

**METHODS:** This prospective observational study used real-time prescription (Rx) claims from the Humana Research Database to identify initiators (no Rx in previous 6 months) of MR or AM within 1 week of first Rx. Medicare patients were identified to participate in a longitudinal series of 3 phone surveys over 90 days. Survey measures included the OAB-S (7 scales). Claims measures included demographics and clinical characteristics. Analyses included descriptive, inferential, and ANCOVA controlling for patient characteristics to examine 90-day trends.

**RESULTS:** 1,897 MR and 2,444 AM initiators were identified; 174 MR and 193 AM completed all 3 surveys. MR initiators were older (76 vs. 74 years, P = 0.032), included more males (32% vs. 22%, P = 0.044), were more likely to have prior treatment for OAB (21% vs. 13%, P = 0.048), and had greater comorbidity (RxRisk: 6.0 vs. 5.5, P = 0.014) than AM initiators. There were no between-group differences in the OAB-S at any time point or on any scale; however, there were within-group differences over time. The trend was significant for 3 of the OAB-S scales: ‘impact on daily living’, with less impact on daily living over the course of the 90-day survey period for both the MR (P = 0.008) and AM (P < 0.001) initiators; ‘interruption of day-to-day life’, with less interruption of day-to-day life for both the MR (P < 0.001) and AM (P < 0.001) initiators; and change in ‘OAB control’ for MR (P < 0.001) and AM (P < 0.001).

**CONCLUSIONS:** Findings of this study suggest that MR and AM treatments are being used in different segments of the OAB population. MR and AM initiators reported similar trends in patient reported OAB outcomes over the first 90 days after initiating treatment. Further research may be necessary to understand use in different segments of the OAB population, and factors associated with initiation of specific treatments.

**SPONSORSHIP:** This study was funded by Astellas Pharma Global Development as part of the Astellas-Humana Research Collaboration.

**N07 Network Meta-Analysis of OnabotulinumtoxinA Compared to Mirabegron and Anticholinergics for Overactive Bladder**

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-0.96 ± 0.07 mEq/L (thiazide/thiazide-like only), -0.67 ± 0.23 mEq/L (loop plus thiazide/thiazide-like), -0.95 ± 0.06 mEq/L (any diuretic), and -1.05 ± 0.07 mEq/L (no diuretic). Reductions in s-K+ were similar in patients receiving any diuretic vs. those not on diuretics. Patiromer was generally well tolerated; mild-to-moderate constipation was the most common adverse event (7.6% of patients on any diuretic), and hypokalemia (s-K+ < 3.5 mEq/L) was infrequent (2.3% of patients on any diuretic).

**CONCLUSIONS:** The s-K+-lowering efficacy of patiromer in hyperkalemic patients was unaffected by concomitant diuretics.
BACKGROUND: Anticholinergics, mirabegron and onabotulinumtoxinA are commonly used to treat symptoms of overactive bladder (OAB). Approximately 90% of OAB patients who start with an anticholinergic fail their first prescribed therapy. These patients will continue cycling through other anticholinergics or mirabegron, or move on to alternative therapies like onabotulinumtoxinA. Data comparing the efficacy of these OAB treatments are lacking in the current literature.

OBJECTIVE: To assess the relative efficacy of onabotulinumtoxinA compared to other commonly used treatments in the network, using network meta-analysis (NMA) and meta-regression (NMR).

METHODS: Electronic databases, review documents, guidelines, and websites were searched for randomized blinded trials, of at least 2 weeks duration that compared any dose of onabotulinumtoxinA, mirabegron, or eligible oral/transdermal anticholinergics, with each other or placebo, in adults with OAB. Candidate studies were selected by two independent reviewers. Eligible studies were assessed for similarity, based on quality of study methods, confounding factors, common treatment arms, and outcome measures. A Bayesian random effects NMA model was used to assess the odds of achieving 100% reduction in UI episodes (UIE) at week 12, and a Bayesian random effects NMR model was used to synthesize results for change from baseline in UIE, urgency episodes, and micturition frequency at week 12. The NMR adjusted for differences in baseline severity.

RESULTS: 56 trials were included in the networks based on trial similarity and reporting sufficient data for each outcome; results are presented for licensed treatment doses. The NMA and NMR model results indicated that onabotulinumtoxinA was associated with the greatest improvements for each outcome compared to all other treatments in the networks. Compared to the next best treatment, onabotulinumtoxinA had 1.9 times higher odds (95% credible interval [CrI] 1.3-2.9) of achieving 100% reduction in UI episodes than fesoterodine, 0.69 (CrI 0.18-1.21) fewer mean daily UIE than solifenacin, 0.69 (CrI 0.11-1.28) fewer mean daily urgency episodes than solifenacin, and 0.26 (CrI 0.18-1.21) fewer mean daily micturition episodes than solifenacin.

CONCLUSIONS: This analysis suggests that at week 12, onabotulinumtoxinA 100U provides the greatest reduction in OAB symptoms and higher likelihood of being dry than all other licensed doses of mirabegron and anticholinergics in the network.

SPONSORSHIP: Research was funded by Stratis Group.
Primary Nonadherence to Overactive Bladder Medications in an Integrated Managed Care Healthcare System

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BACKGROUND: Despite the availability of effective medications, overactive bladder (OAB) treatment remains suboptimal in the U.S. Primary nonadherence (PNA) refers to patients’ failure to fill their initial prescription. This is the first study to evaluate PNA in patients with OAB in a U.S. managed healthcare system.

OBJECTIVE: To measure PNA to OAB medications and identify factors associated with PNA.

METHODS: A retrospective analysis was performed using the IMS PharMetrics Plus database. Patients ≥18 years of age who received a new prescription (index date) for an oral immediate-release oxycodone, hydrocodone or codeine containing product for short-term use (≤15 days) between 10/1/13-9/30/14 (index period) were included. Those with evidence of opioid use in the 180 days prior to the index date (baseline period) or comorbid conditions commonly associated with NV (e.g., cancer) were excluded. Patients with a medical claim for NV (ICD-9-CM 787.0x) with or without an antiemetic prescription (NV ± AEm) were compared to patients with no evidence of NV or antiemetic prescription (No NV/AEm) to assess differences in all-cause healthcare costs (pharmacy, inpatient, outpatient, total in USD) over a 1-month follow up period. Propensity score matching (PSM) was done to adjust for baseline differences and PNA patients with NV ± AEm compared to those with No NV/AEm respectively. After PSM, mean costs remained higher for patients with NV ± AEm compared to those with No NV/AEm: inpatient costs [$2,318 vs. $302; P < 0.0001; ACR (95% CI): 2.50 (2.45-2.56)], pharmacy costs [$230 vs. $80; P < 0.0001; ACR (95% CI): 2.50 (2.45-2.56)], outpatient costs [$1,407 vs. $1,641; P < 0.0001; ACR (95% CI): 1.32 (1.30-1.34)], and total healthcare costs [$6,714 vs. $2,249; P < 0.0001; ACR (95% CI): 2.98 (2.93-3.04)].

CONCLUSIONS: Among patients receiving a new opioid prescription for short-term use, evidence of nausea and vomiting was associated with significant economic burden. Given the nearly three-fold increase in total healthcare costs associated with this side-effect, efforts to reduce nausea and vomiting could provide cost savings to the healthcare system.

SPONSORSHIP: Daiichi Sankyo.
**R06**

**Appraising the Value of Digital Health Technologies from the Managed Care Perspective: Insights for Evidence Assessment and Reimbursement in the U.S.**

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**BACKGROUND:** Digital health technologies (DHTs) have accelerated in both number and utility in recent years, prompting managed care organizations (MCOs) to define the segment’s value and role in improving the healthcare of their members. In this context, many technology manufacturers have initiated clinical trials to generate evidence supporting DHTs, however limited guidance remains on how MCOs formally evaluate these products.

**OBJECTIVE:** To understand how medical and pharmacy directors assess the value of DHTs in the U.S., and to identify best practices for supporting their reimbursement determinations.

**METHODS:** Medical and pharmacy directors within Xcenda’s Managed Care Network (MCN) were invited to complete a 10-part, double-blinded, web-based questionnaire. Respondents were asked to grade their organization’s current demand and coverage policy of 9 distinct categories of DHTs. 11 major disease classes were evaluated based on the potential impact DHTs can have for addressing unmet needs. Specific evidence requirements for reimbursement of DHTs were then proposed and rated. Finally, strategies for manufacturers to interface with MCO’s were examined.

**RESULTS:** 37 pharmacy directors (60.7%) and 24 medical directors (39.3%) completed the questionnaire. The respondents’ MCO’s cover approximately 180 million lives in the U.S., with a mix of national (34.4%) and regional (65.6%) plans. Of the 9 technologies evaluated, mobile apps (80.3%) and fitness trackers (60.7%) scored the highest (34.4%) and regional (65.6%) plans. Of the 9 technologies evaluated, mobile apps (80.3%) and fitness trackers (60.7%) scored the highest impact for potential DHTs to address unmet needs. Peer reviewed literature (96.7%) was ranked as the most important evidence resource in evaluating the DHTs, followed by real world analysis (95.1%) and cost effectiveness models (78.7%). Clinical benefit (96.7%) was rated highest in potential impact for DHTs to address unmet needs. Specific evidence requirements for reimbursement of DHTs were then proposed and rated. Finally, strategies for manufacturers to interface with MCO’s were examined.

**CONCLUSIONS:** MCOs are actively evaluating a wide range of DHTs in a variety of disease states. Traditional appraisal strategies used in the evaluation of medical devices and pharmaceutical products are seen to also apply in evaluating DHTs. Respondents indicated that more robust evidence communication strategies with technology manufacturers and MCOs are needed for coverage decision making.

**SPONSORSHIP:** This research was funded by Advera Health Analytics, a private corporation.

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**T03**

**A Randomized, Placebo- and Active-Controlled Phase 2b Study Investigating Oliceridine (TRV130), a Novel µ Receptor G Protein Pathway Selective (µ-GPS) Modulator**

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**BACKGROUND:** Opioids are widely employed for management of moderate to severe acute pain, however, opioid-related adverse events (ORAEs), including respiratory depression and gastrointestinal dysfunction, increase risk and may limit dosing required for analgesic efficacy. Conventional opioids bind to µ receptors and non-selectively activate two intracellular signaling pathways: the G protein pathway, associated with analgesia, and the β-arrestin pathway, associated with ORAEs and inhibition of G protein-mediated analgesia. Oliceridine (TRV130) is a novel µ receptor G protein Pathway Selective (µ-GPS) modulator that activates G protein while mitigating β-arrestin recruitment to the µ receptor.

**OBJECTIVE:** To investigate the efficacy, safety, and tolerability of oliceridine compared to placebo (PBO) and morphine in patients (pts) with moderate to severe pain following abdominoplasty.

**METHODS:** This was a randomized, double-blind, adaptive patient-controlled analgesia (PCA) phase 2b study. Pts (N = 200) were randomized to intravenous oliceridine (two 0.75 mg loading doses followed by either 0.1 mg or 0.35 mg self-administered demand PCA doses), PBO, or morphine (4 mg loading followed by 1 mg demand PCA doses), in a 1:1:1:2 ratio. All treatment arms included a 6-min PCA lockout period.

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**S00-T98**

**Injury, Poisoning, and Certain Other Consequences of External Causes**

(i.e., Adverse Events, Side Effects)

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**T02**

**Predicting FDA Alerts: A Pharmacovigilance Signaling System Based on Past Regulatory Action**

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**BACKGROUND:** Many serious adverse events (AEs) only become evident well after a regulatory body has approved a drug. Therefore, the development of signaling methods to use with postapproval AE databases appears vital to comprehensively assess a drug’s real world safety profile. With millions of potential drug/AE pairs to analyze, however, the issue of focus is daunting.

**OBJECTIVE:** To develop a signaling platform that will focus on AEs with historically demonstrated regulatory interest and to analyze such AEs with a disproportional reporting method that offers broad signal detection and acceptable false positive rates.

**METHODS:** Over 1,500 U.S. Food and Drug Administration (FDA) safety communications and drug label changes issued from 2008 to 2015 were analyzed in order to construct a list of eligible signal AEs that were subjected to previous regulatory action by the agency. The FDA’s Adverse Event Reporting database (FAERS) was used to evaluate disproportional reporting rates, constrained by minimum case counts and confidence interval limits, of these selected AEs for a group of 109 training drugs. This step lead to 45 AEs that appeared to have a low likelihood of being added to a label by FDA, so they were removed from the signal eligible list. We then measured disproportionality reporting for the final group of eligible AEs on a test group of 29 drugs.

**RESULTS:** In a group of 29 test drugs, our model reduced the number of potential drug/AE signals from 41,834 to 97 and predicted 73% of individual drug label changes. The model also predicted at least one AE/drug pair label change in 66% of all the label changes that occurred for the test drugs.

**CONCLUSIONS:** By concentrating on AE types with already demonstrated interest to FDA, we were able to construct a signaling system that provided focus regarding drug/AE pairs and suitable accuracy with regard to the issuance of FDA labeling changes. We suggest that such a focus on historical regulatory actions may increase the utility of pharmacovigilance signaling systems.

**SPONSORSHIP:** This research was funded by Advera Health Analytics, a private corporation.
The primary endpoint was time-weighted average change in numeric pain rating scale over 24 hrs (NPRS TWA 0-24). Rescue analgesics were available as necessary.

**RESULTS:** Oliceridine 0.1 mg and 0.35 mg regimens reduced model based NPRS TWA 0-24 change vs. PBO by 2.3 and 2.1 points, respectively (P=0.001 and P=0.0005 vs. PBO), similar to morphine (2.1 points; P<0.0001 vs. PBO). Median time to meaningful pain relief was 1.1 and 0.3 hrs with oliceridine 0.1 mg and 0.35 mg, respectively, compared with 1.1 hrs with morphine 1 mg. AEs associated with oliceridine were similar in nature to ORAEs, however, both the 0.1 mg and 0.35 mg oliceridine groups had a lower prevalence of hyperventilation (10% and 31% vs. 41%), nausea (41% and 46% vs. 72%), and vomiting (13% and 15% vs. 42%) than the morphine group (post hoc P<0.05 for both oliceridine regimens vs. morphine). No serious AEs were reported.

**CONCLUSIONS:** In pts with pain following abdominoplasty, oliceridine achieved a magnitude of pain relief comparable to morphine over 24 hrs. Oliceridine 0.35 mg tended to achieve a more rapid onset of meaningful pain relief. Both dose groups of oliceridine had a lower prevalence of ORAEs than the morphine group. These results suggest that oliceridine may widen the therapeutic window between effective, rapid analgesia and typical ORAEs.

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

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**U00-U99 Codes for Special Purposes and AMCP Unclassified Abstracts**

(e.g., Care Management, Specialty Pharmacy, Rare Diseases, Star Ratings, Pharmacist Services, MTM, Med. Rec., Outcome Analyzers, Part D, Multidisease Studies, ACO, ACA)

**U19 Do Low-Cost Physicians Refer to Low-Cost Specialists? Considerations for the Development of Accountable Care Organization Networks**

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**BACKGROUND:** Policies to reduce healthcare spending include Accountable Care Organizations (ACOs) aimed to organize providers into high-performance networks.

**OBJECTIVE:** To evaluate if primary care physicians (PCPs), who measure highly on quality and cost of care measures, preferentially refer patients to specialists who perform well on the cost.

**METHODS:** A retrospective study was conducted using administrative claims data from a large health plan in 2014, which included individuals receiving coverage through self-insured employer groups and commercial insurers in the Northeast U.S. Each patient was attributed to a PCP. Cost and quality of care measures were used to calculate a composite score for each PCP. Scoring ranged from 1-5. A score of 4-5 was used to identify high performance PCPs and a score of 1-2 was used to identify low performance PCPs. Specialists seen by attributed patients were, in turn, attributed to the PCP. An episode group was used to calculate expected and observed cost for each episode of care. Expected cost for each specialist was plotted by specialty, and by the 5 most frequently occurring episodes within each specialty to examine association between PCP performance and specialist cost. A ratio > 1.00 indicated PCP referral to a high cost specialist.

**RESULTS:** The 5 most common specialties by episode count were: ophthalmology (17,201), dermatology (14,929), orthopedics (9,745), cardiology (9,670), and gastroenterology (6,367). Ratio of observed to expected cost was > 1.00 for all specialties (1.17-2.04), and all episodes within the specialties. Within the high performance PCP category, ratios were, ophthalmology: 1.07-1.58, dermatology: 1.20-2.93, orthopedics: 1.06-3.43, cardiology: 1.20-2.93, and gastroenterology: 1.07-1.58. Within the low performance PCP category, ratios were, ophthalmology: 1.07-1.58, dermatology: 1.11-1.52, orthopedics: 1.08-2.24, cardiology: 1.53-2.82, and gastroenterology: 1.18-1.53.

**CONCLUSIONS:** Both high and low performance PCPs refer to high cost specialists, irrespective of specialty and condition, providing evidence that cost and quality are not always aligned. PCPs are likely unaware of specialist cost. The question remains if, under an ACO framework, providers will employ data to identify high quality, low cost physicians or simply develop organizations around physicians with established relationships.

**SPONSORSHIP:** Health Advocate and West.
BACKGROUND: Specialty pharmacy (SP) products are pharmaceuticals designed to treat specific, complex chronic diseases. SP products are: written by specialists, have few prescribers/centers, and are costly; often require reimbursement assistance, prior approval, or special handling with unique/limited distribution processes. SP products often special training to administer, and have patient adherence programs. In 2014 SPs accounted for one third of spending, up from 2% in 2009.

OBJECTIVE: To determine how medical and pharmacy directors (MDs+PDs) of U.S. health plans, insurers, and PBMs manage specialty pharmaceuticals (SPs).

METHODS: Managed care (MC) MDs+PDs from public and private plans covering multiple types of members completed an online interactive survey of: advisor+plan information; use of specialtypharmacies, and current/future coverage of SPs.

RESULTS: Fifty-four percent of respondents were MDs, the remainder mostly pharmacists. Most worked for a health plan (83.6%) and the plans were: 39.6% = local; 35.4% = National; 25.0% = regional. SP providers were restricted by 53.7% of the plans, with those restrictions: the majority restrict SP provider services to a small set under contract (63.0%), 17.4% allow any SP, and 6.5% only restricted products available through multiple specialtypharmacies. Plans covered clinician administered products (i.e., injections and infusions) under the medical benefit (MB = 67.3%), none exclusively under the pharmacybenefit (PB = 0%); and 32.7% based on cost thresholds. Most plans (72.9%) do not anticipate a change, 18.8% expect a change before 2016 and 2.1% prior to 2018. Oral Biologics (OBs) were managed under the PB 78.3%; 10.9% under the MB; the other 10.9% based on cost thresholds. Benefits for OBs are not expected to change by 71.1% of the plans, 11.1% were currently making changes; 13.3% expect changes prior to 2016; and 4.4% before 12-2018. SP and OB copays vary by group and benefit design and are shifting from fixed to percent copays. Responses to open ended questions placed SP products at the top causes for concern currently, and for the coming years.

CONCLUSIONS: Expenditures for SP products and the use of specialty pharmacy will continue to grow. The environment for MC is undergoing a series of changes, and payer MD and PD, who commonly serve as P&TT Committee members, have distinct opinions as to how to alter the process to adapt to these influences.

SPONSORSHIP: The TPG-NPRT (National Payor Roundtable).

Effect of Pharmacist-Supported Transition-of-Care Program on 30-Day Readmission Rates: A Systematic Review and Meta-Analysis

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BACKGROUND: Transition of care (TOC) programs may help reduce hospital readmission rates. Currently, quantitative evidence to evaluate the impact of pharmacist-supported TOC programs on readmission reduction is lacking.

OBJECTIVE: To examine pharmacist-supported TOC programs for: (1) intervention components; (2) patient populations targeted; and (3) effect on 30-day readmissions.

METHODS: Studies examining pharmacist-supported TOC programs in the United States published between January 1995 and November 2014 were identified in bibliographic databases (N = 11), professional association websites (N = 11), and topic-relevant grey literature. Included studies had a comparison group and reported a 30-day readmission outcome. The RCT and non-RTC tools from the Cochrane
Collaboration were used to assess risk of bias. Intervention and targeted population categories were generated to help describe TOC programs. A meta-analysis was performed to assess the impact of pharmacist- and nurse-supported TOC programs on 30-day readmissions. The I-squared statistic was calculated to assess study heterogeneity. Subgroup analyses were conducted to investigate the effect of confounding factors, including: (1) study design; (2) readmission reporting; and (3) level of pharmacist participation in the intervention.

RESULTS: Of the 2,289 studies reviewed, 17 met the inclusion criteria and included four RCTs, study samples ranged from 61 to 19,659 patients. The most common interventions were medication reconciliation; patient counseling; and patient-centered follow-up. Interventions differed by patient outreach method and most occurred at- or post-discharge. Patients targeted for TOC interventions varied across studies, yet populations with a large number of medications documented at discharge were most commonly studied, followed by those admitted for heart failure and those using high-risk medications. The meta-analysis showed a 41% reduction in readmission rates (OR = 0.59; 95% confidence interval, 0.49, 0.72) compared to usual care; however, significance was observed across studies (I-squared = 44%; P = 0.019). When stratified into subgroups, meta-analyses showed potential confounders (e.g., study design) were statistically insignificant with regard to the effect on readmission reduction.

CONCLUSIONS: In this meta-analysis, pharmacist-supported TOC programs were associated with reduced hospital readmissions across multiple disease states.

SPONSORSHIP: None.

U28 Impact of Mailed Letters on Medication Adherence in a Medicare Advantage Plan

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BACKGROUND: Medication adherence has become integrated into managed care organization quality measures, including the Centers for Medicare and Medicaid Services (CMS) Part D Star Ratings. Consequently, Medicare Advantage Plans (MAPs) are looking for effective ways to improve their members’ adherence to maintenance medications. One intervention conducted was to identify those who are not refilling on time, yet were unable to be reached telephonically, and mail them an adherence-focused letter.

OBJECTIVE: To (a) determine if mailed letters highlighting the importance of adherence can improve medication adherence for members in a MAP and (b) examine if medication type and/or various member characteristics are associated with adherence.

METHODS: A retrospective pre-post study was performed on adult members enrolled in a MAP with prescription drug coverage from May 2014 through June 2015. The 6-month proportion of days covered (PDC) of the letter-specified medication was obtained for before and after the mailed letter. Medication adherence was assessed as both change in PDC and a final PDC ≥ 0.8. A multiple logistic regression analysis was conducted with an adherence outcome defined as a final PDC ≥ 0.8. Independent variables included medication type and member characteristics. A multiple linear regression analysis with the same independent variables was also carried out with an outcome of change in PDC. A sub-analysis of those with at least 1 medication fill after the letter was sent was also performed.

RESULTS: A total of 460 members aged 69.98 ± 10.48 years of age, 50.2% female and 66.7% white were assessed. After the mailed letter, 24.1% became adherent to the specified maintenance medication (Fisher exact test, P = 0.001) and there was a net change in PDC of -0.10 ± 0.40. Those who received greater than a 30-day supply at a time were more likely to become adherent after the mailed letter than those who received a 30 day supply or less (Chi square: P = 0.013; Linear Regression: P = 0.002, Logistic Regression: P = 0.003). Furthermore, initial PDC was also found to be a significant predictor of becoming adherent after the mailed letter (t-test: P = 0.013; Linear Regression: P = 0.001; Logistic Regression: P = 0.007). A total of 284 members had at least 1 medication fill after the letter was sent. Of those members, 39% became adherent after the letter was mailed and the net change in PDC was 0.15 ± 0.28.

SPONSORSHIP: NIH grant ULTR00427.

U27 The Influence of a Community Pharmacy Automatic Prescription Refill Program on CMS Adherence Metrics

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BACKGROUND: The Centers for Medicare and Medicaid Services (CMS) adherence metrics have motivated the development of new methods to improve patient adherence. Automatic prescription refill programs in community pharmacies are one intervention that has seen widespread adoption in recent years. The programs anticipate and initiate prescription refills on a standardized, recurrent basis. This study measures the effect of an automatic prescription refill program on three adherence metrics used by CMS.

OBJECTIVE: To compare the value of CMS adherence metrics for an automatic prescription refill program relative to a manual prescription refill program.

METHODS: Prescription claims data from a chain of 29 pharmacies in a Midwestern state were used to conduct the analysis. A post-only, quasi-experimental design separated patients into automatic and manual prescription refill cohorts. Refill adherence was calculated using proportion of days covered (PDC) for each of the three adherence metrics used by CMS for statins, renin angiotensin aldosterone system antagonists (RASA) and non-insulin diabetes medications. The adherence metric was defined as the proportion of patients with a PDC greater than or equal to 80%. Inclusion criteria for patients followed the CMS criteria. Chi-square analysis and multiple logistic regression were used to examine differences in PDC greater than or equal to 80% between the two study groups.

RESULTS: There were 1,018, 1,006, and 368 patients for the automatic refill group and 3,928, 3,409, and 1,207 patients for the manual refill group in the statin, RASA, and diabetes adherence metrics, respectively. The proportion of adherent patients ranged from 73.6% to 76.4% for manual refill cohorts, and 77.9% to 85.6% for automatic refill cohorts. Differences between study groups were statistically significant for all the adherence metrics based on chi-squared test (P < 0.05). Patients enrolled in the automatic prescription refill program were more likely to be considered adherent to their medication. Enrollment in automatic prescription refill programs could be encouraged by health plans and pharmacists due to their potential effect on CMS Five Star ratings. Concerns about the extent to which these programs actually improve medication adherence and not just improve the metric itself still exist.

SPONSORSHIP: None.
CONCLUSIONS: Mailed letters describing the importance of adherence can improve adherence as 24% of the nonadherent members became adherent thereafter.

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

U30 Pharmacist- and Nurse-Managed, Interprofessional, Post-hospital Discharge Transition of Care Program

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PROBLEM DESCRIPTION: A gap in the continuum of intensive pharmacovigilance exists for patients at high-risk of readmission following hospital discharge.

GOAL: The Discharge Companion (DC) Program works in tandem with the hospital’s chronic disease coordination (CDC) team by providing a personalized medication therapy management (MTM) transition service to: (a) reduce readmissions; (b) improve patient health outcomes; and (c) decrease patient and hospital costs.

PROGRAM DESCRIPTION: The DC Program engages patients discharged with certain diagnoses (e.g., hypertension) to ensure provision of pharmacist- and nurse-delivered services for those with highest potential benefit. The DC nurse enhances the patient care continuum experience by coordinating provider appointments and addressing barriers to care. DC pharmacists provide telephonic MTM services at 1- and 3-weeks post-discharge. Prior to the initial call, the DC team reviews the discharge summary and CDC team’s notes in the hospital’s electronic health record (EHR) and assesses for therapeutic issues. Initially, acute disease-state interventions are made (e.g., determining appropriateness of adding a diuretic in heart failure patients). Call notes are documented in the patient’s EHR for the CDC team’s review. Providers and community pharmacists are contacted to resolve identified issues. During the follow-up call, the DC team addresses: chronic disease state interventions; new concerns; vaccine updates; and resolution of previously discussed issues.

OBSERVATIONS: A 72% participation rate was observed in the first 4 months of recruitment (152 of 211 enrollees). The team approach to care provision and multiple patient touch points are postulated as major contributors to the high participation rate.

FINDINGS/RECOMMENDATIONS: Initial qualitative analyses showed positive reactions to the Program. Patients reported the DC team actively engages and educates while concurrently addressing concerns. To bridge the gap in care continuity, the DC team shared EHR discharge and MTM summaries per provider request, before patients’ follow-up appointments. The DC pharmacist and nurse served as intermediaries between patients and providers to facilitate focused, follow-up appointments to resolve patient concerns and therapeutic issues promptly. Providers benefited from therapeutic recommendations for: drug-drug/disease-drug interactions; renal-dose adjustments; and treatment guidelines. Future research is needed to quantify effectiveness and cost-effectiveness of this and like TOC programs, and evaluate the program with other payer types and in new settings.

SPONSORSHIP: The University of Arizona College of Pharmacy HOPE Center and SinfoniaRx.

U32 Impact of Managed Care Restrictions on Medication Adherence, Clinical and Economic Outcomes, Healthcare Resource Utilization, and Treatment Satisfaction: A Systematic Literature Review

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BACKGROUND: Formulary restrictions are implemented to reduce pharmacy costs and ensure appropriate utilization of pharmaceutical products. As adoption of formulary restrictions increases with rising pharmacy costs, there is a need to better understand the potential impact of formulary restrictions on patient outcomes.

OBJECTIVE: To conduct a systematic literature review to assess the impact of formulary restrictions on the following patient outcomes: medication adherence (MA), clinical outcomes (CO), economic outcomes (EO), healthcare resource utilization (HCRU), and treatment satisfaction (TS).

METHODS: Studies published in 2005 or later were identified from MEDLINE, EMBASE, Cochrane, and NHS EED using two sets of search terms. A total of 17 formulary restriction terms (step-therapy and/or prior authorizations) and 55 terms for patient outcomes were included, resulting in 935 unique search term combinations. Two reviewers independently conducted title, abstract, and full article reviews. The search was limited to English-language articles that evaluated the impact of step-therapy and/or prior authorizations placed by U.S. third-party payers on the following patient outcomes: MA, CO, EO, HCRU, and TS.

RESULTS: From 1,971 reviewed articles, a total of 59 articles met study inclusion criteria. Included studies assessed the impact of step-therapy (29%), prior authorizations (63%), or both (8%) on MA (n = 13), CO (n = 10), EO (n = 40), HCRU (n = 19), and TS (n = 2). A subset of articles (n = 17) that evaluated the impact on multiple EOs (medical, pharmacy, and/or total costs) revealed that formulary restrictions led to no savings (47%) or increase in total costs due to increase in medical costs (29%). Similarly, majority of the articles that assessed HCRU showed increased outpatient (73%) and ER visits (62%) due to formulary restrictions. Further, evaluation of results from subgroup-analyses revealed that magnitude and direction of the impact may vary based on disease, plan-types, and reasons for formulary restriction.

CONCLUSIONS: Formulary coverage decisions may have unintended consequences on patient outcomes; therefore, careful evaluation of restrictions prior to policy implementation and continued re-evaluation after implementation should be warranted.

SPONSORSHIP: Novartis Pharmaceuticals.

U33 Primary Care Physician Perception of an E-Newsletter Within a Medicare Advantage Plan

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BACKGROUND: Strong managed care partnerships with Primary Care Physicians (PCPs) are a crucial component in bringing quality care to Medicare Advantage Plan (MAP) beneficiaries. Communication with PCPs, especially educational in-nature, must be timely and accurate. E-newsletters can serve as a platform to dispense information to PCPs and provide tips on improving CMS Star measures.

OBJECTIVE: To evaluate PCP satisfaction of an E-Newsletter and to assess its impact on PCP intent to prescribe generics and/or 90-day supplies.
OBJECTIVE: A survey was developed and administered to PCPs contracted with MAP in Texas. Demographic and practice variables such as gender, race, age, and years in practice were recorded. Survey questions evaluated level of satisfaction with the layout, overall content, and practicality of information provided. Likelihood to prescribe generics and/or 90-day supplies after reading the PCP E-Newsletter was assessed. Group differences for responses were evaluated using chi-square test for categorical variables and t-test for continuous variables.

RESULTS: A total of 194 PCPs aged 53 ± 10 years (76% male; 24% female) were surveyed. Eighty-nine of 194 (45.9%) PCPs claimed to have previously viewed the E-Newsletter whereas 105 (54.1%) PCPs claimed to have not. Among the 89 PCPs who viewed the E-Newsletter, no PCP (0%) indicated that they were dissatisfied with the layout while 24 (27%) PCPs were somewhat satisfied and 65 (70%) PCPs were satisfied or very satisfied. No PCP (0%) indicated that they were dissatisfied with overall content while 19 (21%) PCPs were somewhat satisfied and 65 (73%) PCPs were satisfied or very satisfied. For practicality of information provided, 1 (1%) PCP was dissatisfied, 23 (26%) PCPs responded somewhat satisfied, and 65 (73%) PCPs were satisfied or very satisfied. Eighty-eight (96.7%) PCPs agree that they are more likely to write generics and 87 (95.6%) PCPs agree that they are more likely to prescribe 90-day supplies after reading the E-Newsletter. PCPs with greater years of practice were more likely to be satisfied or very satisfied with overall content (M = 21, SD = 7.6) compared to PCPs with fewer years of practice experience (M = 23, SD = 8.3). There were no other statistically significant differences observed between PCP responses and demographic variables.

CONCLUSIONS: A majority of PCPs were satisfied or very satisfied with the E-Newsletter. Also, PCPs were more likely to prescribe generics and/or 90-day supplies indicating that the E-Newsletter may serve as an effective medium for provider education.

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

U35 Variability in State Medicaid Medication Therapy Management (MTM) Initiatives

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BACKGROUND: State interest in improving care quality and lowering healthcare expenditures has spurred experimentation with MTM programs to optimize medication regimens and population health management, improve medication adherence, and manage medication costs. State Medicaid programs are contracting MTM services, however, little is known about the variability of programs.

OBJECTIVE: To conduct a survey of state Medicaid pharmacy directors to report MTM covered services and program implementation challenges.

METHODS: A survey was developed based on a literature review of MTM services and sent to state Medicaid pharmacy directors (Feb 2015). Survey data focused on the type/extent of pharmacist-provided MTM services, pharmacist qualifications, patient eligibility criteria, MTM delivery settings, MTM program evaluations, program costs, sustainability models, and key implementation challenges. A reminder was sent to non-respondents after 2 weeks.

RESULTS: 14 states indicated current/past MTM programs; 9 states completed the survey. Many Medicaid MTM programs followed Part D requirements. Highly variable findings due to different Medicaid eligibility criteria, pharmacist integration with health team, access to EMRs, MTM delivery methods/settings to optimize drug therapy regimens. Implementation challenges were: (1) Lack of sustainable funding; consider MTM as a component of intensive care management programs and statewide strategies for care delivery/pay-ment reform; calculate estimated savings from reduced hospitaliza-tions/ED visits; (2) Pharmacist integration on care teams: pharmacists can be co-located/embedded/contracted for MTM services; pharma-cists enhanced shared decision-making on drug therapy alternatives; (3) Lack of EHR access: pharmacists need patient health information via EMRs to make comprehensive assessment and recommendations for care plans and improved care coordination; (4) Low patient engagement: <10% eligible patients enroll in MTM programs; consider opt-out process and population health strategy for high-risk patients; (5) MTM continuity: annual MTM visits fail to catch medication-related problems in patients with multiple conditions and prescribers; consider up to 4 MTM visits/year; (6) MTM payment model: need to consider capitation/alternative payment models.

CONCLUSIONS: Findings can be considered in Enhanced MTM Part D programs; MTM implementation improves with pharmacists on care teams; MTM evaluation funding is critical to measure program impact; robust criteria needed to determine MTM program impact on care quality improvement and total healthcare cost savings.

SPONSORSHIP: University of Connecticut School of Pharmacy and New Hampshire Medicaid Program.

U36 State Variation in the Use of Mail Order Pharmacy in the U.S.: Findings from the 2015 National Consumer Survey on the Medication Experience

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BACKGROUND: The use of mail order pharmacies has increased steadily since their inception. Ownership of mail order pharmacies has also shifted from independently owned and operated to more often being owned and operated by a Pharmacy Benefit Manager (PBM). This shift in ownership has been met with growing concern over their impact on traditional brick and mortar pharmacies, which has been further exacerbated by the use of mandatory mail order programs offered by some PBMs. Some states have attempted to limit these tactics by passing laws to limit a PBMs ability to implement mandatory mail order programs.

OBJECTIVE: To describe current users of mail order pharmacies across the U.S. and to compare the use of mail order pharmacies between New York, who has the ban on mandatory mail order programs, compared to all other states.

METHODS: Data from the 2015 National Consumer Survey on the Medication Experience, which included 26,173 adults from throughout the United States, was used to evaluate patient reported use of mail order pharmacies. Data was restricted to respondents who reported use of at least one prescription medication.

RESULTS: On average, approximately one-quarter (24.3%) of participants reported receiving prescription drugs from a mail order pharmacy. Participants residing in Rhode Island reported the lowest rate of utilizing mail order pharmacies (14.8%) and those residing in Texas reported the highest use of mail order services (35.5%). Participants residing in New York reported higher rates of mail order pharmacy compared to overall use, with 29.1% reporting use of mail order services.

CONCLUSIONS: There is significant state-to-state variability in use of mail order pharmacy usage according to the reports from participants of this study. New York did not show a reduction of mail order usage compared to other states, with a higher percentage reporting use than that of the overall population. Further research is needed to determine...
Z01 Rates of Hospitalization and Repeat Procedures in Patients Receiving Sodium Picosulfate/Magnesium Citrate Bowel Preparation Prior to Colonoscopy

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BACKGROUND: Bowel preparation is critical for a safe and effective colorectal cancer (CRC) screening colonoscopy. Inadequate preparation is associated with an increased adenoma miss rate and may require an early repeat colonoscopy. High volume (HV) preparation agents are poorly tolerated and many patients are unable to consume the entire solution, increasing the risk of a poor preparation. Low volume (LV) agents are better tolerated and have shown similar clean-up quality compared with HV. Sodium picosulfate/magnesium citrate (P/MC) is a LV bowel preparation agent that requires patients consume 10oz of solution, followed by clear liquids.

OBJECTIVE: To determine pharmacists’ perceptions of the likelihood of biosimilars having competitive pricing, the impact of biosimilars on the cost of reference biologics, and biosimilars impact on patient out-of-pocket costs.

METHODS: A cross-sectional survey of 781 members of the Academy of Managed Care Pharmacy and the Hematology/Oncology Pharmacy Association was conducted using an online survey. Respondents were restricted to active pharmacist members with a reported email address to the respective association.

RESULTS: Participants reported a general perception that biosimilars will be associated with reduced acquisition costs compared to that of the reference product (89.1%). In addition, participants reported expecting reference products’ acquisition costs to drop following the approval of a competing biosimilar (51.6%). Lastly, participants reported anticipated reductions in patient out-of-pocket costs when an interchangeable biosimilar was dispense in place of the reference product (60.6%). For each of the categorical savings, respondents predominately felt the price reductions would be modest, choosing the slightly lower cost option over substantially lower cost options the majority of the time.

CONCLUSIONS: Pharmacists who participated in this survey reported a perception of likely cost savings associated with the introduction of biosimilars. Respondents believe the likely savings will be present for both the overall system and the patient. With the predicted modest cost savings that is anticipated by respondents, this does suggest that such patient savings may be unlikely to come to fruition. Actual impact on cost will not be known until more biosimilars are approved and sold throughout the U.S. Additional research is needed to measure the actual impact of biosimilars on the cost of current and future biologics.

SPONSORSHIP: None.

Z16 Drug Pricing in the United States: Payers Evaluate Strategies Proposed by Presidential Candidates to Lower Drug Costs

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BACKGROUND: The issue of rising drug costs has become an important aspect of the presidential candidate platforms leading up to the 2016 election in the United States. While significant media attention has been given to the discussion of proposed strategies, limited evidence has been gathered to evaluate payer perceptions of these new ideas.

OBJECTIVE: To evaluate payer perceptions of the current drug pricing landscape and to assess the potential impact of proposed presidential candidate strategies on the healthcare system.

METHODS: A double-blinded, web-based survey was administered to pharmacy and medical directors within Xcenda’s Managed Care Network in November 2015. The survey included a series of questions
assessing payer opinions on current drivers of drug pricing, need for new drug pricing strategies, familiarity with proposed strategies, and potential impact of proposed strategies on managed care and on the healthcare system as a whole.

**RESULTS:** 53 payers completed the survey, including pharmacy directors (66%) and medical directors (34%). Payers reported that clinical trial efficacy (87%), cost of development (62%), and burden of disease (45%) should be the most significant drivers of drug pricing. While the majority of payers (94%) reported a need for new strategies to control drug costs, lower payers (68%) reported familiarity with the strategies proposed by the presidential candidates to lower drug costs. Of the proposed strategies, payers indicated that increasing transparency in drug pricing (72%), shortening the biologic exclusivity period (64%), and prohibiting direct-to-consumer advertising (51%) would be most effective in lowering drug costs for the healthcare system as a whole. Payers also indicated that increasing transparency in drug pricing (72%), prohibiting pay-for-delay settlements (53%), and requiring higher rebates from manufacturers if the price increases at a greater rate than inflation (45%) would be the strategies most likely to be enacted in the next 5 years.

**CONCLUSIONS:** As proponents of having new strategies implemented to control drug pricing, payers are stakeholders that should be more involved in shaping and negotiating such strategies. Increasing transparency in drug pricing was consistently recognized as a strategy that would be most beneficial to managed care, most likely to be implemented in the next 5 years, and most likely to lower drug costs for the healthcare system as a whole.

**SPONSORSHIP:** This research was conducted by Xcenda/Amerisource Bergen Consulting Services without external funding.

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**Z17 Financial Impact of a Medicare Part D Assistance Program in a High-Risk Patient Population**

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**PROBLEM DESCRIPTION:** Medicare Part D prescription drug plans change annually; from increased deductibles and premiums to new formulary changes and restrictions. These changes can provoke financial hardships in this elderly, fixed-income population while also restricting access to established medication regimens. Surprisingly, only 13% of Medicare beneficiaries pick a new prescription drug plan each year. This rate is even lower (4%) for low-income subsidy (LIS) Medicare patients. Reasons for low participation are multifactorial with many patients citing difficulty comparing plans and overall confusion with the process.

**GOAL:** To increase enrollment in a cost-effective Medicare Part D prescription drug plan that provides optimal drug coverage among medically complex Medicare Part D beneficiaries using a focused intervention.

**PROGRAM DESCRIPTION:** Patients eligible for intervention had to be enrolled in the high-risk care management program at Brigham and Women’s Health Care as of May 2015 and have an active Medicare D plan. Other inclusion criteria include high-cost medications or polypharmacy. A review was conducted by a pharmacy technician using the “Plan Finder” tool on Medicare’s website. The patient was extensively educated on the results over the phone and a follow-up letter was mailed to the patient’s home, nurse case manager, and primary care physician.

**OBSERVATIONS:** Of the 305 charts reviewed, 105 met inclusion criteria and were reviewed for a 2016 Medicare Part D plan. A preferable plan was identified for 70 patients. The Medicare Plan Finder estimated a total cost savings of $323,816 (average $4,693 per patient). Additionally, 72 prior authorizations were avoided in 2016 by switching Medicare D plans. Of note, the review results differed greatly between the LIS segment and the general Medicare population. LIS patients showed a threefold increase in savings and avoided three times the amount of prior authorizations. However, despite this abundant cost-savings and better coverage, only 10% of patients changed their plans for 2016.

**FINDINGS/RECOMMENDATIONS:** Switching Medicare D plans annually can considerably reduce out-of-pocket costs, total medical expenses, and prior authorizations, all of which have the potential to contribute to improved medication adherence. However, a large percentage of high-risk Medicare beneficiaries do not change plans despite a plan review and extensive education. Further research to identify the barriers to patients making changes to their Medicare D plans that would result in cost-savings for them could inform future important policy change in this area.

**SPONSORSHIP:** Brigham and Women’s Physician Organization.

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**Z18 Results of the Implementation of Pharmacy Network Continuing Participation Verification Program for a Large Managed Care Organization**

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Blue Cross Blue Shield of Michigan

**PROBLEM DESCRIPTION:** During a review of select pharmacies, we discovered inconsistencies in how pharmacies report business changes, such as a change in business location and/or ownership. This leads to inaccuracies in our pharmacy directories and/or pharmacy contracts on file. To address these items, we developed a continuing participation verification process. Under this process, we review pharmacy information on file every two years, primarily based on pharmacy license expiration.

**GOAL:** To implement and execute a scheduled monitoring program for participating network pharmacies. This process will lead to maintaining up-to-date pharmacy information to ensure compliance with contract requirements. Also, it will help us and our participating pharmacies comply with federal and state requirements.

**PROGRAM DESCRIPTION:** Between August and September, 2014, 448 participating pharmacies were identified and mailed continuing participation verification applications to complete. Pharmacies were asked to include copies of the following documents with their applications: DEA certificate license, Pharmacy license, Pharmacy certificate of liability insurance, Owner/dispensing pharmacists’ Licenses, Owner’s full name and date of birth, and Pharmacy’s certificate of occupancy (if not on file).

**OBSERVATIONS:** 280 pharmacies completed the application, leaving 168 pharmacies outstanding. This represents a completion rate of 62.5%. Items identified in the 168 pharmacies outstanding: Change of ownership not reported (n = 87), Application not returned after several notices (n = 29), Application still being worked on (n = 23), Closed pharmacies (n = 18), Pharmacies removed from participating (n = 7), and Other (n = 4).

**FINDINGS/RECOMMENDATIONS:** After researching industry literature, we found no process for ongoing monitoring of pharmacy business information. Our program demonstrates the need for biennial checks with participating pharmacies to make sure the most up-to-date pharmacy information is on file and that the pharmacy complies with contractual requirements. We will continue to educate pharmacies through our communications channels on the importance of providing us with up-to-date business information.

**SPONSORSHIP:** Blue Cross Blue Shield of Michigan.
Z19 Onsite Health Clinics: Do They Lower Healthcare Cost and Resource Use?
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BACKGROUND: An increasing number of employers are “opting out” of the traditional healthcare system and providing access to healthcare through onsite primary care clinics. Onsite clinics have been proposed as providing quality healthcare while lowering cost and improving employee satisfaction but their outcomes have not yet been validated.

OBJECTIVE: To compare total healthcare cost and health resource use (HRU) of utilizers and non-utilizers of onsite clinics, which were provided by Crossover Health for this review.

METHODS: This was a retrospective administrative claims analysis examining 2 large employers, (EMP1, EMP2), whose employees had access to Crossover Health onsite clinics. Patients who were eligible for at least 6 months and had at least one claim were evaluated for inclusion in one of two cohorts: Non-users (did not use an onsite health clinic) and Engaged (at least 2 visits or ≥ 50% of their visits to an onsite health clinic). Multiple regression models adjusting for demographics and comorbidities (modified Elixhauser) were used to assess annualized costs and resource use.

RESULTS: A total of 5,801 (3,476 engaged and 2,325 engaged) and 2,267 (1,709 non users and 558 engaged) were included for evaluation for EMP1 and EMP2 respectively. Mean (SD) annual total health care costs per person were significantly lower (P < 0.001) for engaged vs. non-users for both groups: $2,854 ($16,936) vs. $3,321 ($13,921) for EMP1 and $2,229 ($8,097) vs. $3,211 ($13,921) for EMP2. On average, engaged patients spent 0.72 cents (EMP1) and 0.67 cents (EMP2) for every dollar spent by non-users. Engaged patients had significantly fewer office visits costs vs. non-users for both employers (P < 0.0001). For both employers, inpatient, outpatient and ER costs trended lower for engaged vs. non-users, however these differences were not statistically significant. When HRU was evaluated, EMP1 engaged patients had significantly fewer inpatient and outpatient visits but significantly greater office visits (P < 0.0001). There was no difference in ER visits. EMP2 engaged patients had significantly fewer ER visits and significantly greater inpatient and office visits vs. non-users (P < 0.0001).

CONCLUSIONS: Engaged users of onsite health clinics have lower total healthcare costs when compared to non-users with a savings of 28 to 33 cents for each dollar spent by non-users. This research supports the hypothesis that comprehensive patient centric primary care leads to significantly lower healthcare costs.

SPONSORSHIP: Crossover Health.

Z20 Is Real-World Evidence Cited in P&T Monographs and Therapeutic Class Reviews?
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BACKGROUND: Decision making is dependent on the availability and use of evidence. Payers often seek information on treatment effectiveness in real-world patients and care settings. New data sources such as electronic health records, data networks, and administrative claims offer the promise to inform decision making about treatment effectiveness. However, little is known about the usefulness of these new real-world evidence sources for pharmacy and therapeutic (P&T) committee decision making.

OBJECTIVE: To describe the sources of evidence used by managed care organizations in P&T committee monographs and therapeutic class reviews.

METHODS: A convenience sample of managed care organizations was convened to examine the use of evidence in healthcare decision making. Representatives from pharmacy benefit managers, health system, and health plans were asked to provide 3 P&T and 2 therapeutic class reviews (or the references from such documents) within the preceding 2 years. Two individuals examined references and classified them into published primary research, compendia and secondary/tertiary references, clinical reviews, unpublished studies, and various other sources.

RESULTS: This analysis included 389 references cited in 21 monographs/therapeutic class reviews from 5 organizations. Several of the common therapeutic areas of interest included: diabetes; cardiovascular, Hepatitis C, and chronic obstructive pulmonary disease. The number of references ranged from 7 to 50 for the eleven therapeutic class review monographs, 1 to 64 for the ten monographs. Published clinical trials accounted for the most cited sources (n = 119, 31%), followed by manufacturer provided information (n = 103, 26%; e.g., product labels, “daily med”). Expert consensus statements, FDA reports, systematic reviews, and compendia each comprised 3%-8% of references. Published real-world evidence and non-systematic review articles each comprised just 2% of references. AMCP dossiers, books, third-party tech assessments, and meeting abstracts each account for less than 1% of the cited references. Only one monograph cited internal data analyses.

CONCLUSIONS: Efficacy information (from clinical trials, product labels, etc.) was the most commonly cited source of evidence in P&T materials. Effectiveness information, even among class reviews where real-world data is available, was rarely cited. Additional research is needed to more completely understand which types of studies are most useful to inform P&T decision making.


Z21 Plan Sponsor Perceptions on the Influence of Quality Metrics on Formulary Coverage Decisions
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BACKGROUND: As payers like the Centers for Medicare & Medicaid Services (CMS) focus on the Triple Aim, plan sponsors are increasingly being held accountable for their ability to achieve those aims through programs like the Medicare Star Ratings program and the Quality Rating System (QRS) for the Exchange Marketplaces. These programs have begun to drive plan sponsor priorities and focus, but it is unclear how plans are thinking about quality as part of their coverage decision-making process.

OBJECTIVE: To understand the influence of quality metrics on coverage decision-making and evaluate the importance of aligning manufacturer labels and evidence with quality metrics.

METHODS: A double-blinded, web-based survey was conducted via Xcenda’s Managed Care Network (MCN). The survey included a series of multiple-choice questions requesting feedback on the influences of quality metrics on tier placement/preferred coverage status, trends in quality metric influence on coverage status, and effect of disease-state specific quality metrics. In addition, importance of manufacturer labeling alignment to quality metrics, and development of pharmacoeconomic evidence linking outcomes to quality metrics was evaluated.

RESULTS: A total of 57 advisors were surveyed, which consisted of pharmacy directors (57.9%), medical directors (35.1%), and others
The Impact of Pharmaceutical Manufacturer Copay Cards on Patient Access to Biologics

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BACKGROUND: Biologic drugs are effective therapeutic options for many patients, however, out-of-pocket (OOP) costs may limit their use. To mitigate the cost burden on patients, manufacturers often offer copay cards. In 1988, Massachusetts (MA) became the only state to ban the use of copay cards. In July 2012, MA lifted the ban, providing a natural experiment to examine the impact of these cards on biologic uptake.

OBJECTIVE: To analyze the change in biologic uptake following the lift of the MA ban among patients with autoimmune disorders—rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis, Crohn's disease.

METHODS: Symphony transactional data were used that captured copay card use and medical and pharmacy claims. The study sample consisted of commercially-insured adults diagnosed with any of the aforementioned autoimmune disorders and with pharmacy activity 21 months pre and post ban lift (10/2010-3/2014). Medicaid and Medicare patients were excluded. Patients from MA were compared to patients in 8 nearby states that had no change in copay card access (control). In 1988, Massachusetts (MA) became the only state to ban the use of copay cards. In July 2012, MA lifted the ban, providing a natural experiment to examine the impact of these cards on biologic uptake.

RESULTS: The study sample consisted of 5,783 patients (MA: 667; control: 5,116) with 800 classified as lower income (MA: 80; control: 720). Pre-ban lift, the MA and control groups were similar in age and gender, but differed in diagnoses and income. Adjusted analyses showed an increase in biologic uptake among MA patients in the long-term, after the ban lift relative to control state patients (6.0%; P = 0.02) (there was no significant effect in the short-term). For lower income patients, this increase appeared in both the short- and long-term (10.5%; P = 0.03 and 13.6%; P = 0.01).

CONCLUSIONS: The findings suggest a positive relationship between copay card availability and biologic access, with potentially larger effects for lower income patients. Results indicate copay cards play an important role in reducing OOP costs that may limit biologics access.

SPECIALTY MEDICATION CAPTURE RATES THROUGH ELECTRONIC PRESCRIPTION ORDER DATA WITHIN A HEALTH SYSTEM

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BACKGROUND: Treatment abandonment (failure to initiate therapy after prescription) is common among patients (pts) prescribed specialty pharmaceuticals. AbbVie provides a pt support program (PSP), Humira Complete, to adalimumab (ADA)-treated pts, which includes assistance with medication costs, ambassador nurse support, injection training, pen disposal, and medication reminders. Potential impact of PSP on abandonment has not been studied.

OBJECTIVE: To assess association between PSP participation and rate of ADA treatment abandonment.

METHODS: A longitudinal study was conducted using pt-level data from AbbVie’s PSP database linked with Source Healthcare Analytics administrative claims data. Pts aged ≥ 18 years with a diagnosis of rheumatoid arthritis, Crohn’s disease, ulcerative colitis, psoriasis, psoriatic arthritis, or ankylosing spondylitis, ≥ 1 pharmacy claim (paid or reversed) for ADA, and no ADA claim prior to 2012 were included; earliest ADA claim from 01/2012 to 01/2015 was defined as index date. Medical and pharmacy coverage for 3 months before index date, and pharmacy coverage for 3 months after index date were required. Abandonment was defined as reversal of initial ADA prescription (ie, pt did not take possession of medication) with no paid claim during 3-month follow-up. Abandonment rate was compared between pts who enrolled in any component of the PSP (PSP cohort) vs. those who did not (non-PSP cohort), controlling for potentially confounding baseline characteristics.

RESULTS: 24,767 pts (12,694 PSP, 12,073 non-PSP) were included. 57.2% of pts were diagnosed with RA. Pts in PSP cohort vs. non-PSP cohort were younger (mean age 47.7 vs. 49.0 years; P < 0.0001), more likely to be female (67.3% vs. 64.3%; P < 0.0001), and had fewer comorbidities (mean CCI 0.51 vs. 0.54; P < 0.0004). PSP cohort had 33.9% lower expected per-patient out-of-pocket contribution for ADA ($211 vs. $319; P < 0.0001) and 14.4% greater frequency of specialty pharmacy use for 1st ADA fill (60.2% vs. 52.6%; P < 0.0001). Abandonment risk was 78% lower for PSP vs. non-PSP (4.9% vs. 22.9%; odds ratio = 0.223; P < 0.0001), after controlling for baseline characteristics.

CONCLUSIONS: Enrollment in AbbVie’s free-to-patient PSP was associated with reduced abandonment of ADA treatment. Additional study of support services and impact on direct and indirect costs of care are needed. Reference: [1]https://www.humira.com/humira-complete.

SPONSORSHIP: This study was designed, conducted, and financially supported by AbbVie.

Impact of a Patient Support Program on Abandonment of Adalimumab Treatment Initiation

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BACKGROUND: Treatment abandonment (failure to initiate therapy after prescription) is common among patients (pts) prescribed specialty pharmaceuticals. AbbVie provides a pt support program (PSP), Humira Complete, to adalimumab (ADA)-treated pts, which includes assistance with medication costs, ambassador nurse support, injection training, pen disposal, and medication reminders. Potential impact of PSP on abandonment has not been studied.

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SPONSORSHIP: This study was designed, conducted, and financially supported by AbbVie.
BACKGROUND: University of Illinois Hospital & Health Sciences System (UIH) utilizes Cerner as an electronic medical record, which also provides a capability to electronically route prescriptions. UIH outpatient pharmacies, including a URAC accredited specialty pharmacy, receive prescriptions through this electronic routing service. The service has an option of sending prescriptions to outside pharmacies. The ability to route prescriptions outside of the health system leads to varying prescription capture rates for the UIH outpatient pharmacies.

OBJECTIVE: To analyze electronically routed prescription data to determine overall capture rate and specialty medication capture rate within the UI Health outpatient pharmacies.

METHODS: De-identified prescription order data between the dates of 08/01/2014 and 07/31/2015 were downloaded to a spreadsheet by UIH Pharmacy Information Systems from the electronic prescription database on Cerner. The prescription data were then categorized by drug and analyzed through pivot tables. Capture rates for specialty medications managed by UIH Specialty Pharmacy Services were studied individually and compared to the capture rates for all electronic prescriptions. Results were studied for statistical significance through paired t-tests with a P value of 0.01.

RESULTS: A total of 622,616 Rx orders were downloaded to a worksheet of which 434,752 orders were electronically routed to pharmacies. The other 187,864 orders were not routed electronically and thereby excluded from the analysis. UIH pharmacies received 97,145 orders from the 434,752 routed, yielding a capture rate of approximately 22%. The remaining 78% were routed to other retail or independent pharmacies. An analysis on several specialty medications: Harvoni(ledipasvir-sofosbuvir), Enbrel (etanercept), Humira (adalimumab), and Betaseron/Extavia (interferon beta-1b) was conducted. The listed medications totaled 965 prescriptions of which 883 were electronically routed to pharmacies. 626 were routed to UIH pharmacies, yielding a capture rate of 71%. UIH’s capture rate for all electronic prescriptions is 22% whereas its capture rate for the sample of specialty prescriptions is 71% which is statistically significant (P<0.01).

CONCLUSIONS: UIH captured the sample of electronically routed specialty medication prescriptions at a rate of 71%, significantly higher than UIH’s capture rate of 22% for all electronically routed prescriptions. The significant difference was reflected when other specialty medication capture rates are similarly analyzed.

SPONSORSHIP: JoAnn Stubbs, UI Specialty Pharmacy Services.

Z225 The Prevalence and Predictors of Low-Cost Generic Program Use in the Pediatric Population

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BACKGROUND: Low-cost generic drug programs (LCGP) increase the accessibility and affordability of prescription medication in the United States. Since they were implemented in 2006, LGCPs are now available at eight of the ten largest pharmacy chains and include a wide variety of medication classes. LCGP medications are often purchased out-of-pocket; thus, a pharmacy claim may never be submitted and the exposure may go unobserved in claims data. There is little data regarding the utilization of these programs and estimates of their use can provide important insights into the potential impact LCGPs may have on exposure misclassification in claims data. No studies have assessed the prevalence and predictors of LCGP use in the pediatric population.

OBJECTIVE: To (a) assess the prevalence and predictors of LCGP use in the pediatric population; (b) analyze trends in LCGP use since their implementation; and (c) determine which medications are most commonly purchased for children through these programs.

METHODS: Cross-sectional data were utilized from the 2007-2012 Medical Expenditure Panel Survey (MEPS). Each prescription fill was classified as an LCGP or non-LCGP fill. The proportions of LCGP fills and LCGP users were assessed each year from 2007-2012. Comparisons were conducted between users and non-users during the latest available study cohort (2011-2012) using chi-square and t-tests. Multivariable logistic regression was used to identify factors associated with LCGP use in the most recent MEPS panel.

RESULTS: Of 2,754 children meeting all inclusion criteria, 23.7% were classified as LCGP users, representing over 10 million adolescent LCGP users over the 2011-2012 period. LCGP users were significantly more likely to be female, privately insured, white, reside in urban areas, lack prescription drug coverage, and be in a higher income bracket than non-users. Significant predictors of LCGP use included age, prescription drug coverage, insurance type, race, region of residence, and number of unique medications used.

CONCLUSIONS: While 1-in-4 children use LCGPs, certain subgroups that may benefit the most from the programs are using them at a lower rate and use of these programs has important effects on medication utilization quality assurance and research.

SPONSORSHIP: The Institute for Pharmaceutical Outcomes and Policy at the University of Kentucky College of Pharmacy.

Z228 Cost Savings from the Implementation of a Compound Drug Management Program

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BACKGROUND: Managed care pharmacy has recently seen a five-fold increase in annual expenditures and a substantial rise in utilization of compounds. As a result, OptumRx has implemented the Safe & Effective Compound Use Reassurance Effort (SECURE) program to promote cost-effective management of these drugs. This program includes a network pharmacy compound credentialing program, rigorous prior authorization criteria, a maximum dollar threshold, compound kit and select bulk chemical exclusions, advanced analytics, and reporting.

OBJECTIVE: To evaluate the effect of the program on compound and overall pharmacy costs.

METHODS: The study utilized a matched cohort design. The intervention group included members from a large managed care organization (MCO) who attempted to adjudicate a compound prescription claim between April 1 and May 31, 2015. The control group included members from MCOs without the SECURE program in place, who also presented a compound claim for adjudication during the same time period. The control group was propensity-score matched to the intervention group in order to estimate the overall cost savings. Descriptive statistics, t-tests, and Pearson’s chi-square tests were used to determine the significant differences between the two groups and the pre and post time periods.

RESULTS: The intervention group (n = 549) and control group (n = 549) had no significant differences in baseline characteristics. The intervention group had a total compound cost savings of $178 PIMPM
Recovery Opportunities in a Pediatric Accountable Care Organization Claims Database

Valerie Vecchiet, Anahita Patel, Andreas Zacharias, Zhen C, Gleeson, Layla Middleton

PROBLEM DESCRIPTION: Coordination of Benefits (COB) recovery remains an important data integrity process to correct and recoup claims that have been incorrectly billed to Medicaid. Partners for Kids (PFK), a Medicaid Accountable Care Organization (ACO), has identified a unique method for identifying COB recovery opportunities. This method identifies patients with high prescription claims and low medical claims. This trend suggests that a Medicaid patient with commercial coverage has the commercial payer correctly billed as primary payer for medical coverage, but incorrectly billed as a secondary payer for pharmacy coverage. Using quality improvement methodology, PFK has developed an internal auditing process to identify and validate claims that follow this trend to recoup pharmacy claims over the past six years that were incorrectly billed to Ohio Medicaid.

GOAL: To measure the accuracy of a unique COB recovery method that identifies pharmacy claims in an ACO database that have been incorrectly billed to Medicaid.

PROGRAM DESCRIPTION: Claims were extracted from an ACO database containing over 330,000 pediatric lives across five contracted Medicaid managed care plans. Patients were included if medical claims over a 12-month period were less than $50 and prescription claims greater than $1,000. A list of potential patients with primary medical insurance was generated in the order of the highest pharmacy claims paid. Investigation for primary insurance occurred utilizing the list generated. The objective for each patient’s investigation was to confirm commercial pharmacy coverage and dates of eligibility. For patients identified, claims paid by Medicaid on dates of commercial pharmacy eligibility were compiled and submitted to the commercial payer for reimbursement. In addition, correction of the benefits was communicated to the state of Ohio.

OBSERVATIONS: Between 1/1/2014 and 3/30/2015, 1,190 unique patients were identified and the top 365 patients with highest pharmacy claims paid were investigated. Of the 365 patients investigated, 98 had confirmed commercial prescription coverage with $1.18M in prescriptions claims paid by Medicaid during a period of confirmed commercial pharmacy eligibility.

FINDINGS/RECOMMENDATIONS: COB recovery is an important focus for Medicaid managed care plans given changes that occur in member eligibility. Current COB recovery efforts effectively identify COB recovery opportunities through reactive processes. The method described here represents a proactive approach to COB recovery that complements current processes to achieve a common goal of managing Medicaid funds efficiently.

SPONSORSHIP: Funding for this study was provided by OptumRx.
States. Cost-effectiveness of LARC increases over time. The break-even point for IUD use compared to short acting contraception is approximately 2-years. Early discontinuation of devices limits their cost effectiveness. At present, there is limited information comparing the duration of use of LARC methods in real-world, mixed payer settings.

OBJECTIVE: To determine and compare the proportion of women using LARC devices: the levonorgestrel (LNG) IUD, the copper (Cu) IUD, and etonogestrel implants for ≥ 2 years and examine the influence of patient characteristics on the duration of use.

METHODS: This study is a retrospective chart review of women who had an IUD or contraceptive implant inserted within the University of Utah Healthcare system (UUHS) between January 1, 2004 to December 31, 2012. IUD and implant users were identified using the University of Utah Electronic Data Warehouse by querying ICD 9 codes and CPT codes identifying LARC. Analyses are based on continuous periods of use identified by codes demarcating insertion and removal of a LARC device. Multivariable logistic regression was conducted to relate the probability of 2 years of continuous use to device type.

RESULTS: Data on 2,691 LARC device users were obtained. The majority used a LNG IUD (17,92, 66.6%) with fewer women using a Cu IUD (297, 11.0%) or implant (602, 22.4%). Two-year continuation rates were 67.2%, 64.6% and 56.8% for the LNG IUD, Cu IUD, and implant (respectively) (P<0.05). IUD users were 1.3 times (95% CI 1.2-1.9) as likely to continue use past two years compared to women who used the implant. There was no significant difference in 2-year continuation between the LNG IUD and Cu IUD (OR 0.88, 95% CI 0.66-1.18). Older age at insertion also increased the odds of a user continuing past 2 years regardless of device (OR 1.02, 95% CI 1.00-1.04). Race/Ethnicity, payer-type, and linkage to a live birth in the UUHS records were not associated with use beyond 2 years.

CONCLUSIONS: Two-thirds of women having an IUD inserted continue using it 2 years after insertion. Two-year continuation is higher for IUD users than implant users.

SPONSORSHIP: Bayer Healthcare Pharmaceuticals.

INSPIRE: Increasing Competence, Confidence, and Frequency of Smoking Cessation Interventions Among Retail Clinicians and Access to Counseling Resources

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1The Foundation for Health Smart Consumers; 2Convenient Care Association; 3Public Health Management Corporation

PROBLEM DESCRIPTION: Clinicians practicing in the retail clinics need evidence-based training on conducting brief, motivational interventions and counseling resources for supporting patients to quit tobacco.

GOAL: To increase tobacco interventions in retail-based clinics by providing attending clinicians with online, on-demand, evidence-based training and counseling resources.

PROGRAM DESCRIPTION: The Foundation for Health Smart Consumers and the Convenient Care Association initiated the accredited Inspire Smoking Cessation Training Program with Retail Health Systems and Clinicians. Inspire aims to promote tobacco use cessation. Clinicians participate in this program, which involves learning about smoking cessation through partnerships 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 (knowledge, confidence, buy-in and behavior) and patient reach.

OBSERVATIONS: CE trainings at Retail Clinician Education Congresses and online trainings garnered 838 trainees across 38 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 options or pharmacotherapies; following trainings 99% of trainees report being more comfortable discussing cessation aids with patients. In comparing paired pre/post data, trainees report significant increases in confidence regarding ability to refer patients to quit tobacco and in confidence helping patients quit tobacco (P<0.01, 95% CI). Trainees report high feasibility to consistently intervene in the future (Mean=8.83, Mode=10 on a 1-10 scale). 3-month follow-up data indicate increases in consistency of Ask, Advise, Refer use. CDC OSH disseminates Inspire training to healthcare provider organizations, including pharmacists and hosts Inspire on their site. CDC’s Tips Campaign is integrated in Inspire’s counseling toolkit.

FINDINGS/RECOMMENDATIONS: Retail-based clinic expand care access and is a benefit covered by many health plans. Retail clinicians work directly with pharmacists to coordinate cessation interventions and referrals. Approximately 1.2M patients impacted by tobacco have received counseling by Inspire trained clinicians.

SPONSORSHIP: Grant provided by Pfizer Independent Grants for Learning & Change and supported by the Smoking Cessation Leadership Center at University of California, San Francisco. CDC Office on Smoking and Health provided a stipend to include the Tips from Former Smokers program into the Inspire program.
percent of residents had cognitive impairment per MDS assessments; CMRs were conducted with someone other than the beneficiary in those instances. Based on CMRs and interactive interviews, 7,527 drug therapy problem recommendations were made to prescribers, which has led to 2,193 drug therapy problem resolutions (30%), including reductions in polypharmacy and high-risk medications.

**FINDINGS/RECOMMENDATIONS**: The CMR process and written summary in CMS SF works effectively for residents in LTC when performed by CPs in the facility, as evidenced by high completion rates and drug therapy problem identification/resolution. Part D plans should consider further-utilizing CPs to conduct CMR in LTC.

**CONCLUSIONS**: A majority of PCPs preferred email as the method of communication for an educational E-Newsletter. There were no statistically significant differences in preferences by PCP age, years in practice, or gender.

**SPONSORSHIP**: Cigna-HealthSpring and University of Houston College of Pharmacy.

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**Z42 Examination of Physician Preference Regarding Mode of E-Newsletter Communication: A Sub-analysis of a Physician Survey Within a Medicare Advantage Plan Regarding PCP E-Newsletters**

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**BACKGROUND**: Improved communication between healthcare providers and managed care organizations is believed to advance patient care. Electronic newsletters (E-newsletters) can be used to share information that is not considered time-sensitive such as clinical guidelines, formulary information, and Centers for Medicare and Medicaid Services Star-related information. It is unclear if Primary Care Physicians (PCPs) contracted to care for a Medicare Advantage Plan (MAP) population prefer a specific form of delivery of this educational information. The literature reports variable physician preferences with communication methods such as fax, email, and texting.

**OBJECTIVE**: To examine the preferred method for communicating information via an E-newsletter that is not considered time-sensitive to PCPs.

**METHODS**: A survey was distributed to MAP contracted PCPs in Texas to examine trends in physician preferences regarding mode of E-newsletter communication. The PCP choices included fax, email, letter by post, or face-to-face. Overall physician responses and responses sorted by the characteristics of PCP age, gender, and years of practice were analyzed. Group differences were evaluated using a chi square test for categorical variables and t-tests for continuous variables. A logistic regression model with outcomes of email vs. other communication methods was used to examine associations of physician characteristics.

**RESULTS**: A total of 194 PCPs aged 53 ± 10 years (76% male, 24% female) were surveyed. Of those surveyed, 92 responses (47.4%) were recorded regarding physician preferred mode of communication. A total of 70 PCPs (76.1%) preferred email while 22 PCPs (23.9%) preferred other methods of communication. No statistical significance was noted regarding age between PCPs that preferred email (M = 55.2; SD = 11.2) versus those that preferred other modes of communication (M = 25.7; SD = 9.7), P = 0.4974. Out of 73 male PCPs, 54 (73.9%) preferred email. Of 19 female PCPs, 16 (84.2%) preferred email (P = 0.4361).

**CONCLUSIONS**: A majority of PCPs preferred email as the method of communication for an educational E-Newsletter. There were no statistically significant differences in preferences by PCP age, years in practice, or gender.

**SPONSORSHIP**: Omnicare.

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**Z45 Clinical Pharmacy Medication Therapy Management and Patient Follow-up to Improve Real-World Adherence to Novel Oral Anticoagulants: A Single-Center Prospective Study**

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**BACKGROUND**: Patients prescribed Xarelto (rivaroxaban), Eliquis (apixaban), Pradaxa (dabigatran), or Savaysa (edoxaban) for chronic use are not frequently monitored by anticoagulation teams as traditionally done for patients taking warfarin for similar indications. Limited evidence has been gathered to address the real-world adherence of patients to novel oral anticoagulants (NOACs) in the United States.

**OBJECTIVE**: To assess real-world adherence and barriers to adherence for patients chronically taking NOACs and to review benefits of pharmacy medication therapy management (MTM) and regular monitoring of NOAC patients.

**METHODS**: This single-center, single-arm prospective study used Sharp Rees-Stealy registry data to identify patients who initiated chronic (≥ 3 months) NOAC therapy between January 26, 2015 and September 25, 2015. Included patients received an initial phone call and at least one follow-up call by a registered clinical pharmacist to perform MTM. During the initial call, the pharmacist performed a comprehensive medication review and assessed patient knowledge and understanding of NOAC therapy. During each follow-up call, patients were asked to self-report their adherence to NOAC therapy and identify any barriers to adherence.

**RESULTS**: 107 patients received an initial call and at least one follow-up call, including 68 (63.6%) patients on rivaroxaban, 36 (33.6%) on apixaban, 3 (2.8%) on dabigatran, and none (0%) on edoxaban. 104 (97.2%) patients had filled their NOAC prescription by the initial call and 106 (99.1%) reported having the medication on-hand during the follow-up calls. Only 50 (46.7%) patients were aware of potential adverse drug reactions (ADRs) of NOACs and only 33 (30.8%) knew how to manage missed doses. 18 (16.8%) patients reported missing at least one dose in the past week and 34 (31.8%) reported missing at least one dose in the past month during follow-up calls. Based on 23 responses, the most prevalent barriers to adherence were forgetfulness (43.5%), cost (34.8%), and ADRs (17.4%). On average, initial and follow-up calls lasted 11.6 and 4.6 minutes, respectively.

**CONCLUSIONS**: Approximately one-third of patients miss at least one NOAC dose per month due to forgetfulness, cost, ADRs, or other reasons. Limited patient understanding of NOAC ADRs and missed dose management identifies an opportunity for pharmacists to fill knowledge gaps and improve adherence through MTM and regular patient follow-up.

**SPONSORSHIP**: This research was a collaboration between Sharp Healthcare and Xcenda/AmerisourceBergen Consulting Services without external funding.
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