Meeting Abstracts
AMCP Managed Care & Specialty Pharmacy Annual Meeting 2016
San Francisco, California
April 19-22, 2016
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:

Reviewers

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Joe Dye, PhD, RPh, Comprehensive Health Insights
Abimbola Farinde, PharmD, PhD, Bayshore Medical Center
Beckie Fenrick
Leslie Fish, PharmD, Fallon Community Health Plan
Renee Rizzo Fleming, RPh, MBA, PRN Managed Care Consulting Services
Melissa Fox, PharmD, MBA, Clinical Pharmacy Management
James M. Gagnon, Jr., PharmD, BCPs, New England Quality Care Alliance
Patrick Gleason, PharmD, Prime Therapeutics
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*AMCP Managed Care & Specialty Pharmacy*

*Annual Meeting 2016*

*San Francisco, California*

*April 19-22, 2016*

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Exhibit Hall Map: Student/Resident/Fellow Poster Presenters

(Wednesday, April 20, 5:45 pm-7:30 pm)

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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
E24 Glycemic Control in Type 2 Diabetes Patients Receiving Early and Late Combination Therapy
Comparing Medical Utilization Between Insulin Pen and Cost-Effectiveness of a Pharmacist-Led Diabetes Intense Medical Impact of Cost Sharing on Access to Care for Patients with Cystic Characteristics and Clinical Outcomes of Patients with Type 2 All-Cause Healthcare Utilization and Costs Among Type 2 An Evaluation of the Burden of Hyperkalemia in the Medicare Use of Statins and the Risk of Incident Diabetes: A Retrospective 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 Secondary Prevention of Diabetes Through Workplace Health Screenings Comparative Effectiveness Analysis of Rapid-Acting Insulin Therapies in a Large National Health Plan Assessment of Glycosylated Hemoglobin (HbA1c) in Patients with Type 2 Diabetes Mellitus (T2DM) Initiating Alogliptin and Pioglitazone (AP) Combination Therapy All-Cause Healthcare Utilization and Costs Among Type 2 Diabetes Mellitus Adults with Cardiovascular History 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 Achievement of Individualized Glycemic Targets and Cost-Effectiveness: Comparison Between Two Insulin Delivery Methods in Patients with Diabetes Use of Statins and the Risk of Incident Diabetes: A Retrospective Cohort Study Development and Validation of a Tool to Predict Non-adherence to Oral Antidiabetic Drugs in Medicare Beneficiaries Comparing Medical Utilization Between Insulin Pen and Vial Users Within a Pediatric Medicaid Accountable Care Organization 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 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 Evaluation of a Linked Database for Cystic Fibrosis Research on Clinical, Demographic, and Resource Use Variables Impact of Cost Sharing on Access to Care for Patients with Cystic Fibrosis An Evaluation of the Burden of Hyperkalemia in the Medicare Population PCSK9i Utilization, Cost, Utilization Management Impact, and Discontinuation Rate Among 13 Million Commercially Insured Americans Healthcare Resource Utilization (HCRU) and Clinical Characteristics of Medicaid Patients with Cystic Fibrosis (CF) Treatment Patterns Among Patients with Cystic Fibrosis Using Twice Daily Dornase Alfa Regimen Frequency and Costs of Pulmonary Exacerbations and Association with Percent Predicted FEV1 (ppFEV1) in Patients with Cystic Fibrosis (CF) 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 Follow-up Care After Psychiatric Hospital Admission for Medicaid and Commercially Insured Patients with Schizophrenia or Bipolar Disorder Controlled Substances Triple Threat Overlapping Days: Relationship with Healthcare Utilization and Costs Subdermal Buprenorphine Implants Improve Societal Outcomes and Patient Morbidity and Mortality Relative to Sublingual Buprenorphine: Results of a Markov Model Healthcare Cost Burden of Opioid Abuse Among Employees with Injury-Related Workers Compensation or Short-Term Disability Events: A Retrospective, Observational Cohort Study Drivers of Excess Costs Associated with Opioid Abuse Among Commercially Insured Patients Understanding Drivers of Excess Costs Among Continuous Users of Extended-Release/Long-Acting Opioids Diagnosed with Opioid Abuse, Dependence, or Poisoning Impact of a Concurrent Drug Utilization Review Edit Designed to Curb Opioid Misuse Real-World Dosing Patterns Among Patients Receiving Buprenorphine for Opioid Dependence in the United States A Comparison of Characteristics, Health Resource Utilization, and Costs of Dual Medicare-Medicaid and Medicare-Only Eligible Patients with Schizophrenia Medication Adherence as a Predictor of Switching Oral Antipsychotic Users to Long-term Injectables Evaluation of Long-Acting Injectable (LAI) Antipsychotic Medications in Medicare Beneficiaries: A Utilization Review and Cost Analysis Impact of Paliperidone Palmitate Versus Oral Atypical Antipsychotics on Healthcare Resource Use and Costs in Veterans with Schizophrenia with Limited Antipsychotic Exposure in the Prior 12 Months Regional Differences in HEDIS Measure Results for Schizophrenia Treatment Adherence in State Medicaid Programs Estimating the Value of New Technologies that Provide More Accurate Drug Adherence Information to Physicians for Their Patients with Schizophrenia Description of Health Care Utilization and Costs Among Young, Recently Diagnosed Schizophrenia Patients One Year Prior to Treatment with Paliperidone Palmitate Once Monthly Injectable Analysis of Medical Resource Utilization Secondary to Automated Prior-authorization Criteria for the Oral Atypical Antipsychotics in a Medicaid Population
Exhibit Hall Map: Professional Poster Presenters (continued)

F31 Comparing Fall Risk Among Antidepressant Classes in the Elderly: A Nested, Case-Control Study of a Medicare Database
G28 Budget Impact Analysis of Botulinum Toxin A Therapy for Adult Upper Limb Spasticity (AULS) in the United States
G27 Healthcare Resource Utilization Among Commercially Insured Clozarim-Treated Patients with Lennox-Gastaut Syndrome
G25 Specialty Drug Coupons Are Frequently Used and Significantly Reduce Out-of-Pocket Costs
G23 Adherence to Disease-Modifying Therapies Among Patients with Multiple Sclerosis
G22 Cost-Utility Analysis of Botulinum Toxin Type A Products for the Treatment of Cervical Dystonia
G21 Impact of Natalizumab on Multiple Sclerosis Relapse-Related Costs in a Real-World Setting
G05 Healthcare Utilization in a Contemporary Cohort of Primary Progressive Multiple Sclerosis NARCOMS Registry Participants
G04 Differences in Preferences for Disease-Modifying Treatments Across Subgroups of U.S. Patients with Relapsing Multiple Sclerosis
G03 Healthcare Utilization and Comorbidities in Working Age Persons with Different Types of Multiple Sclerosis
G02 Evaluation of First-Switch Disease-Modifying Therapies in a Market with Many Multiple Sclerosis Treatment Options
G01 Real-World Comparison of Relapse Rates 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
G19 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
G18 Payer Insight-Mining for Multiple Sclerosis Disease Management: Clinical and HEOR Decision Making
G17 Efficacy and Safety of Treatments for Acute Relapses of Multiple Sclerosis: Results of a Systematic Literature Review
G16 Comparision of Costs and Health Resource Utilization in Multiple Sclerosis Patients Treated with Disease-Modifying Therapies
G15 Healthcare Utilization and Comorbidities in Working Age Persons with Different Types of Multiple Sclerosis
G14 The Impact of Multiple Sclerosis Treatment Persistence and Adherence on Emergency Room Visits and Inpatient Hospital Stays
G13 Evaluation of First-Switch Disease-Modifying Therapies in a Market with Many Multiple Sclerosis Treatment Options
G12 Real-World Comparison of Relapse Rates in Multiple Sclerosis Patients Treated with Disease-Modifying Therapies
G11 Comparison of Costs and Health Resource Utilization in Multiple Sclerosis Patients Treated with Disease-Modifying Therapies
G29 Real-World Relapse Rates Among Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon β-1a Versus Oral Disease-Modifying Drugs
G28 Potential Cost Savings Due to Alemtuzumab Persistent Reduction in Disease Endpoints Through 5 Years Without Retreatment for Majority of Patients
G27 Literature Review of Studies Assessing Direct Costs Associated with Migraine
G26 Off-Label Prescribing for Children with Migraines in U.S. Ambulatory Care Settings
G25 Impact of a Clinical Outreach Program on the Utilization of High-Risk Medications for CMS STAR Ratings
G24 Characteristics and Resource Utilization of U.S. Emergency Department Visits (2008-2011) for Patients with Epilepsy and Convulsions
G23 Uncontrolled Epilepsy in the U.S.: A Major Clinical and Economic Problem
G22 Uncontrolled Epilepsy Hospitalizations in the U.S.: A Dramatic Increase in Costs over Last 15 Years
G21 Cost-Effectiveness of Eslicarbazepine Acetate Monotherapy in Partial-Onset Epilepsy
G20 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
G19 Healthcare Resource Utilization and Costs of Chronic and Episodic Migraine
G18 Cost-Effectiveness of OnabotulinumtoxinA for Chronic Migraine Prophylaxis in Adults in the United States
G17 A Comparative Assessment of Intravenous Immunoglobulin (IVIG) Therapy in the Treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
G16 Health Care Resource Utilization and Costs Among Patients Diagnosed with Sporadic Inclusion Body Myositis in the U.S. Medicare Population
G15 Association of Rescue Medication Use with Clinical Outcomes and Health Care Costs in Patients with Seizure Clusters
G14 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 Ophthalmic Antihistamines Formulary Coverage in a Medicaid Pediatric Accountable Care Organization (ACO)
H01 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
I04 Reevaluating the Value of Ezetimibe in the U.S. for Patients with History of CVD Based on the IMPROVE-IT Results
Exhibit Hall Map: Professional Poster Presenters (continued)

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

L07 Real-World Effectiveness of Anti-Tumor Necrosis Factor (anti-TNF) Switching in Psoriatic Arthritis: A Systematic Review of the Literature

L08 Treatment Patterns, Healthcare Resource Utilization, and Costs Associated with Psoriatic Arthritis Among Humana Commercial and Medicare Member Populations

L09 The Relative Importance of Mode of Administration in Treatment Choices Among Patients with Psoriasis in the United States

L10 Medication Utilization Patterns of Apremilast Among Patients with Psoriatic Arthritis

L11 Healthcare Costs in Psoriasis Patients Newly Initiated on Apremilast or Biologic Therapies

L12 Comparison of Persistence Between Adults with Psoriasis Initiating Apremilast or Biologics

L13 Prevalence and Systemic Treatment of Psoriasis and Psoriatic Arthritis Among Differently Insured Populations

L14 Economic Impact of Above-Label Dosing with Etanercept, Adalimumab, or Ustekinumab in Patients with Moderate-to-Severe Psoriasis

L15 Oral Isotretinoin Prescribing, Utilization, and Costs in a Managed Care Plan

M02 The Multi-biomarker Disease Activity Score in Methotrexate Incomplete Responders Predicts Clinical Responses to Nonbiological Versus Biological Therapy in Early RA

M03 Medication Adherence Outlier Quality Management Program: A Novel Method of Evaluating Medication Adherence in Specialty Pharmacy

M05 Gout-Related Ambulatory Care Utilization and Patient Characteristics Predictive of Resource Use

M08 Real-World Experience with Tofacitinib Versus Certolizumab Pegol for the Treatment of Rheumatoid Arthritis in Biologic-Naive Patients and After First Biologic Experience

M09 An Economic Evaluation of Tofacitinib (Xeljanz) Treatment After One or Two TNF Inhibitors in Rheumatoid Arthritis from the United States Perspective

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.

M12 Impact of Site of Care on the Drug and Administration Costs of Certolizumab Pegol Versus Infliximab in Rheumatoid Arthritis

M13 Increased Out-of-Pocket Costs and Limited Access to Specialists Are Associated with Lower Quality of Care for Patients with Rheumatoid Arthritis

M17 Real-World Treatment Patterns and Demographic, Clinical, and Economic Characteristics of Systemic Lupus Erythematosus (SLE) Patients Initiating Repository Corticotropin Injection Therapy

M18 Clinical Characteristics and Disease Activity in Psoriatic Arthritis Patients with Dactylitis or Enthesitis in a Real-World Setting Results from Corrona Registry

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

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

M21 Misalignment Between Physician and Patient Satisfaction with Current Psoriatic Arthritis Treatment

M22 Satisfaction in Psoriatic Arthritis Patients Despite Active Joint Disease

M23 Medicaid Osteoporosis Drugs Utilization and Expenditures: The Effect of Generic Drugs Market Entry

M24 Adherence and Persistence with Oral Bisphosphonate Therapy Within an Integrated Healthcare Delivery System

M25 Prevalence and Direct Costs of Patients at Risk for Opioid Abuse and Risk Model in Medicare Beneficiaries

N01 Contemporary Anemia Management in U.S. Hemodialysis Patients

N02 Patiromer Lowers Serum K+ and Prevents Recurrent Hyperkalemia in CKD Patients ≥65 Years of Age on RAAS Inhibitors

N03 Trends in the Use of IV Iron and ESAs Under the Prospective Payment System: ESRD Commercial and Medicare Populations

N04 Chronic Diuretic Therapy Does Not Impair the Effectiveness of Patiromer in Hyperkalemic Patients with CKD

N05 Medicare Beneficiaries Initiating Mirabegron Versus Anti-muscarinic Treatment for Overactive Bladder: Patient-Reported Adherence and Claims-Based Adherence Rates

N06 A Prospective Study of Medicare Beneficiaries Initiating Mirabegron Versus Anti-muscarinic Treatment: Patient-Reported Outcomes from the Overactive Bladder Satisfaction Scales (OAB-S)

N07 Network Meta-Analysis of OnabotulinumtoxinA Compared to Mirabegron and Anticholinergics for Overactive Bladder

Q01 Increasing Management of Orphan Drugs

R02 Burden of Illness in Adult Patients with Nocturia

R03 Primary Nonadherence to Overactive Bladder Medications in an Integrated Managed Care Healthcare System

R05 Healthcare Costs Associated with Nausea and Vomiting in Patients Receiving Oral Immediate-Release Opioids for the Management of Acute Pain in the Outpatient Setting

R06 Appraising the Value of Digital Health Technologies from the Managed Care Perspective: Insights for Evidence Assessment and Reimbursement in the U.S.

R07 Predicting FDA Alerts: A Pharmacovigilance Signaling System Based on Past Regulatory Action

R09 A Randomized, Placebo- and Active-Controlled Phase 2b Study Investigating Oliceridine (TRV130), a Novel μ Receptor G Protein Pathway Selective (μ-GPS) Modulator

T05 EPIPEN4SCHOOLS Survey Combined Analysis: Staff Training and Use of Epinephrine Auto-Injectors

U19 Do Low-Cost Physicians Refer to Low-Cost Specialists? Considerations for the Development of Accountable Care Organization Networks

U23 The U.S. Payor Landscape for Specialty Pharmacy: Results from a Survey of Medical and Pharmacy Directors

U25 Factors Associated with Time to Complete a Comprehensive Medication Review for Medicare Part D MTM-Eligible Beneficiaries
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?
U26 Effect of Pharmacist-Supported Transition-of-Care Program on 30-Day Readmission Rates: A Systematic Review and Meta-Analysis
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U33 Primary Care Physician Perception of an E-Newsletter Within a Medicare Advantage Plan
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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

Suvapan 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

Justin Giguere; [F07] Controlled Substances Triple Threat Overlapping Days: Relationship with Healthcare Utilization and Costs

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; [I09] 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 L. 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, MSHS; [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; [B16] Effect of a Novel Prior Authorization and Management Program on HCV Treatment Adherence and Cost

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

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; [U13] Improving Part D Staus 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 ENRESTOTM (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; [G05] Real-World Dosing Patterns Among Patients Receiving Buprenorphine for Opioid Dependence in the United States

Xiaolan Ye; [G05] Real-World Dosing Patterns Among Patients Receiving Buprenorphine for Opioid Dependence in the United States

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

Zobair 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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To evaluate the diagnosis and timing of 30-day readmissions in patients with heart failure, predictive models are needed to identify patients who are at high risk for unplanned re-hospitalization. Due to the high rate of unplanned re-hospitalization in patients with heart failure, readmission rates nationally accumulate to more than 20%. Within 30 days of hospital discharge, heart failure 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 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, 1.58; 95% CI, 1.15 to 2.15) and a length of stay greater than five days (OR, 2.82) 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.
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=0.017). 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), or 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.

**Z27** Association of Socioeconomic and Clinical Factors with Rates of High-Risk Medication Use in Medicare Advantage Plans

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Avalere

**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

**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/HIV coinfection cases from 2003-2007 (OR = 2.32, 95% CI: 1.29-4.20) and 2008-2012 (OR = 0.84, 95% CI: 0.79-0.90) (< 0.05), though not for asymptomatic HIV/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 coinfection 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 are decreasing over time versus asymptomatic HIV/HCV coinfections, more aggressive screening and clinical intervention may be warranted in those with asymptomatic HIV, particularly in rural locations.

**SPONSORSHIP:** None.

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

**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.

B02 Treatment Patterns and Medication Use in Patients with Postherpetic Neuralgia

**BACKGROUND:** Postherpetic neuralgia (PHN), which is a frequent complication of herpes zoster (HZ) infection characterized by chronic neuropathic pain, is a frequent complication of herpes zoster (HZ). 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 data from 2010-2014 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)
that 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.
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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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 compelling for formulary decision-making (mean ranking of 2.17, 2.87, and 4.06, respectively). Sustained virologic response (SVR) was also 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 adjusted associations between regimen type (sofosbuvir + ribavirin, sofosbuvir + simeprevir, sofosbuvir + interferon + ribavirin), demographic characteristics (age, sex, race/ethnicity, homelessness), clinical characteristics (comorbidity, advanced disease, substance use, mental illness), and pharmacy type (community, specialty, hospital-based) and adherence.

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-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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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
patient’s clinical presentation, adherence to current AASLD practice guidelines, and cost savings when appropriate to be completed by a Therapy Management (TM) clinical pharmacist. This also includes an evaluation of the patient’s current medications to screen for drug-drug interactions.

**GOAL:** To characterize the provider and patient education interventions that were completed as a result of the implementation of the proactive clinical evaluation. We investigated the number of interventions, type of interventions, and cost savings associated with these interventions.

**PROGRAM DESCRIPTION:** The TM pharmacist interventions between July 6th, 2015 through November 30th, 2015 were characterized to create this descriptive analysis. The types of interventions were divided into two major categories: HCV regimen interventions and medication reconciliation interventions.

**OBSERVATIONS:** During this five month period there were 552 new HCV patients that had proactive clinical evaluations completed. Out of the 552 patients evaluated there were opportunities for modifying the HCV regimen in 6% (n = 34) of patients. Of these 34 proposed interventions, 62% (n = 21) were accepted. Additionally, of the 552 patients evaluated there were opportunities for provider education based on drug-drug interactions from the patient’s medication list in 50% of patients (n = 276). Of these 276 patients, 5% (n = 15) were on a medication that was contraindicated. Additionally, 37% (n = 103) patients were prescribed ledipasvir/sofosbuvir and were also taking a Proton Pump Inhibitor (PPI) or H2 antagonist.

**FINDINGS/RECOMMENDATIONS:** Proactive clinical evaluation of patient’s HCV regimens and evaluation of their current medications was important to prevent adverse events or unnecessary risk of treatment failure. In addition to identifying shortcomings in prescribed medication regimens, there were a significant number of patients who were at risk for drug-drug interactions with HCV antivirals. An additional benefit of the proactive clinical evaluation process was the cost savings associated with the pharmacist’s interventions. Over the five month period $440,000 in healthcare spending was saved based on the AWP of ledipasvir/sofosbuvir as a result of cost-saving regimen interventions.

**SPONSORSHIP:** There was no external funding for this research.

**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, simeprevir 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 and management 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.

B17 Development of a Specialty Medication Prior Authorization Service at an Urban Academic Medical Center

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BACKGROUND: Many insurance companies require completion of time-consuming prior authorizations (PAs) before approving high-cost medications, such as hepatitis C virus (HCV) treatment. The HCV clinical pharmacist at an urban academic medical center enlisted the help of pharmacy students to complete paperwork associated with HCV treatment.

OBJECTIVE: To develop a PA service program to assist in obtaining HCV medication approval to allow the clinical pharmacist to spend more time on other clinical responsibilities. The service development program offered the students the chance to earn elective class credit while increasing disease state education, clinical training, and opportunities for verbal and written communication skills with patients, providers, and insurers.

METHODS: After training, students developed a protocol for completing PAs, appealing denials, and obtaining PA extensions. They developed a procedure to utilize efficient methods for medication approval as well as documentation of PA status in the electronic medical record. The PA team also referred patients who were uninsured or underinsured to various medication assistance programs. Students collaborated with clinical pharmacist providers to submit documented proof of medical necessity in the event of medication denials. They worked with insurers, specialty pharmacies, and patients to ensure timely approval and receipt of medications.

RESULTS: From May 2014 until March 2015, students spent 240 hours developing the PA protocol and completing 88 PAs; this resulted in an overall medication approval rate of 87.7%. Eighteen patients were identified as having HCV and being co-infected with 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.

CONCLUSIONS: 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 undetectable RNA levels) after completion of antiviral therapy for chronic HCV infection. SVR results are pending regarding the remaining 23 patients.

SPONSORSHIP: Funding for this study was provided by Aetna.

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. 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 undetectable RNA levels) 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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‘Gilead, ‘Landmark Health, ‘OptumRx

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/daclabuvir (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...
Patients in the United States

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/interferon (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 SIM, 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, elvitegravir/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.

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**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: outpatient: 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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**BACKGROUND:** For the treatment-naïve 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 = $6,898 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 = 0.99, RPV/TDF/FTC = $4,899 P = 0.69, and ATV/r + ABC/3TC = $5,855 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.

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**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 effected by PHN.

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

**C00-D49 Neoplasms (e.g., Breast Cancer, Lung Cancer, GIST, Melanoma, CML, CLL, Multiple Myeloma)**

**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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**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 $7,708 per cycle, or $46,246 per year (assuming 6 chemotherapy cycles per patient per
year). Rolapitant’s PMPM cost was estimated at around $0.009, and PMPY at $0.107.

CONCLUSIONS: For a hypothetical plan of 1M members, introduction of oral rolapitant for guideline-recommended prevention of CINV is expected to result in a negligible additional cost of $0.009 PMPM in 2018. The model is conservative since it does not include potential cost-saving of wider rolapitant adoption, e.g. potential decreased treatment costs of delayed CINV events, or improved oncology outcomes due to continued therapy.

SPONSORSHIP: TESARO.

C02 A Conceptual Framework for Value-Based Oncology Treatment: A Societal Perspective
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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 until 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.

C03 Impact of an Oral Oncology Program in Specialty Pharmacy
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BACKGROUND: Oncology has become one of the most rapidly growing sectors in specialty pharmacy. A recent oncology trend report from the Institute for Healthcare Informatics showed total global spending on oncology reached $100 billion in 2014 and is expected to hit $130 billion by 2020. Oral oncology medication adherence is an important factor when it comes to improving progression free-survival and overall survival. For oral anticancer agents, adherence rates were reported to be as low as 20 percent, due to treatment-related factors that include expensive medications, complexity of regimens, and undesirable side effects. The Commcare Oncology Assist program was designed to help improve medication adherence, provide patient education, and reduce healthcare costs through clinical interventions.

OBJECTIVE: To assess the impact of an oral oncology program that focuses on increasing medication adherence, managing side effects and assisting with financial assistance for specialty oral oncology medications.

METHODS: A retrospective review Commcare’s oncology patients (n = 3,639) from January 2014 through October 2015 assessed overall adherence rates, pharmacist interventions, financial assistance, and cost savings associated with the program. Patients enrolled in Oncology Assist are contacted by an oncology clinical pharmacist or nurse prior to starting therapy and once every two weeks for the first two months to assess medication adherence and tolerability. Follow-up calls then continue on a monthly basis. Other follow-up methods included smart phone text message and e-mail.

RESULTS: Adherence was measured using medication possession ratio (MPR). Compliance with drug therapies significantly improved among patients enrolled in Oncology Assist, compared to published studies. The adherence rate for patients in the Oncology Assist program have an average MPR of 93.8 percent (n = 357). Additionally, the average length of therapy for the top oral oncology medications was 8 months duration. Clinical pharmacists documented 360 interventions with an associated cost avoidance of $252,000. Furthermore, of the 38 percent that required copay assistance, the program has helped 80 percent of those patients lower their copays substantially.

CONCLUSIONS: Specialty pharmacy programs such as Oncology Assist have the ability to promote medication adherence, improve survival rates, and reduce costs. These programs, implemented globally, can improve overall population health and patient outcomes.

SPONSORSHIP: This research was completed by Commcare Specialty Pharmacy without external funding.

C04 Industry Diagnostic Test Information Provision Versus Expectations
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BACKGROUND: Targeted drug therapy, biomarkers, and companion diagnostic tests (CDT’s) are increasingly being used to guide therapeutic decisions. The importance of this is seen in the CDT Addendum included in The AMCP Format for Formulary Submissions Version 3.1 detailing CDT evidentiary standards payers need to make formulary decisions on corresponding medications.

OBJECTIVE: To characterize how drug and CDT manufacturers respond to unsolicited information requests about FDA approved,
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.

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**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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Sanofi U.S.

**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 $0.3150. Changes in the utilization rates of biologic agents including, for example, a hypothetical increase in ziv-aflibercept...
utilization (3.4% to 20.1%), would decrease annual costs by 5.932% ($366,579) to $5,813,487, a PMPM cost decrease of $0.0305. The model suggested that these cost savings were primarily due to lower unit costs for ziv-aflibercept and lower death-related costs (costs incurred for resources used in the month of death and 2 months before), rather than decreased adverse event management.

CONCLUSIONS: The model estimates a PMPM cost saving with increased utilization of biologics, including ziv-aflibercept. Inclusion of additional user-defined scenarios allows plan-specific modeling of 1-year budgetary impact.

SPONSORSHIP: Sanofi U.S.

C07 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 receive treatment until progression or death. 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, an additional 0.44 quality 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).

SPONSORSHIP: This work was funded by Genentech.


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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 (pemetrexed/carboplatin, pemetrexed/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 cost 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.

C10 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 time-frame, 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 discontinued crizotinib within one year. Because 33% patients without CNS involvement at crizotinib initiation developed brain metastasis while on crizotinib treatment within a year, options with central nervous system activity are necessary.

SPONSORSHIP: Genentech.

C12 Comparative Effectiveness of Everolimus-Based Therapy Versus Fulvestrant Monotherapy Among Postmenopausal Women with HR+/HER2- Metastatic Breast Cancer: A Real-World Analysis

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BACKGROUND: Clinical evidence supports the use of everolimus-based therapy (EVE) and fulvestrant monotherapy (FUL) among postmenopausal women with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2−) metastatic breast cancer (mBC) whose disease progressed on a nonsteroidal aromatase inhibitor (NSAI). However, direct evidence is lacking on the comparative effectiveness of these agents.

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

METHODS: This retrospective chart review examined postmenopausal HR+/HER2− mBC patients in community-based oncology practices who received EVE-based therapy or FUL monotherapy (index therapy) for mBC after NSAI. Stratified sampling was used and quotas were implemented to ensure sufficient sample size in each treatment group by line of therapy (first, second, third, later line). PFS from index therapy initiation was used and compared using Kaplan-Meier analyses, and hazard ratios (HR) were estimated using a Cox proportional hazards model adjusting for index therapy line and characteristics at mBC diagnosis and index therapy initiation.

RESULTS: A total of 192 and 156 patients received EVE or FUL, respectively. 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 had 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.

C13 Time on Treatment of Everolimus, Fulvestrant, and Capecitabine for the Treatment of Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative (HR+/HER2-) Metastatic Breast Cancer (mBC): A Retrospective Claims Study in the U.S.

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BACKGROUND: Treatment guidelines for HR+/HER2− mBC recommend extending the time on treatment (TOT) of endocrine therapy (ET) before the initiation of chemotherapy (CT) to avoid its serious side effects and preserve patients’ quality of life. Everolimus-based therapy (EVE), fulvestrant monotherapy (FUL), and capecitabine monotherapy (CAP) are among the ET and CT agents approved for the treatment of HR+/HER2− mBC in the U.S.

OBJECTIVE: To compare TOT among postmenopausal HR+/HER2− mBC patients who received EVE vs. FUL or CAP.

METHODS: Patients who initiated ≥ 1 new line of therapy for mBC between 7/20/2012 (EVE approval date, latest of the therapies) and 3/31/2014 (allows ≥ 3 months potential follow-up) after a nonsteroidal aromatase inhibitor were identified from the MarketScan Commercial and Medicare Supplemental and PharMetrics databases using an algorithm adapted from the literature. Treatment discontinuation was defined as a treatment gap ≥ 60 days. Patients’ lines of therapies were classified into mutually exclusive regimen groups (i.e., EVE, FUL, CAP) and followed until discontinuation of the line of therapy, end of insurance eligibility, or data cutoff (6/30/2014). Treatment-level analyses were conducted. Patients who did not discontinue their treatment were censored at the end of follow-up. TOT was compared between EVE vs. FUL or CAP 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,
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 \( [HR] = 0.87, 95\% \text{ confidence interval} \ [CI] 0.76-0.99 \)) 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 (TOTT) 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 \( [HR] = 0.37, 95\% \text{ confidence interval} \ [CI] 0.22-0.63 \)), PFS (HR = 0.70, 95\% CI: 0.50-0.97), and TOTT (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 TOTT 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 TOTT 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 discontinuation, 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 = -$3,453, P < 0.01) and BC-related ($2,510, P < 0.01) total medical costs. Cost differences were driven by lower IP ($1,897, P < 0.01) and OP ($1,595, P < 0.01) service costs.

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 (ABT) 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-naïve 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 26 and the associated cost was $57,467.

**CONCLUSIONS:** The results of the present study suggest that treating chemotherapy-naïve 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 for 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. To compare real-world OS and PFS among 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 extent to which 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 discontinued 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 for all subgroups, except for pts with <6 months on sunitinib or sorafenib as 1st TT [HR (95% CI): 2.98 (1.10, 8.12)]. 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.

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 Pharrmatics 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 $263,437. 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 average 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 or Improvement of Carcinoid 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: Carcinoid syndrome is a clinical entity that is associated with a significant disease burden. It is associated with a range of symptoms, including diarrhea, flushing, abdominal pain, and hypotension.

OBJECTIVE: To assess the economic benefits associated with resolution or improvement of carcinoid syndrome symptoms following treatment with above-standard dose of octreotide LAR in patients with neuroendocrine tumors.

METHODS: Patients with neuroendocrine tumors treated with octreotide LAR at above-standard dose were included in this chart review study. The chart review was conducted across 28 U.S. institutions. The primary outcome was the percentage of patients who experienced resolution or improvement in symptoms.

RESULTS: A total of 100 patients were included in the analysis. The majority of patients (80%) experienced resolution or improvement in symptoms. The average cost savings per patient was $5,000, with a range of $1,000 to $10,000. The average time to resolution or improvement was 12 weeks, with a range of 8 to 16 weeks.

CONCLUSIONS: The chart review demonstrated that treatment with above-standard dose of octreotide LAR is associated with a high percentage of patients experiencing resolution or improvement in carcinoid syndrome symptoms, with significant cost savings. Further research is needed to validate these findings in a larger population.

SPONSORSHIP: This research 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-Efficacy 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 ($243,452) and 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.

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

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BACKGROUND: Lenalidomide (LEN), an immunomodulatory agent and bortezomib (BTZ), a proteasome inhibitor (PI), have become standards of care in the treatment of multiple myeloma (MM). A majority of patients with MM experience relapse. While treatment of RRMM is rapidly evolving, unmet needs remain for novel therapies whether they be monotherapies or synergistic combinations with an immunomodulatory compound or PI in the appropriate patients.

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 OPTIMISMM study. A second indication for the PI 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. Daratumumab (DAR), a monoclonal antibody (mAb), was approved in 11/2015 for monotherapy use; however, Phase III trials of DAR in triplet regimens, in combination with LEN/DEX (Pollux trial) and in combination with BTZ/DEX (Castor trial), are underway.Ixazomib (IXA) from the PI class was approved in 11/2015 in combination with BTZ/DEX based on 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

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

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OBJECTIVE: To evaluate the cost-effectiveness of second-line nilotinib (NIL) vs. dasatinib (DAS) at 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 $4,106,265; initiating second-line with DAS was associated with 9.51 LYs, 7.30 QALYs, and total costs of $4,118,235. 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

Long-term CML Treatment with Tyrosine Kinase Inhibitors in a National Cohort of Veterans

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BACKGROUND: The introduction of Tyrosine Kinase Inhibitors (TKIs) was a breakthrough in the treatment of CML that drastically improved outcomes. Since TKIs have been broadly accepted into clinical practice, long-term treatment patterns need to be elucidated to allow the development of pragmatic expectations and optimization of treatment.
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 institutions 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 4.4% of patients receiving first-line treatment experienced a ≥60-day gap in therapy. First-line treatment persistence rates were 75%, 65%, and 53% 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 before 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

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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.

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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1Evidera; 2Amgen

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., 2013) 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 vs. 18.0 and 57.9 vs. 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.

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.
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 29.7 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 or Vd in panobinostat’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.
In a hypothetical 1-million member Medicare health plan were performed for a 1-year time horizon. Sensitivity analyses were performed 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 within 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, \(P = 0.0008\)) and baseline comorbidities of cardiomyopathy (OR: 1.776, \(P = 0.0008\)) and thrombophlebitis (OR: 4.881, \(P = 0.0008\)).

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.
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 IU ($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
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).

CONCLUSIONS: In a real-world setting, a considerable proportion of MF patients discontinued RUX treatment or required dose adjustment. Dose adjustment was associated with cytopenias and increased healthcare costs. These findings suggest the need for improved pharmacologic management of MF.

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

**D06 Patterns and Predictors of Repository Corticotropin Injection Therapy Use in Patients with Sarcoidosis**

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BACKGROUND: Sarcoidosis is a rare, cryptogenic disease involving abnormal collections of inflammatory cells (granulomas) throughout the body. Estimated prevalence in the U.S. is 1 to 40 cases per 100,000 and varies by race. Corticosteroids are usually first-line treatment. In advanced cases, other treatments such as cytotoxic agents, anti-malarial medications, tumor necrosis factor-alpha (TNF-a) inhibitors, rituximab, or repository corticotropin injection (RCI; H.P. Acthar Gel) may be used in real-world clinical practice.

OBJECTIVE: To describe the profile of sarcoidosis patients receiving RCI and predictors of its use.

METHODS: Claims of sarcoidosis patients were combined from three commercial health insurance databases in the U.S. from July 1, 2009 to June 30, 2014. Demographics, clinical characteristics, hospitalizations, and total costs were examined in the year prior to RCI. Odds ratios (OR) and 95% confidence intervals (CI) were calculated from a logistic regression model to examine potential predictors (demographics, type of sarcoidosis, prior medications, disease scores, prior resource use, prior cancer, and prior organ transplant) of RCI use compared to other later line treatments.

RESULTS: A total of 170,913 patients were identified with a diagnosis of sarcoidosis with 58 (0.03%) 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, 3.89) 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.

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

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Magellan Rx Management

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, and members all decreased in the first quarter 2015 by 17%, 11%, 7%, 9%, and 7%, respectively, compared with the first quarter 2014.

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.
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 baseline 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: 1,659 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 IVlg 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.

E02 Medication Adherence Among 340B Patients with Hypertension, Hyperlipidemia, and Diabetes
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BACKGROUND: The 340B Drug Pricing Program is a federal drug discount program that requires participating drug manufacturers to provide outpatient drugs to eligible health care organizations at significantly reduced prices permitting such organizations to stretch scarce federal resources. The current research findings provide the first empirical evidence on how the program impacts patient outcomes.

OBJECTIVE: To determine whether patients with diabetes, hypertension or hyperlipidemia (all among the top five therapeutic classes for which 340B prescriptions are dispensed), who receive medications for these diseases through a 340B program have higher medication adherence rates than a comparable patient population which does not receive medications through the 340B program.

METHODS: This retrospective propensity matched cohort study compared medication adherence for a national sample of patients who received medications through a 340B program to a matched cohort of patients who did not receive 340B-purchased medications between years 2008 and 2014. Patients were matched by state, age, gender, initial dispensing year, generic dispensing rate, and 91 therapeutic classes. Medication adherence was measured using the proportion of days covered (PDC) metric. One-to-one matching resulted in approximately 90,000 matched pairs. We used mixed modelling methods to assess statistical differences.

RESULTS: Among the patients who received medications through a 340B program and whose prescriptions for such medications originated from 340B clinics (e.g., Consolidated Health Center Programs and Title X Family Planning Clinics), mean medication adherence was 5% higher for patients with diabetes, 3.4% higher for patients with hyperlipidemia, and 2.9% higher for patients with hypertension than the respective comparison cohort. Patients who received medications through a 340B program and whose prescriptions for such medications originated from 340B hospitals (e.g., Disproportionate Share Hospitals and Critical Access Hospitals) showed greater advantages in medication adherence relative to the general patient population. Mean medication adherence was 7.2% higher for patients with diabetes, 6.0% higher for patients with hyperlipidemia, and 5.0% higher for patients with hypertension.

CONCLUSIONS: The results from this study show that patients who receive medications through a 340B program have higher medication adherence rates than comparable patients who do not receive medications through the program.

SPONSORSHIP: Walgreen Co and University of Chicago.

E03 Diagnosis and Treatment of Osteoporosis Before and After Fragility Fractures: A Side-by-Side Analysis of Commercial Osteoporosis Patients and Medicare Advantage Osteoporosis Patients
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BACKGROUND: Osteoporosis (OP) is largely untreated and undiagnosed.

OBJECTIVE: To determine the rates of OP diagnosis and treatment in the year pre- and post-index fragility fracture in Medicare Advantage and Commercial populations, and to characterize those patients.

METHODS: The study was conducted using two databases: Humana Medicare Advantage claims (Medicare), and Optum Clininformatics Data Mart commercial claims (Commercial). No comparisons were made between the databases. Patients were included in the study if they had a claim for an OP-related fracture (for Medicare patients a Medicare benefit on the claim was required), were continuously enrolled in the health plan for 1 year before (baseline) and after (follow-up) the index fracture, and were 65 + years old in Medicare or age 50+ in commercial data at index fracture. Patients were excluded if they had a fracture claim in the year prior to the index date at the same fracture site, or comorbidities associated with fracture such as metastatic cancer. Descriptive statistics for baseline characteristics, comorbidities, and diagnosis and treatment rates pre- and post-fracture were calculated. All analyses were conducted by fracture type (vertebral, hip, non-hip non-vertebral (NHNV), multiple).

RESULTS: 45,603 patients were identified for inclusion in Medicare and 54,145 were identified in commercial claims. The mean ages of Medicare and commercial patients were 78 years and 62 years, respectively. In Medicare, 28% of patients were male and 72% were female, whereas commercial patients were 38% male and 62% female. At baseline, OP diagnosis rates ranged from 12-15% (Medicare) and 6-12% (commercial) for all fracture types, with the exception of vertebral fracture patients (21% Medicare). After fracture, osteoporosis diagnosis rates almost doubled for most fracture types but did not exceed 42% (vertebral) in Medicare and 28% (vertebral) in commercial. Treatment rates at baseline were similarly low, ranging in Medicare...
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 26.3% (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.

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**E18 The Relationship Between Digital Health Program Activity Tracking and Medication Adherence Among Members Age 50+ Years**

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**Walgreens Co.**

**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 Proportion 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 ∆ = 5.6%; P < 0.0001; % OA ∆ = 11.2%; P < 0.0001; HL: PDC ∆ = 2.9%; P < 0.0001; % OA ∆ = 4.5%; P = 0.0007). Higher biometrics activity tracking was also associated with higher adherence to antihypertensives and oral antidiabetics (HTN (≥ 2x weekly): PDC ∆ = 3.0%; P < 0.0001; % OA ∆ = 6.8%; P < 0.00192; DB (≥ 1x weekly): PDC ∆ = 5.2%; P = 0.0005; % OA ∆ = 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 136 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.

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
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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 DM (T1) and Type 2 DM (T2) and trends in DM drug therapy in a commercial population to support use and cost modeling of new insulins.

METHODS: All commercially insured members in 12 health plans continuously enrolled between 1/1/2011 and 6/30/2015 were defined as being treated for T1 or T2 if they had a pharmacy claim (Rx) for any DM drug other than Metformin (Met) or Met with two or more medical claims with a diagnosis code (Dx) for DM, excluding those whose only Dx was for gestational DM. Those with only non-insulin or insulin + non-insulin other than Met or Parlmidine were categorized as T2. Next, those with T1 Dx > 50% of total T1 or T2 Dx claims or younger than 40 years or with a Dx for diabetic ketoacidosis were categorized as T1. All remaining were categorized as T2. Diabetes Rx cost and regimen were determined in each 6-month interval. Incidence of new DM drug therapy was defined as members whose first Rx was later than 6/30/2011, and T2 members adding or switching to insulin as those whose first insulin Rx was > 183 days after first non-insulin DM Rx.

RESULTS: There were 3,947,165 members in the sample; mean age 39.4 years. Over 4 years: T1 increased 13.4% from 0.335% to 0.380%; T2 with insulin increased 65.7% from 0.64% to 1.06%; T2 with only non-insulin increased 39.7% from 2.69% to 3.76%; incidence per year per 1,000 members of new T1 therapy was 21 and new T2 therapy 601, 9.3% T2 members added or switched to insulin; cost of insulin Rxs increased from 3.0% to 5.4% of cost of all pharmacy benefit drugs for sample members; and mean cost per treated member for all DM Rxs for 6 months increased 95.2% for T1 from $1,310 to $2,556, T2 with insulin 109.2% from $1,596 to $3,338, and T2 with only non-insulin
E24 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 age ≥18, had 12 months of continuous enrollment prior to (baseline [(B/L) period]) and after (follow-up [F/U]) the index date, evidence of T2DM, no pharmacy claims for an anti-diabetic agent in the B/L period and no claims for insulin in the B/L or F/U periods. 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 = 0.025). 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.

E25 Evaluating Cost of Therapy and Clinical Efficacy with V-Go in Patients with Sub-optimally Controlled Diabetes from an Endocrine Specialty System

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BACKGROUND: Managing diabetes can produce significant expenditures and the steady rise in the cost of insulin presents a financial dilemma for many patients and payers. The affordability of insulin can affect adherence which can impact rates of diabetes-related health complications. These events may affect overall health care costs due to needed medical intervention including emergency room visits, hospitalization, and other therapy considerations. Addressing patients’ concerns for an affordable and efficacious insulin regimen is necessary as the number of people with diabetes increases and subsequently those that will need insulin therapy.

OBJECTIVE: To evaluate costs and efficacy for patients with sub-optimally controlled diabetes being switched to the V-Go Disposable Insulin Delivery Device (V-Go) to simplify insulin delivery.

METHODS: An electronic medical records database from a large endocrine system was queried. The efficacy variable was the reduction in A1C for patients on insulin at baseline switched to V-Go. Cost evaluation was calculated using wholesale acquisition cost (WAC) pricing for insulin, delivery devices, and concomitant antidiabetic medications (CAM).

RESULTS: Sixty patients were identified who had transitioned to V-Go therapy from previous insulin therapies. At baseline patients had an average of 9.6 ± 2.08% body weight of 95 ± 20.35 kg, and total daily insulin dose (TDD) of 82 u/day (0.86 u/kg). Additionally, 58% (N = 35) were on CAMs and 77% (N = 46) were on multiple daily insulin injections (MDI). At the 1st office visit (OVI) with a mean duration of 61 ± 36 days, switching to V-Go resulted in a mean A1C reduction of -1.2 ± 1.6% (P < 0.0001) and a 50% reduction in patients with an A1C ≥ 9.0%. Despite the robust improvement in A1C the overall incidence of reported hypoglycemia was similar to baseline and there was a mean increase of 2.1 ± 19.43 kg in weight observed. Baseline cost of $950 per patient per month (PMPM) was reduced to $867 PMPM in part due to a 22% (-19 u/day-21 u/kg) TDD reduction. Additional realized savings were attributed to having a reduced percentage of patients on CAM (58 to 50%).

CONCLUSIONS: Patients with sub-optimally controlled diabetes switching to V-Go achieved significant A1C improvements with a reduction in TDD and an improved cost impact for payers which should improve affordability for patients. This real world assessment validates similar findings of previous observations with V-Go.

SPONSORSHIP: Grant for data collection sponsored by Valeritas.

E26 Translating Trial-Based Efficacy and Safety into Cost-Comparison for New Insulin Glargine 300 U/mL (Gla-300)

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BACKGROUND: In the EDITION 1, 2, and 3 trials, Gla-300 provided similar glycemic control to insulin glargine 100 U/mL (Gla-100) with fewer hypoglycemic events in patients with type 2 diabetes (T2D).

OBJECTIVE: To (a) test the hypothesis that Gla-300 will offset all or part of health plan costs from a reduction in the number of hypoglycemic events, using a hypothetical patient population corresponding to patients in the EDITION trials and (b) design a cost comparison model (CCM) to estimate hypoglycemia-related cost offsets of
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 Gla-100 in U.S. patients with T2D. Three T2D patient-population subgroups were analyzed: previous basal-bolus insulin-naive (AD; n = 878). Severe and non-severe 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 Gla-100 are the same over the entire T2D population.

RESULTS: Across T2D populations over 6 months, the incremental per-patient cost for treatment with Gla-300 vs. Gla-100 was -$33.19. In the overall T2D population and in two of the three groups, Gla-300 was dominant over Gla-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 regimen of non-insulin antidiabetes drugs. For this subgroup, Gla-300 was associated with $49.31 higher pharmaceutical costs, $9.52 lower medical costs, and 0.71 lower 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 Gla-100 over the entire T2D population. The cost offset is driven by a lower rate of hypoglycemic events and hypoglycemia-associated costs. Previously insulin-naive 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.

E27 Total Budget Impact of Insulin Glargine 300 U/mL (Gla-300) to a Health Plan in the U.S. Setting

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BACKGROUND: In the light of rising pharmacy spending, new therapies, and budgetary constraints, health plans and other decision makers need to consider the cost implications of adding new therapeutic options to their formularies; it is important to estimate the projected cost of incorporating these new agents into a health system.

OBJECTIVE: To estimate the budget impact of introducing Gla-300 for the treatment of type 1 diabetes (T1D) and type 2 diabetes (T2D) to the formulary of a U.S. health plan, using a user-friendly, customizable, Excel-based budget impact model (BIM).

METHODS: The BIM is implemented as a Markov cohort model with a 6-month cycle length using T2D patient populations corresponding to the Gla-300 EDITION trials. The patient groups were: T2D with (1) previous basal-bolus insulin, (2) previous basal insulin + non-insulin antidiabetes drugs, or (3) insulin-naive; and (4) T1D with previous basal-bolus insulin. Based on results from EDITION, the model assumed Gla-300 was comparable with other basal insulins in terms of effectiveness and safety, with lower hypoglycemia rates. Treatment-use data came from EDITION results for Gla-300 and from published literature for comparators. The budget impact of Gla-300 was estimated against market shares of other basal insulins, glucagon-like peptide-1 receptor agonists, and oral agents (e.g., dipeptidyl peptidase 4, sodium glucose co-transporter 2 inhibitors etc.). Pharmacy, supplies/monitoring, and hypoglycemia-related medical costs were included. The base case scenario was from the perspective of a commercial health plan with a hypothetical cohort of 1 million members containing 5,095 T1D and 14,869 T2D, respectively. The cost of Gla-300 was estimated to maintain dose adjusted parity with Gla-100. The base case analysis provides a 1-year analysis timeframe.

RESULTS: Total annual incremental cost for adding Gla-300 was -$202,592; incremental costs per member per month were -$0.017 and incremental costs per treated member per month were -$0.846. Lower pharmacy costs for Gla-300 (-$113,276) were based on taking market share from more expensive comparators. Cost savings of -$81,416 were estimated for treating hypoglycemia and -$7,900 for supplies/monitoring.

CONCLUSIONS: Introduction of Gla-300 to a U.S. commercial health plan is associated with a minimal but favorable budget impact on per-member costs, driven by market capture from more expensive treatments and also by offsets from lower hypoglycemia-related costs.

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

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

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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), 0.95 (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.
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**


**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. In this study, more than 10% of patients experienced 30-day readmission. Females had lower likelihood of readmission. 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.

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


**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. 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:** 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 discriminant ability that could target readmission reduction programs.

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

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: 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 (FPG), 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 317 diabetic individuals who returned for a screening one year later, significant differences in glucose and BMI were observed between the intervention and pre-intervention time frames.
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.

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**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 A1c (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 0.91, \(P = 0.13\); OR 1.12, \(P = 0.10\)), new or worsening diabetic complications (OR 0.97, \(P = 0.53\); OR 1.05, \(P = 0.48\)), 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; \(P = 0.778\)), 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.

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**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, 20.4%) and TZDs (n = 56, 28.7%) 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.

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**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.
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

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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-naive, 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 lixisuglude, 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 ($4,161 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.

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.
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 glycemic goals (60% for V-Go and 52% for MDI). The mean direct pharmacy cost difference PPPM for all patients achieving glycemic targets was $309 for V-Go and $439 for MDI from baseline.

CONCLUSIONS: Administration of IIT using V-Go resulted in overall more patients achieving A1C targets at a lower incremental cost than those using MDI to deliver insulin.

SPONSORSHIP: Independent review board funded by Valeritas.

E40 Use of Statins and the Risk of Incident Diabetes: A Retrospective Cohort Study
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BACKGROUND: Even though several landmark statin trials have demonstrated the beneficial effects of statin therapy in both primary and secondary prevention of cardiovascular disease, several studies have suggested that statins are associated with a moderate increase in risk of new-onset diabetes. These observations prompted the FDA to revise statin labels to include a warning of an increased risk of incident diabetes mellitus as a result of increases in 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 ofLovastatin, 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.

E41 Development and Validation of a Tool to Predict Non-adherence to Oral Antidiabetic Drugs in Medicare Beneficiaries
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BACKGROUND: The low adherence to oral antidiabetic drugs (OADs) in the Medicare population has been an issue that can greatly reduce CMS star ratings for managed care organizations (MCOs).

OBJECTIVE: To develop and validate a risk assessment tool to proactively predict and identify high risk patients within MCOs expected to be non-adherent to OADs using Medicare claims data.

METHODS: In this retrospective cross-sectional study claims data of members enrolled in a Medicare Advantage Prescription Drug (MA-PD) program in Houston, TX were used. Baseline data from 2012 were used to identify key variables to predict non-adherence in the follow-up period (2013). Members 65 years and older with diabetes diagnosis, at least one prescription for OADs (biguanides, sulfonylureas, thiazolidinediones, or dipeptidyl peptidase -IV inhibitors), no insulin prescription, and continuously enrolled for both years were included in the study. The outcome of interest was non-adherence to OADs in 2013, defined as proportion of days covered (PDC)=80%. Multivariable logistic models using 200 bootstrap replications (with replacement) identified factors associated with non-adherence. The final model was tested for discrimination and calibration statistics; and validated using 10-fold cross-validation. Using weighted ß-coefficients of the predictors, the risk assessment tool was created to stratify non-adherence risk. The tool was tested for sensitivity, specificity, positive prediction value, and negative prediction value.

RESULTS: A cohort of 7,028 MA-PD members resulted in seven predictors that were statistically significant in >50% of the bootstrapped samples identified from the logistic models. Variables identified were: age, total number of refills of OADs, total number of different classes of OADs that were refilled, days of supply of OAD that was last refilled, pill burden, coverage of last OAD refilled, and past adherence. The final model demonstrated good discrimination (C-statistics = 0.75) and calibration (Hosmer-Lemeshow goodness-of-fit P = 0.05) statistics, with high internal validity (area under the curve = 0.73). The risk assessment tool demonstrated good sensitivity statistics; sensitivity = 0.73, specificity = 0.63, positive prediction value = 0.74, and negative prediction value = 0.62.

CONCLUSIONS: Pharmacists in MCOs can use the validated risk assessment tool to effectively identify their high risk patients expected to be non-adherent to OADs and develop targeted intervention programs which can assist in improving the MCOs CMS star ratings.

SPONSORSHIP: This study was partially funded by Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation.

E43 Comparing Medical Utilization Between Insulin Pen and Vial Users Within a Pediatric Medicaid Accountable Care Organization
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BACKGROUND: Type 1 diabetes (T1DM) is commonly managed with exogenous insulin administration via insulin pens or vials. Although vials are less expensive than pens, studies have shown cost effectiveness of insulin pens over vials when considering the correlation on health outcomes such as: medical utilization, hypoglycemia,
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 the 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-II), 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 (1-year 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 A1C levels > 9% at Gla-300 initiation, there was significant reduction in mean A1C to 8.35% in the 6-month period prior to starting Gla-300 therapy. After Gla-300 initiation, there was significant reduction in mean A1C to 8.25% (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.
E60 Evaluation of a Linked Database for Cystic Fibrosis Research on Clinical, Demographic, and Resource Use Variables
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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 277.0x) 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 need to assess the generalizability of this resource to determine its strengths and limitations for research along with the availability of cost data.

SPONSORSHIP: This survey was conducted by Shugoll Research in partnership with and funded by the Cystic Fibrosis Foundation.

E61 Impact of Cost Sharing on Access to Care for Patients with Cystic Fibrosis
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BACKGROUND: The rising cost of health care coupled with a trend toward increased patient cost sharing is of significant concern in the cystic fibrosis (CF) community. A 2014 Commonwealth Fund study found nearly one in four privately insured adults with deductibles under 5% of their annual income skipped needed care; this rose to 40% of individuals with deductibles accounting for 5% or more of their income. With specialty medications and care forming the core of the CF treatment regimen, higher costs for CF patients could impact access to timely and lifesaving care.

OBJECTIVE: To determine the impact of out-of-pocket costs on access to care and treatments for patients with cystic fibrosis.

METHODS: An anonymous online survey was sent to 17,513 viable email addresses, 1,082 cystic fibrosis patients or caregivers responded in full. The survey collected information on patient demographics, cost sharing responsibilities and their impact on care-seeking behavior, insurance coverage, and the use of supplemental coverage or financial support.

RESULTS: Ninety-nine percent of patients reported having health insurance in 2015. Of those insured, 20% had two forms of insurance. A third of patients reported coverage by Medicare, Medicaid, CHIP, or a state program. Due to cost concerns, 22% of patients reported delaying medical care and 24% reported taking fewer or smaller doses of prescribed medications. Patients with higher out-of-pocket responsibilities or lower household incomes reported delaying care or reducing medications more often than those with lower out-of-pocket expenses or those in the highest income bracket. Patients covered by Medicaid or Medicare reported reducing the dose or frequency of prescribed medications significantly more often than those with other types of insurance (29% and 46%, respectively).

CONCLUSIONS: This survey informs payers of the financial burdens that influence care-seeking behavior and access to care for patients with cystic fibrosis. Individuals covered by publicly funded programs, those with higher out-of-pocket expenses, and those with lower household incomes are more sensitive to elevated out-of-pocket spending and more likely to reduce doses of prescribed medications or delay seeking care as a result. For patients with CF, such reductions in care or treatment could result in serious adverse health consequences. Further research should address the impact of cost-sharing on clinical outcomes.

SPONSORSHIP: This survey was conducted by Shugoll Research in partnership with and funded by the 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 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 in MDCR, focusing on prevalence, mortality, medical utilization and cost.

METHODS: This was a descriptive claim-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 (PPPM) 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 Truven 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 43.3% 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 prescriptions 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.
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), 47.0% 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: Vertex Pharmaceuticals.
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.

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 test 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 overlap days (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.

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

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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.

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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 overlap days (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.
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 (BI, Probuphix) 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 BI 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: BI 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 BI 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 pharmacokinetic profile of the implants. While these results should be confirmed in subsequent studies, it can be conservatively concluded that BI treatment used for stable opioid dependent patients will have a positive societal benefit beyond the current standard of care.

SPONSORSHIP: Braeburn Pharmaceuticals.

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 ‘opioid 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 nondiagnostic 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 75% 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. 4.3, 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; $25,693 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: Pfizer.

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 a mean excess costs of Abuse of $9,847 (2012 USD).

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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.

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### 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 overdose. 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 users, opportunity still exists to curb opioid overdose 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 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.

Medication Adherence as a Predictor of Switching Oral 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 injectables 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, 2015. 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.
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 grouped in low-cost or high-cost categories using a threshold of $200.

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 CDs. 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 care 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
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 \( \geq 1 \) inpatient or \( \geq 2 \) 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 \( \geq 0.80 \) 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 \( \geq 12 \) 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 2013 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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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 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 65%, 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.
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% confidence interval [CI]: 1.18-1.23, P < 0.001). The second cohort consisted of 28,459 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 Analystsource). 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 $141,579 in year 3 (or an annual cost savings of $94,384 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 Pharmaceuticals.

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 pre-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) and 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
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. 5.3%; 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).

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 co-morbidities were associated with worse adherence.

SPONSORSHIP: AbbVie
Impact of Natalizumab on Multiple Sclerosis
Relapse-Related Costs in a Real-World Setting

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BACKGROUND: In clinical trials, natalizumab reduced relapses in relapsing-remitting multiple sclerosis (MS) and, in a real-world study, reduced MS-related inpatient costs and corticosteroid use. However, the impact on overall MS relapse-related costs in real-world settings is unknown.

OBJECTIVE: To compare the one-year MS relapse-related costs prior to and after initiating natalizumab.

METHODS: MS patients were identified from 7/1/10 to 12/31/13 using SelectHealth insurance claims if they had: (1) ≥2 claims for MS (ICD-9: 340) OR (2) ≥1 claim for MS plus a claim for any MS disease-modifying therapy (DMT). Included patients were adults (≥18 years) with ≥2 claims for natalizumab (first claim defined initiation), were continuously enrolled for ≥1 year pre- and post-initiation, and had ≥1 natalizumab claim from a local MS clinic to facilitate future analyses using chart data. Patients with Crohn’s disease or ulcerative colitis otherwise meeting criteria were excluded. Relapses were defined as either: (1) an inpatient claim with a primary ICD-9 for MS or (2) an outpatient claim with a primary or secondary ICD-9 for MS with ≥1 corticosteroid claim within 7 days. Outpatient claims were excluded if asthma, chronic obstructive pulmonary disease, gout, or rheumatoid arthritis was the primary or secondary ICD-9. Relapse events within 30 days were considered a single relapse. Relapse-related costs were the sum of all inpatient MS, outpatient MS, and corticosteroid claims during a relapse. Comorbidities were reported using descriptive statistics and adherence was assessed using proportion of days covered (PDC). Pre- and post-initiation MS relapses and relapse-related costs were compared using Wilcoxon signed-rank tests.

RESULTS: A total of 297 patients received natalizumab during the study period and 69 of those met all inclusion criteria. Mean (SD) age was 42.6 (11.6) years, 59% were female, and 81% were commercially insured. The most common comorbidities were depression (17%) and hyperlipidemia (13%). No pre-initiation claims for DMTs were found in 61% of patients and mean PDC for natalizumab was 75%. The mean number of relapses in the pre- and post-initiation years was 0.41 (0.67) and 0.35 (0.72), respectively (P=0.71). MS relapse-related costs significantly decreased from the pre- to the post-initiation years [mean: $1,217 ($2,894) vs. $604 ($2,328), P=0.03].

CONCLUSIONS: Natalizumab resulted in a significant reduction of MS relapse-related costs in the year following initiation in a real-world setting.

SPONSORSHIP: This work was sponsored by a grant from Biogen.
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 stated 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 based 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 44.5 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% vs. 19.7%).
Patients with an MS diagnosis between 10/1/2010 and MS-diagnosed, disease-modifying therapy (DMT) users in a large U.S.

OBJECTIVE: To describe first-switch treatment patterns amongst (MS) treatment in 2010, several highly effective treatments have been

BACKGROUND: Since the emergence of the first oral multiple sclerosis

covering > 37 million lives. Patients were aged ≥ 18 years, with ≥ 12

Database, a nationally representative U.S. commercial health plan

5/31/2014 were identified from the HealthCore Integrated Research

overall first-switch rate was 24.6%. The proportion of patients switch -

or MS diagnoses in the pre-index period, and ≥ 1 DMT in the post-

after the earliest MS diagnosis date (index date), with no DMT claims

months of continuous medical and pharmacy eligibility before and

POST-INDEX FOLLOW-UP WAS 934.6 DAYS (MEDIAN, 889 DAYS), WITH 599

(mean, 169 days) 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

1Healthcore; 2Genentech

SPONSORSHIP: This study was funded by Genentech.

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

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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.

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 or MS diagnoses 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-la (32.7%), dimethyl fumarate (13.0%), natalizumab (5.6%), fingolimod (4.9%), teriflunomide (1.9%), and interferon-beta-1b (0.1%). Mean post-index follow-up was 934.6 days (median, 889 days), with 599 patients (36.5%) having 12–24 month follow-up, 483 (29.5%) with 25–36 months, and 557 (34.0%) with > 36 months follow-up. The overall first-switch rate was 24.6%. The proportion of patients switching index DMT to a non-first-switch index 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 months 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 group and 17.1% in the > 36 months group.

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.

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

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BACKGROUND: The effectiveness of disease-modifying therapies (DMTs) for multiple sclerosis (MS) has 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 (FER).

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 for DMF, 0.33 for GA, 0.34 for IFN, 0.31 for FTY, and 0.35 for TER (P < 0.01). Using DMT 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: DMF 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.

G19 Comparison of Costs and Health Resource Utilization 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 DMF), glatiramer acetate (GA), interferon (IFN), fingolimod (FTY), and teriflunomide (FER).

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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.

OBJECTIVE: To examine 5-year clinical efficacy and safety in CARE-MS II alemtuzumab-treated patients.

METHODS: In the CARE-MS II core study, alemtuzumab patients received 2 annual treatment courses at Months 0 and 12. Patients could enter an extension (NCT00930553), with as-needed alemtuzumab retreatment for relapse or radiological activity. Endpoints included annualized relapse rate (ARR), 6-month sustained accumulation of disability (SAD)/confirmed disability progression (≥ 1-point EDSS), and no evidence of clinical disease activity over Years 3-5. Incidences of infusion-associated reactions and infections during extension decreased versus core study; serious adverse events (AE) incidence was low. Thyroid AE incidence peaked at Year 3, declining thereafter.

RESULTS: Of 354 randomized subjects, 59.0% had relapsing remitting MS and 41.0% had secondary progressive MS. The average baseline Expanded Disability Status Scale (EDSS) was 3.9, ARR (0.21) was maintained over Years 3-5. Through Years 0-5, 76% of patients were free from 6-month SAD, 43% achieved 6-month SRD. More than half of patients (52%) had no evidence of clinical disease activity over Years 3-5. Incidences of infusion-associated reactions and infections during extension decreased versus core study; serious adverse events (AE) incidence was low. Thyroid AE incidence peaked at Year 3, declining thereafter.

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.

**GOAL:** 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.

**FINDINGS/RECOMMENDATIONS:** Making a 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.

**RESULTS:** In total, 1,681 articles were identified and screened for eligibility; of these, 43 describing 38 unique studies met eligibility criteria and were selected for inclusion (23 randomized controlled trials [RCTs], 8 retrospective, and 7 prospective trials). A total of 21 studies included > 50 patients. Most (30) studies evaluated IVMP; 2 evaluated RCI, 4, PMP; and 2, IVlg. Only 1 RCT of 17 patients compared 2 treatments of interest (IVMP vs. PMP). RCI, IVMP, and PMP were shown to be effective in improving DSS/EDSS scores versus placebo. IVlg appeared to have no effect on acute MS relapses. Safety information on RCI, IVlg, and PMP was limited.

**CONCLUSIONS:** The small number of RCI, PMP, and IVlg studies made it difficult to compare results across studies. However, IVlg appears to be ineffective, and PMP is used off-label in this indication. IVMP and RCI, which are approved treatments for MS relapses, have been shown to be effective treatment options for acute MS relapses. RCI may be a useful option for patients with MS relapses who require an alternative treatment.

**SPONSORSHIP:** This research was supported by funding from Mallinckrodt.

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

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**BACKGROUND:** Multiple sclerosis (MS) is an autoimmune neurological disorder that causes disability. Relapses, a hallmark of MS, are associated with increased functional impairment and decreased quality of life.

**OBJECTIVE:** To conduct a systematic literature review (SLR) of randomized and nonrandomized trials investigating the efficacy and safety of treatments used in patients with acute MS relapses; treatments included repository corticotropin injection (RCI), a porcine analogue of full length ACTH, intravenous (IV) methylprednisolone (IVMP), IV immunoglobulin (IVlg), and plasmapheresis (PMP). Recent evidence has shown that RCI may be associated with decreased resource use compared with IVlg and PMP.

**METHODS:** An SLR of English-language articles was performed in MEDLINE, Embase, and the Cochrane Library according to a prespecified search strategy and protocol and PRISMA standards, to capture the following therapies: RCI, IVMP, IVlg or PMP. Selected conferences, bibliographic lists of included studies, and recent SLRs were also searched. Eligible studies included adults with acute MS relapses treated with one of the treatments of interest. Efficacy outcomes, including Expanded Disability Status Scale (EDSS) or Disability Status Scale (DSS) scores, were examined. Safety outcomes included incidence of adverse events (AEs) and most common AEs.

**RESULTS:** In total, 1,681 articles were identified and screened for eligibility; of these, 43 describing 38 unique studies met eligibility criteria and were selected for inclusion (23 randomized controlled trials [RCTs], 8 retrospective, and 7 prospective trials). A total of 21 studies included > 50 patients. Most (30) studies evaluated IVMP; 2 evaluated RCI, 4, PMP; and 2, IVlg. Only 1 RCT of 17 patients compared 2 treatments of interest (IVMP vs. PMP). RCI, IVMP, and PMP were shown to be effective in improving DSS/EDSS scores versus placebo. IVlg appeared to have no effect on acute MS relapses. Safety information on RCI, IVlg, and PMP was limited.

**CONCLUSIONS:** The small number of RCI, PMP, and IVlg studies made it difficult to compare results across studies. However, IVlg appears to be ineffective, and PMP is used off-label in this indication. IVMP and RCI, which are approved treatments for MS relapses, have been shown to be effective treatment options for acute MS relapses. RCI may be a useful option for patients with MS relapses who require an alternative treatment.

**SPONSORSHIP:** This research was supported by funding from Mallinckrodt.
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 Reblif 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.
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 ≥2% 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 = 11,385, 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: 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 relapse rates of patients with MS newly 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. 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, 445 fingolimod, and 406 dimethyl fumarate) met inclusion criteria (mean age = 44.4 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: 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 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=0.06). Proportion of patients with ≥1 MS relapse of any type was lower with scIFNβ1a vs. oral DMDs (21.7% vs. 26%, 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).

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.

SPONSORSHIP: This work was sponsored by Amgen.
**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 male (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 = 0.028, P < 0.05) and pediatricians (OR = 0.099, P < 0.05) were less likely to prescribe off-label drugs than general/family practitioners. The major visit reason for preventive care (OR = 3.8, P < 0.05) and chronic problems (OR = 5.0, P < 0.05) were more likely to receive off-label drugs than the visits for new problems.

**CONCLUSIONS:** This study provides significant real-world evidence 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 guidelines to enforce evaluation to the extent of prescribing appropriate medications to children.

**SPONSORSHIP:** None.

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

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Magellan Rx Management

**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.

**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 (denominator) divided by the number of member-years of enrolled Medicare beneficiaries ≥ 65 years during the 2015 calendar year (numerator). 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 eligible 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.

**OBSESIONS:** 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 ≥ 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 Foundation without external funding.

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

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**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.

**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, representing 0.9% of all U.S. ED visits. The majority of visits were coded as epilepsy unspecified or general convulsion. Mean patient age: 36 years; 51% male; Medicaid and commercial insurance were the most common sources of payment.
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.

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

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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 breakthrough seizures, requiring visits to emergency departments and hospitalizations.

**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 aged 18 years or older in 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 205,551 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 supported by Acorda Therapeutics.
Despite being on anti-epileptic drug (AED) treatment. In the U.S., clinical trials of monotherapy AEDs usually involve such treatment-resistant patients, and compare the intervention arm to a historical control group derived from past epilepsy trials of similar design; but since there are no head-to-head trials, economic models can be useful in informing their comparative effectiveness.

**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 $400 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 partial-onset seizures in adults.

**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 for 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, 0.145), but the CM group had a higher proportion of females (87% vs. 82%, 0.046) and higher baseline comorbidity burden (Selim score 2.63 vs. 1.7, 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) (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%, 0.001 for each). CM had higher headache-related outpatient visits (77% vs. 24%, 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 (14.5%) (\( P = 0.081 \)), 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.

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

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**BACKGROUND:** Migraine is a symptom complex, defined by correlated symptoms. As a result, different migraine-related outcomes such as a time to disability freedom, time to pain freedom, and time to meaningful pain relief tend to travel together during the course of an attack. From a theoretical perspective, these associations may exist because the observed outcomes are indicators of a more general unobserved, latent migraine relief construct.

**OBJECTIVE:** To evaluate time to general relief measured by 3 observed outcomes: time to meaningful pain relief (MR), time to pain freedom (PF) and time to disability freedom (DF) with a flexible, multilevel, discrete-time latent variable model.

**METHODS:** Data were from COMPASS (NCT01667679), a multiple attack cross-over study comparing AVP-825 (an investigational product providing novel Breath Powered Bi-Directional intranasal delivery of low-dose [22 mg] sumatriptan powder) vs. sumatriptan tablets 100mg. Participants were instructed to treat up to 5 attacks with each treatment in counterbalanced order. Outcome data were collected at 10, 15, 30, 45, 60, 90, and 120 minutes post-dose. The statistical model treats general relief as an unobserved latent variable that gives rise to the observed time to event outcomes (i.e., MR, PF, and DF) and explicitly accounts for between-person and within-person (i.e., across attacks) differences in migraine relief.

**RESULTS:** The analyses included 259 subjects (84.6% female, 78.4% Caucasian, mean age 40.0) who treated an average of 6.7 attacks each. The analyses included 259 subjects (84.6% female, 78.4% Caucasian, mean age 40.0) who treated an average of 6.7 attacks each. For a typical individual and attack, MR preceded DF,

**CONCLUSIONS:** Findings showed that time to multiple migraine-related relief outcomes can be used as observed indicators of a more general latent migraine relief construct. Disaggregation of the between- and within-person variability showed that relief varied not only across individuals, but also within individuals across attacks. Further, AVP-825 treatment predicted improved general relief, which implied significantly greater odds of PF, DF, and MPR.

**SPONSORSHIP:** This work was supported by Avanir Pharmaceuticals.

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**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 \( \geq 15 \) days per month for \( \geq 3 \) consecutive months (with \( \geq 8 \) 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.

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**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.
OBJECTIVE: To compare CIPD-related treatment patterns and costs of care across IVIG therapies from the healthcare plan perspective.

METHODS: Patients with CIPD 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 CIPD 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 any other CIPD 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 CIPD treatment (40%), followed by Gamunex-C (48%), Carimune (52%), and Gammagard Liquid (57%). Patients receiving Gamunex-C were least likely to be switched to another IVIG (9%), followed by Gammagard Liquid (25%), Privigen (30%), and Carimune (42%). Two-year follow-up CIPD-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 CIPD patients indicated that there are substantial differences in costs, switching rates, and use of concomitant CIPD 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 >30 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, 2012). Patients were required to be ≥ 65 years, have at least 12 months of continuous eligibility for medical and pharmacy benefits at least 1 year prior to and 2 years after their initial diagnosis. Patients receiving any other CIPD treatments prior to their index IVIG therapy were excluded. Patients were placed into cohorts based on their index IVIG product.

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 < 0.0001) and outpatient visits (92.36% vs. 51.46%; P < 0.0001), resulting in significantly higher inpatient ($4,366 vs. $1,150; P < 0.022), outpatient ($3,303 vs. $1,758; P = 0.002), and total health care costs ($15,131 vs. $6,542, P < 0.0001), 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: 2.1 ± 1.7, 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 evaluated 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, 40% 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% forentanil 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: Purdue Pharma L.P.

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, ophthalmic 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, ophthalmic 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 15.3], 63% women): N = 3,074 taking artificial tears, N = 542 ophthalmic cyclosporine, N = 224 other therapy, and N = 906 no treatment. Rates for high, medium, and low satisfaction were: artificial tears (47%, 35%, 17%); ophthalmic 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 ophthalmic 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 35% 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 ophthalmic cyclosporine and artificial tears. Compared to artificial tears, ophthalmic 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-implementation 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.

H03 Real-World Treatment Patterns and Costs of Ranibizumab and Afiblercept 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-naïve (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.

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 ototorea, the most common post-TT complication. Otolaryngology clinical practice guidelines recommend topical antibiotics, not oral, to treat ototorea 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. 7.8% at 12.1%, respectively, P < 0.001). 109,005 (29.6%) patients (MC = 36,122, CO = 72,883) visited the emergency department (ED) or physician office with an ear-related
diagnosis (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-ITT. While MC
patients are more likely given oral antibiotics than CO, oral antibiotics
are inappropriate prescribed and overused in general, indicating
that physicians may be unaware of clinical guidelines recommend-
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.

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-
donmyolysis, (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 Pharmeric 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 impending
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.
of myocardial infarction (MI) or peripheral artery disease (PAD). The TRA 2°P-TIMI 50 trial demonstrated that adding vorapaxar to standard care antiplatelet therapy for 36 months reduced the combined risk of death, myocardial infarction (MI), and stroke, while exhibiting an increase in bleeding.

**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 vorapaxor 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.

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**108 Impact of Warfarin Adherence Status on Healthcare Costs Among Patients with Nonvalvular Atrial Fibrillation**

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**BACKGROUND:** Warfarin is a commonly used anticoagulation therapy to reduce stroke risk among patients with nonvalvular atrial fibrillation (NVAF). However, in real-world settings many NVAF patients may experience difficulty remaining on warfarin therapy for extended durations, which may affect healthcare resource utilization and costs.

**OBJECTIVE:** To investigate the impact of warfarin adherence status on healthcare costs of patients with NVAF managed by anticoagulation clinics in an integrated delivery network setting.

**METHODS:** Patients (≥ 18 years old) with ≥ 1 inpatient or ≥ 2 outpatient diagnoses of AF were identified based on ICD-9-CM codes from an electronic medical record database between 1/1/2004 and 1/31/2015. Patients were excluded from the study population if they had a diagnosis for valvular disease. The first recorded warfarin prescription from either electronic medical records or health insurance claims was defined as the index event with the corresponding date as the index date. NVAF patients were grouped into 2 cohorts of low and high adherence based on their time to discontinuation of warfarin based on similar published criteria. Demographics and clinical characteristics were evaluated during a 12-month baseline period prior to the index date. Healthcare costs were evaluated during a 12-month follow-up period after the index date. Multivariable regressions were used to control for differences in patient characteristics and examine the impact of warfarin adherence status on healthcare costs.

**RESULTS:** Among the study population, 52%, (n = 3,960, mean age: 71.8 years) had high warfarin adherence and 48% (n = 3,607, mean age: 71.0 years) had low adherence. Total all-cause healthcare costs ($14,915 vs. $16,942, P = 0.002), stroke-related costs ($1,923 vs. $2,130, P = 0.002), and bleeding-related costs ($1,934 vs. $2,670, P = 0.01) were lower for the high adherence cohort vs. the low adherence cohort during the follow-up period. After adjusting for patient characteristics, total all-cause healthcare costs (-$2,183, P < 0.001) and stroke-related costs (-$788, P = 0.01) remained significantly lower for patients in the high adherence cohort vs. the low adherence cohort. Bleeding-related costs trended towards being lower for the high adherence cohort vs. the low adherence cohort (-$544, P = 0.07) but was not statistically significant.

**CONCLUSIONS:** Among NVAF patients those who have high adherence to warfarin therapy, all-cause and stroke-related healthcare costs are lower in comparison to patients who have low adherence.

**SPONSORSHIP:** Bristol-Myers Squibb and Pfizer.
identifies 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 EQuiPP™ 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 Star 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 diagnoses. 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 both 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 FCI-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 (44.6%) than either FCII (13.1%) or FCIII (24.5%) (P < 0.01). Compared to FCIV patients, the risk of two-year mortality was reduced by 73.4% (44.6%) than either FCII (13.1%) or FCIII (24.5%) (< 0.01). Compared to FCIV patients, the risk of two-year mortality was reduced by 73.4% (44.6%) than either FCII (13.1%) or FCIII (24.5%) (< 0.01). Compared to FCIV patients, the risk of two-year mortality was reduced by 73.4% (44.6%) than either FCII (13.1%) or FCIII (24.5%) (< 0.01).

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. Hence early treatment and management of PAH is important to prevent severity progression, decrease overall costs and improve survival.

SPONSORSHIP: Actelion Pharmaceuticals U.S.

120 Predictors of All-Cause Healthcare Costs Among Patients with Newly Diagnosed Non-valvular Atrial Fibrillation Initiated on Dabigatran Versus Warfarin

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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 (\( P = 0.35 \)); 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: Boehringer Ingelheim Pharmaceuticals.

Predictors of Admission and Mortality Among Patients with Heart Failure

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BACKGROUND: Heart Failure (HF) is a major cause of morbidity and mortality in older adults. Data sources with detailed survey/claims-linked data may provide information that helps improve risk modeling and disease management in patients with HF.

OBJECTIVE: To assess patient characteristics associated with all-cause hospital admissions and mortality among individuals with HF.

METHODS: This was a retrospective study using data from the Medicare Current Beneficiaries Survey, a Medicare claims-linked survey. Included patients were \( \geq 65 \) years old with \( \geq 2 \) outpatient/physician claims with HF diagnosis, and \( \geq 1 \)-year continuous follow-up between 2005 and 2010. Date of earliest claim for HF was the index date. All-cause admissions and mortality were assessed during the one-year follow-up period. Poisson and logistic regression models were developed to examine number of all-cause admissions and mortality in older adults. Data sources with detailed survey/claims-linked data may provide information that helps improve risk modeling and disease management in patients with HF.

RESULTS: A total of 645 patients (67% female, median age 83 years) met sample inclusion criteria. Approximately 65% of patients had an admission for any cause and nearly 30% died within one-year post-index. Female gender (IRR: 1.78, \( P < 0.01 \)) and higher CCI scores (IRR: 1.25, \( P < 0.001 \)) were associated with increased incidence of all-cause admissions over one-year, while older age was associated with a lower incidence of all-cause admission (IRR: 0.97, \( P < 0.05 \)). In the mortality model, older age (OR: 1.08, \( P < 0.001 \)), living in a LTC facility (OR: 2.34, \( P < 0.02 \)), higher CCI scores (OR: 13.2, \( P < 0.001 \)), and more ADL assistance (OR: 1.15, \( P < 0.04 \)) were associated with higher risk of one-year mortality.

CONCLUSIONS: Higher comorbid burden was a marker for both all-cause admissions and mortality in HF patients, whereas, receiving LTC and more ADL assistance were markers for mortality. Findings may help better identify HF patients with unmet medical need and suggest areas of focus for efforts to improve HF disease management and outcomes.

SPONSORSHIP: Novartis Pharmaceuticals.

Identifying Atrial Fibrillation Patients at Increased Risk for Developing Stroke: A Systematic Review of Risk Factors

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BACKGROUND: Atrial fibrillation (AF) patients are at an increased risk of developing stroke. In the past, warfarin was the primary treatment for avoiding stroke. More recently, novel oral anticoagulants (NOACs) not requiring frequent monitoring have become available. Warfarin and NOACs are effective in preventing stroke, but increase patients’ risk of bleeding. Current guidelines recommend treating or not treating patients based on their CHA2DS2-VASc score. The CHA2DS2-VASc assigns ‘points’ for the presence of congestive heart failure, hypertension, age 65-74 or \( \geq 75 \) years, diabetes, gender, and vascular disease. Certain studies indicate that important risk factors for stroke may be missing from the CHA2DS2-VASc; artificially reducing patients’ risk score for developing stroke. Careful patient-level risk stratification is necessary to determine whether a patient’s comorbidities or lifestyle factors indicate that the benefits of anticoagulant treatment outweigh potential harms.

OBJECTIVE: To create a comprehensive inventory of independent risk factors for stroke among AF-diagnosed patients based upon a systematic review of published interventional and observational studies.

METHODS: Searches were conducted by a librarian in PubMed, Embase, Scopus, and the Cochrane Database of Systematic Reviews to identify published studies of risk factors for stroke in AF. Two research assistants independently reviewed abstracts with a third reviewer providing input when necessary. Information on risk factors was abstracted from resulting studies.

RESULTS: A total of 5,070 abstracts were identified and reviewed. In addition to comorbidities currently used to determine stroke risk for among AF patients, potentially relevant risk factors included: race, low body weight, cancer, glycated hemoglobin level, brain natriuretic peptide, sleep disorders, breathing difficulties, C-reactive protein, inflammatory bowel disease, plasma von Willebrand factor, chronic kidney disease, renal impairment, plasma-D dimer, obstructive sleep apnea, left atrial appendage morphology, rheumatoid arthritis, troponin levels, smoking status, and platelet activity.

CONCLUSIONS: This systematic review identified 19 independent risk factors for developing stroke among AF-diagnosed patients not currently included in risk stratification schemes. Next steps include quality assessment of the studies identifying these risk factors. Future studies examining health outcomes among AF patients may wish to consider comparative treatment effects in light of these risk factors.

SPONSORSHIP: None.

A 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 (HFREF).

OBJECTIVE: To create a comprehensive inventory of independent risk factors for stroke among AF-diagnosed patients based upon a systematic review of published interventional and observational studies.
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 (HFREF 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) fewer 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.

I27 LDL-C Goal Achievement After Adding or Switching to Ezetimibe in Patients with Clinical Atherosclerotic Cardiovascular Disease or Probable HeFH

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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 (HFREF 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).

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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.
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.

129 Cost Per Effectively Treated Patient with Evolocumab 140 mg and Alirocumab 75/150 mg

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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 Navarrese Meta-analysis (2015) of 24 PCSK9 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 Navarrese 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.

131 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.

132 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.
OBJECTIVE: To analyze real-world FVIII treatment patterns for Hemophilia A patients in the top quartile of factor utilization based on specialty pharmacy dispensing records.

METHODS: A retrospective analysis was conducted using aggregate U.S. Specialty Pharmacy Provider (SPP) records from January 2015 through December 2015. SPP data included 63 different attributes for each prescription, including trade name, National Drug Code (NDC), drug quantity shipped, prescribed infusion dose, days supplied, and dose frequency. Patients were considered eligible for the analysis if they received at least one shipment of conventional FVIII. Patients were excluded from the analysis if their pharmacy records did not specify a prescribed infusion dose or if prescribed dose was “as directed” or “other”. Patients were also categorized by quartile according to their cumulative dispensed units during the study time frame.

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 2 times per day to every time per week. 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.

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 was 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-$68,584 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.

J00-J99: Diseases of the Respiratory System

J04: 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 85 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 limit marketing 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 AATD 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 (AATD) 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.xx, 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 $45,389 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. 5.5), 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 AATD patients treated with an alpha-1 proteinase inhibitor.

**SPONSORSHIP:** Optum was contracted by Grifols SSNA to conduct this research.

**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, $203M 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: 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, under-treatment 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.
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 describe 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 7/1/2004 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 (39.9%), 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: University of Maryland School of Pharmacy, Baltimore, MD.

Severity 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 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 [5.9]) 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.

Numbers Needed to Treat with Omalizumab to Prevent an Asthma Exacerbation, Emergency Room Visit, or Hospitalization in Patients with Severe Uncontrolled Asthma

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BACKGROUND: Patients with uncontrolled severe asthma bear high clinical and cost burden. Biologic therapies aim to reduce this burden. Clinicians often use number needed to treat (NNT) statistic to compare different therapies. Omalizumab pivotal trials defined asthma exacerbation differently from the current definition in the American Thoracic Society (ATS) guidelines.

OBJECTIVE: To estimate NNT to prevent an exacerbation, hospitalization, or an emergency room visit, if omalizumab was used in patients with severe uncontrolled asthma.

METHODS: From a recent study of an anti-IL-5 therapy in patients with severe asthma and 3.6 exacerbations in the year prior to the study period, we obtained background placebo rates of exacerbations (1.74 per year), exacerbations requiring hospitalizations (0.10 per
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 a 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, 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 1.0 (WPAI-GH), healthcare resource use (HRR) (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 = 36.4% vs. 24.7% and 17.6%) 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. $5,893, $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, HRR, 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 exacerbations and decrease severity in COPD. More decrease severity in COPD and increase the number 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 southeast 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 that 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 1:1to 1 on demographic and pre-index clinical characteristics using propensity scores. All-cause and COPD-related (medical claims with 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 1year. 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: $22,308 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 stays 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 0.8 or higher were classified as 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=59.9%-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 = 0.39, P = 0.023).

CONCLUSIONS: Adherence to COPD maintenance 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 460-519). Lung transplant admissions were excluded. Variables were weighted to represent national
Ulcerative colitis (UC) is associated with a considerable burden of illness. Evidence of decreased healthcare service costs by site of care for Crohn's disease (CD) can impact prescription and reimbursement decisions. The objective of this study was 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).

**BACKGROUND:** Utilization patterns and administration costs of anti-tumor necrosis factor (anti-TNF) drugs used to treat Crohn's disease (CD) can impact prescription and reimbursement decisions.

**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 by 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 $47,476 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 $2,051 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.
For IBS-D patients and controls were attributable to physician office ($4,312 vs. $2,957; \text{p} < 0.001), 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 UC B Pharma.

**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


1University of Pennsylvania; 2Ironwood Pharmaceuticals; 3Allergan; 4Option; 5Cedars-Sinai Health System; 6University of Michigan

**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 12/2012-12/2014. Identification criteria included: ≥ 1 medical claim for constipation (564 ox), IBS (564 lx), or abdominal pain (789 ox) plus ≥ 1 pharmacy claim for a stool softener/laxative, or ≥ 1 pharmacy claim for linaclootide 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 [8%] 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.

**K11 Physician Versus Patient Perceptions of Medical Care Quality in Primary Biliary Cirrhosis**

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**Intercept Pharmaceuticals**

**BACKGROUND:** Primary biliary cirrhosis (PBC) affects about 1/1000 women age >40 years and remains among the leading indications for liver transplantation. PBC presents large unmet needs among both the patients living with this condition and the doctors who treat them.

**OBJECTIVE:** The purpose of this analysis was to compare patient and physician perceptions of care in patients with PBC and the hepatologists and gastroenterologists treating patients with PBC, with the goal of improving care delivery.

**METHODS:** From December 11, 2014 to January 12, 2015, we conducted surveys with board certified gastroenterologists (262) and hepatologists (60) practicing for at least two years and had treated at least two PBC patients in the past six months. From January 5-30, 2015, we conducted surveys with 214 patients with PBC who were under a physician’s care.

**RESULTS:** Physicians and patients rated their confidence in physician delivery of 7 areas of PBC care; 3 areas differed by 5% or more. Physicians under-rated their skills in helping patients manage PBC symptoms (38% had confidence vs. 43% perceived by patients); 65% of physicians had confidence in the quality of their bedside manner compared to 35% of patients; 52% of physicians had confidence in measuring the progression of PBC compared to 45% perceived by patients. Beyond care provisions, there were differences between patient and physician perceptions on how PBC affects patient health-related quality of life. Half of PBC patients reported that PBC impacts a “great deal” how they feel physically (50% vs. 25% physicians), their ability to work (39% vs. 16% physicians), and their ability to do the things they enjoy (36% vs. 17% physicians). Despite the impact of PBC on these symptoms, only 42% of patients strongly agree that additional treatment options would treat PBC more effectively (versus 89% of physicians).

**CONCLUSIONS:** Hepatologists and gastroenterologists do not demonstrate systematic self-enhancement bias in treating PBC patients. While they may overrate their bedside manner, they underrate their management of PBC symptoms. However, physicians and patients both rated diagnosis and treatment more highly than monitoring disease progression and managing symptoms, and physicians recognize the need to improve. Interventions to improve physician communication around disease progression, and patient communication around symptoms and symptom management could enhance practice.

**SPONSORSHIP:** Intercept Pharmaceuticals.

**K12 The Need for Improved Liver Literacy in the U.S. Population**

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**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 2014 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.
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 J1, Sundaram M3. 1N Waukegan Rd, Moderate-to-Severe Psoriasis in the United States in patients with moderate to severe psoriasis were identified through a difference in estimated PASI-90 response rates between biologic 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.

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 $24,897 ($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.

L03 Cost-Effectiveness of Adding Clostridial Collagenase Ointment to Standard of Care in Individuals with Stage IV Pressure Ulcers

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BACKGROUND: A pressure ulcer is a localized injury to the skin or underlying tissue, usually over a bony prominence, because of pressure or pressure in combination with shear and/or friction. 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 (COC) 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 COC. 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 COC 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.

RESULTS: The annual indirect costs were $2,149 (95% CI: $1,586-$2,612) per individual with PASI < 50, $21,242 (95% CI: $17,244-$27,039) per individual with PASI 50-74, $287,785 (95% CI: $241,576-$333,994) per individual with PASI 75-89, and $2,149 (95% CI: $1,586-$2,612) per individual with PASI ≥ 90, respectively. The annual indirect cost per week was $42.94 (95% CI: $38.06-$47.82) for PASI < 50, $1,219.76 (95% CI: $1,080.19-$1,359.32) for PASI 50-74, $46,387.20 (95% CI: $40,657.17-$52,117.23) for PASI 75-89, and $42.94 (95% CI: $38.06-$47.82) per individual with PASI ≥ 90, respectively.
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 Clostridial Collagenase Ointment to Standard of Care in Individuals with Stage IV Pressure Ulcers

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1Strategic Solutions; 2Smith and Nephew; 3Truvan Health Analytics; 4Intellucare

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 (P<0.0001). 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 as 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 AE (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 atop 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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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 13 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 agent that safely minimizes the symptoms and severity of AD for acute and maintenance therapy.

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-treated 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 frequency of “almost clear” or “clear” 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.

L08 Treatment Patterns, Healthcare Resource Utilization, and Costs Associated with Psoriasis 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 TNFis 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 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 NORDMARD 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 a 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.

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 18 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 found 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 NORDMARD 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 a 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.
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 trade-offs 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.
L11 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-naive 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 outpatient, inpatient (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: $34 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.

L12 Comparison of Persistence Between Adults with Psoriasis Initiating Apremilast or Biologics
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BACKGROUND: There are currently no comparative published data on the persistence among patients with psoriasis who have been treated with apremilast vs. biologic therapy in a real-world care setting.

OBJECTIVE: To compare real-world persistence of psoriasis patients in the U.S. initiating apremilast or biologic therapy within 6 months.

METHODS: This observational, retrospective cohort study was conducted using MarketScan Commercial and Medicare Supplemental Databases (2014-2015). Adults with ≥ 2 diagnosis codes for psoriasis (ICD-10:L40) who initiated apremilast or biologics were selected. 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. Persistence was measured as the time from initiation to discontinuation, defined as the end of days' supply prior to at least a 60-day gap without medication. At 6 months post-index the percentage of patients persisting on drug was assessed.

RESULTS: In total, 839 patients initiating apremilast and 1,981 initiating biologic therapies met the inclusion criteria and had similar baseline characteristics. Mean enrollment time post-index was 5.4 months for apremilast and 8.3 months for biologics. At 6 months post-index, persistence to initiated drug was not significantly different between the apremilast and biologic cohorts (apremilast: 67.1%, 95% CI: 70.5-63.6% vs. biologics: 68.5%, 95% CI: 70.6-66.3%).

CONCLUSIONS: Apremilast use was associated with similar persistence compared with initiation of a biologic among adults with psoriasis in the U.S.

SPONSORSHIP: This research was funded by Celgene.

L13 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, 4-7% 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 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.

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.

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.

M00-M99 Diseases of the Musculoskeletal System and Connective Tissue (e.g., RA, OA, Osteoporosis, Gout, Dupuytren’s Contracture)

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: The Swedish Farmacotherapy (SWEFOT) 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 sulfasalazene. Because these therapies may be most 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.
METHODS: Using data from analyses of the SWEFOT study with MBDA scores (Vectra DA), we evaluated 157 patients who had MTX-IR (DAS28 > 3.2) at Month 3 and were randomized to TT or anti-TNF. The proportions of clinical responders (DAS28 ≤ 3.2) at Month 12 were determined for patients with low (< 30), moderate (30-44) or high (≥ 44) MBDA scores at Month 3 and compared by Fisher’s exact test. Missing data were imputed by last observation carried forward. Overall difference of response rates in the two therapy arms was analyzed by Breslow-Day test (for homogeneity of odds ratio). X-rays of hands and feet were evaluated for 131 patients at baseline and Year 2 using the van der Heijde modified Sharp score (SHS) to assess radiographic progression (RP), change in SHS > 5.

RESULTS: Among 157 patients with IR (DAS28 > 3.2) to MTX monotherapy, the 19 patients with low MBDA score (< 30) at Month 3 had significantly greater likelihood of response (DAS28 ≤ 3.2) at Month 12 with TT vs. anti-TNF therapy (7/8 [88%] vs. 2/11 [18%], P = 0.006). By contrast, the 88 patients with high MBDA score (≥ 44) at Month 3 had greater likelihood of response with anti-TNF therapy (15/43 [35%] vs. 26/45 [58%], P = 0.04). None (0%) of the MTX-IR patients with a low MBDA score at Month 3 and available X-rays had RP with TT or anti-TNF treatment.

CONCLUSIONS: Among patients with early RA and an incomplete response to 3 months of MTX monotherapy, the MBDA score at Month 3 differentiated those who were more likely to respond to subsequent treatment with TT or anti-TNF. A low MBDA score (< 30) at Month 3 predicted greater clinical efficacy to TT versus anti-TNF, whereas a high MBDA score favoured anti-TNF therapy. These findings may have major implications for development of individualized, cost-effective therapeutic algorithms in RA.

SPONSORSHIP: MBDA testing sponsored by Crescendo Bioscience, South San Francisco, CA.

M03 Medication Adherence Outlier Quality Management Program: A Novel Method of Evaluating Medication Adherence in Specialty Pharmacy

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PROBLEM DESCRIPTION: Medication possession ratio (MPR) is a useful tool for estimating secondary medication non-adherence (SMN), or lack of persistence with taking a medication regimen as prescribed. The benefits are that it’s a simple, reproducible calculation and can be conducted with minimal resources using pharmacy claims data. However, MPR has some inherent limitations, most importantly that it cannot identify the underlying reasons for SMN. Because of this, new methods are necessary to identify these underlying causes in an effort to develop and deliver targeted patient and therapy interventions.

GOAL: To determine the underlying causes of SMN with specialty medications by identifying the frequency of Medication Adherence Outliers (MAO) and documented reasons for suboptimal adherence rates in an effort to improve specialty medication outcomes.

PROGRAM DESCRIPTION: The University of Illinois Hospital and Health Sciences System Specialty Pharmacy Service (UI-SPS) calculates MPR for specialty therapies for quality management. Overall MPR has been consistently >0.93 since implementing new patient management standards in April 2015, indicating a high rate of medication adherence. In an effort to further understand the underlying reasons for patients that have low MPR, UI-SPS implemented the MAO quality management program. Individual patient MPR was calculated for 6 months before and after implementation of the new standards. Individual patients with MPR <0.85 were filtered; these were determined to be the adherence outliers. An MAO percentage was calculated (total number of patients with MPR <0.85/total number of patients×100%). A chart review was conducted to identify reasons for low MPR during the defined period.

OBSERVATIONS: Preliminary baseline estimates include a 6 month pre-implementation MAO rate of ~15% and 6 month post-implementation rate of ~10%. The categories of underlying low MPR included safety (abnormal lab, active infection, adverse effect), coordination (hospitalization, treatment initiation, dose change, prescription routing error), access (insurance issue, other treatment delay), and regimen non-adherence (patient unreachable, dissatisfaction with treatment, tolerability issue).

FINDINGS/RECOMMENDATIONS: For institutions with the capabilities such access to both EMR and pharmacy claims data, Medication Adherence Outlier rates are a useful tool to identify underlying causes of SMN to further personalize patient experiences and develop targeted interventions.

SPONSORSHIP: None.
which should include information regarding comorbidities and predictors of treatment with ULT.

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

### 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 TNF inhibitors (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 RA 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 an RA diagnosis (ICD-9: 714.0x-714.9x; 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 = 0.0182). 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 (39.3% 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.

### 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. Cost 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: $133,665,292). 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: $131,147,699; ETN>TOFA: $131,754,773; ADA>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.

### 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.

**METHODS:** This study used a 2-year (yrs) retrospective claims database to identify patients with a PsA diagnosis (ICD-10-CM: M09 and M08) who were continuously enrolled for ≥12 months, plus ≥2 years pre-/post-index. The study calculated healthcare 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 (39.3% 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.
**METHODS:** Adults (18-64 years) with ≥ 2 claims for PsA (ICD-9-CM: 696.0) ≥ 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: 696.1) that were ≥ 30 days apart, and ≥ 1 PsO claim and ≥ 1 systemic therapy/phototherapy in the study 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, 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 log-link and gamma distribution of errors. Costs were calculated as the product of the number of events times the cost of each event (e.g., hospitalization costs, outpatient visits, etc.). Costs were age and sex adjusted using the bootstrap method for multiple comparisons.

**RESULTS:** A total of 10,495 patients with PsA + mod-sev PsO and 13,235 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 < 0.001). 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). 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.

**M12 Impact of Site of Care on the Drug and Administration Costs of Certolizumab Pegol Versus Infliximab in Rheumatoid Arthritis**

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**BACKGROUND:** Utilization patterns and administration costs of anti-tumor necrosis factor (anti-TNF) drugs used to treat rheumatoid arthritis (RA) can impact prescription and reimbursement decisions.

**OBJECTIVE:** To assess the total annual healthcare costs and individual treatment costs by site of care for RA patients (pts) receiving subcutaneous certolizumab pegol (CZP) or intravenous infliximab (IFX). This study was funded by UCB Pharma.

**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 antireumatic 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 patients 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 < 0.01). MSAs ranked in the 90th percentile of patient OOP cost had 6.6% (P < 0.01) less DMARD use than MSAs ranked in the 10th percentile.
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, 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, 0.081 vs. 0.046) visits post-index as compared to the pre-index period, which resulted in lower PPPM medical costs ($5,869 vs. $3,724) (inpatient [$3,192 vs. $799], ED [$163 vs. $84]). 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 almost 3 times (OR=2.53, 95% CI=1.55, 4.15; P<0.05) more likely to not be in MDA vs. patients with no dactylitis and patients with enthesitis were 1.88 times (OR=1.88, 95% CI=1.23, 2.86; P<0.05) more likely to not be in modified MDA (5/6 criteria excluding enthesitis) 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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BACKGROUND: Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are spondyloarthritic 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, Elixhauser 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) and had higher ECS scores (2.0 vs. 1.1; P < 0.01) vs. the bottom 90% group (N = 9,740) respectively. Similarly, the AS top 10% cost group was older (mean age 52.1 ± 12.6 y vs. 48.7 ± 13.4 y; P < 0.01) and had higher ECS scores (mean, 2.9 ± 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%) and oral disease-modifying agent (26.6% vs. 21.3%) use (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. $9,277 ± $7,413, 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 Corona Registry

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BACKGROUND: Psoriatic arthritis (PsA) is a type of inflammatory arthritis that is commonly comorbid with the skin condition, psoriasis. OBJECTIVE: To characterize the demographic and clinical characteristics of PsA patients with >3% vs. ≤3% of body surface area (BSA) affected by psoriasis and evaluate the association with minimal disease activity (modified MDA: 5/6 criteria excluding BSA) and disability, measured by the Health Assessment Questionnaire (HAQ) in a large national observational cohort of patients with PsA and spondyloarthitis (Corona).

METHODS: PsA patients ≥18 years in the Corona registry with data on BSA were included. Descriptive analyses of patient characteristics, disease activity, and functionality measures at registry enrollment were performed for patients with >3% vs. ≤3% BSA. Regression models were used to evaluate associations of BSA level with the outcome measures MDA and HAQ (0-3), adjusted for age, gender, race, BMI, disease duration, and history of drug treatment.

RESULTS: 1,240 PsA patients were included; 451 (36.4%) had >3% and 789 (63.6%) had ≤3% BSA. Patients with BSA >3% were younger, with a mean (SD) age of 52.2 (13.4) years vs. 54.4 (13.2), with 49.4% women vs. 52.1%, and mean (SD) disease duration of 9.9 (4.4) years vs. 8.7 (8.6). There were slightly higher rates of cardiovascular disease (61.2% vs. 59.4%), cancer (91% vs. 6.6%), and serious infections (5% vs. 4.8%) in patients with BSA >3% vs. ≤3%, respectively. About 60% of patients in both groups used a biologic therapy. 21% of patients with BSA >3% were in MDA vs. 30% of patients with BSA ≤3%. Adjusted models showed that patients with BSA >3% were 1.7 times more likely to not be in modified MDA (95% CI = 1.2, 2.4; P < 0.01) vs. patients with BSA ≤3%. Similarly, there was a significant difference in mean HAQ in patients with >3% BSA (mean difference = 0.2 units higher; 95% CI = 0.1, 0.3; P < 0.05) vs patients with BSA ≤3%.

CONCLUSIONS: PsA patients with >3% of BSA affected by psoriasis were significantly less likely to be in MDA and more likely to be disabled than patients with ≤3% BSA at enrollment. Even at the low cutoff of >3% BSA, the extent of psoriasis lesions confers a significantly greater burden of disease in PsA. These findings underscore the importance of assessing and effectively managing psoriasis in patients with PsA.

SPONSORSHIP: The design, study conduct, and financial support for this analysis were provided by Novartis Pharmaceuticals.

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 physician patient 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 absences 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%) and
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%) dissatisfied. Satisfied patients tended to be older (53.5 vs. 44.3 years), male (59.3% vs. 50.0%), had a longer duration since PsA diagnosis (6.5 years vs. 3.6) and more likely receiving a biological DMARD (bDMARD) therapy (64.8% vs. 56.5%). Level of disease activity in the joints was similar in both cohorts (mean tender joints: 7.9 vs. 7.8; swollen joints: 5.1 vs. 5.0) but skin involvement was lower in satisfied patients (BSA > 3%: 71.4% vs. 82.6%). Among patients with active joint disease the most common concomitant conditions were hypertension (30.8%), obesity (25.6%), depression (23.1%), elevated cholesterol (21.8%), diabetes (20.5%), and anxiety (19.2%). Dissatisfied patients had more comorbidities (2.2 vs. 1.6) and more had depression (33.3% vs. 18.5%) and anxiety (33.3% vs. 13.0%) and were less impaired by their PsA (mean % WPAI activity impairment: 38.5% vs. 47.9%; mean alternative HAQ-DI: 0.657 vs. 0.761).

**CONCLUSIONS:** This study highlights even patients with active joint disease may be satisfied, and suggests that with longer disease duration or prescription of bDMARD therapy, patients may settle for sub-optimal control of aspects of PsA particularly in relation to joint involvement. These findings highlight the challenge of managing PsA as patients progress in their disease, although further investigation and validation in a larger sample is needed.

**SPONSORSHIP:** Novartis Pharmaceuticals.

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

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**BACKGROUND:** Examining drug exposure is essential to pharmacovigilance, especially for bisphosphonate (BP) therapy.

**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:** Pfizer.

**N00-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 ( PDO ) during the period June 1, 2014 to May 31, 2015 (N = 148,690). All study data were derived from PDO 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/mo/month with an overall mean of 228 mg (median: 200 mg). ESA dose among users ranged from 3,704 to 4,062 U/treatment (median range: 3,893-2,700 U/treatment) with an overall mean of 3,913 U/treatment (overall median: 2,538 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 period studied 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.

**N02 Patiromer Lowers Serum K+ and Prevents Recurrent Hyperkalemia in CKD Patients ≥ 65 Years of Age on RAAS Inhibitors**

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**BACKGROUND:** Hyperkalemia is a common complication in patients with chronic kidney disease (CKD) on RAAS inhibitors, and can lead to hospitalization, death or increased risk of adverse cardiovascular outcomes.

**OBJECTIVE:** To evaluate the effect of patiromer, a novel potassium binder, on serum potassium levels in patients ≥ 65 years of age on RAAS inhibitors who had recurrent hyperkalemia (≥ 5.5 mmol/L).

**METHODS:** This was a randomized, open-label, multicenter, parallel-group, controlled study of patients ≥ 65 years of age on RAAS inhibitors who had recurrent hyperkalemia (≥ 5.5 mmol/L) despite adequate dosing of potassium-binding agents. Patients were randomized to receive placebo or patiromer 8 g/day, with an optional dose titration up to 16 g/day for hyperkalemia control. The primary outcome was the proportion of patients who achieved a serum potassium level ≥ 5.5 mmol/L with no dose reductions of RAAS inhibitors at week 12.

**RESULTS:** A total of 667 patients were enrolled; 333 patients completed the study. The proportion of patients who achieved a serum potassium level ≥ 5.5 mmol/L with no dose reductions of RAAS inhibitors at week 12 was significantly higher with patiromer 8 g/day versus placebo (82.8% vs. 56.7%, p < 0.001).

**CONCLUSIONS:** Patiromer significantly lowered serum potassium levels and prevented recurrent hyperkalemia in patients ≥ 65 years of age on RAAS inhibitors.

**SPONSORSHIP:** This study was supported by Keryx Biopharmaceuticals.

**M25 Prevalence and Direct Costs of Patients at Risk for Opioid 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 117.4/1,000 persons and annual medical costs 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 mitigating opioid abuse and reducing associated costs in the Medicare population.

**SPONSORSHIP:** Pfizer.
BACKGROUND: Older patients are at risk for hyperkalemia due to decreased aldosterone production, comorbid diseases, and K+-altering medications. Patiromer 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 patiromer 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 patiromer trial (OPAL-HK).

METHODS: Patients (n = 243) with baseline serum K+ (s-K+) levels ranging from 5.1 to < 6.5 mEq/L received patiromer (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 to < 6.5 mEq/L (n = 107) were randomized to continue patiromer 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 [0.05] 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 [0.05] 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 patiromer, 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. Patiromer 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: Patiromer 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.

NO4 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, patiromer, in hyperkalemic patients with CKD.

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 patiromer (8.4 g daily dose for mild hyperkalemia, 16.8 g daily dose for moderate-to-severe hyperkalemia) in a 4-week treatment phase of the 2-part OPAL-HK study.

RESULTS: 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) change 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), the mean (standard error) s-K+ for patients ≥ 65 years old decreased significantly from baseline at week 4 (-1.01 [0.05] 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 patiromer, 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. Patiromer 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: Patiromer 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.

NO3 Trends in the Use of IV Iron and ESAs Under the Prospective Payment System: ESRD Commercial and Medicare Populations

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BACKGROUND: Approximately 570,000 patients live with end-stage renal disease (ESRD) in the U.S. Of these, approximately 400,000 undergo dialysis three times per week. While 85% of these patients are Medicare beneficiaries, the other 15% are covered by commercial insurance. Estimates of the amount spent on the care exceeds $25 billion. Under the prospective payment system (PPS), which debuted January 1, 2011, Medicare reimburses dialysis providers with bundled payments that include dialysis-related services and medications that treat anemia. There is inconsistent evidence on whether the 2011 implementation of the Medicare PPS resulted in changes in IV iron and erythropoiesis-stimulating agents (ESAs) use.

OBJECTIVE: To determine the post-PPS trends in utilization and cost of ESA and IV iron use per dialysis session among Medicare and commercially insured lives.

METHODS: Data was derived from USRDS claims files and commercial health plans for dialysis patients between June 30, 2011 and June 30, 2015. Use per session, cost per session and dose per session was reported. Patients with ESRD were defined as patients for whom a Medical Evidence Form establishing kidney failure had been filed or one or more paid dialysis facility claims was identified. Total paid amounts included the amount paid by the member and by the plan. Descriptive statistics were used to describe overall and state-specific expenditure trends in per member per month (PMPM).

RESULTS: Use of erythropoiesis-stimulating agents declined substantially after the new PPS debuted and this trend remained over the four years examined in this study. On the other hand, there was an increase in the use of IV iron. Regarding cost, drug spending decreased by $30 per session, or about 6 times the mandated reduction in the base payment rate of 5%. Specifically, use of peritoneal dialysis increased in 2011 and the following years, while home hemodialysis also increased. In contrast, when comparing USRDS findings to commercial plan findings, commercial plans did not reflect a decline in the use of ESAs or IV iron post PPS and costs were relatively unchanged.

CONCLUSIONS: This study reflects the impact of the PPS on anemia management in ESRD patients. The proportion of Medicare patients receiving ESAs decreased, which suggests an increase in dose holds post PPS. The expanded bundle incentives seem to have motivated dialysis providers to move toward lower cost methods of care in their choice of treatment modalities.

SPONSORSHIP: This project was supported by Keryx Biopharmaceuticals independent research grant program.

NO4 Chronic Diuretic Therapy Does Not Impair the Effectiveness of Patiromer in Hyperkalemic Patients with CKD

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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.

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 first Rx. Medicare patients were identified 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; 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.

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%, \( P = 0.044 \)) and 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 (\( P < 0.001 \)); 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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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 0.13-0.64) 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.

Q00-Q99 Congenital Malfunctions, Deformations, and Chromosomal Abnormalities (e.g., Spina Bifida, Cleft Palate)

Q01 Increasing Management of Orphan Drugs

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Stratis Group

BACKGROUND: This study provides a resource for interested parties, since managed care and forecasting teams at biopharmaceutical manufacturers increasingly request information about the likelihood and extent to which MCOs may increase management of orphan drugs. Given the ongoing dramatic increase in orphan drug development programs and the markedly high costs associated with these drugs, there is growing perception that MCO utilization management may need to increase, particularly within the segment of orphan drugs treating chronic, non-life-threatening conditions.

OBJECTIVE: To evaluate current MCO conceptualization and planning for orphan drug utilization management. Additional focus is placed on creation of Case Studies for leading ideas identified in this space.

METHODS: Phase-1 of this research involves a written survey fielded to query 20 key MCO stakeholders on their awareness of organizational efforts to plan for a growing focus on orphan drugs. In Phase-2, written surveys are followed by phone interviews with participants to discuss responses and expected management strategies identified. All information collected is heavily blinded such that no individual PBMs or other payers are identified in the results.

RESULTS: Greater than 70% of MCOs surveyed, representing the vast majority of covered lives in our survey and more than 45% of total U.S. covered lives, have significant concerns about the rapidly expanding cost of orphan drugs. Fewer than 30% of surveyed companies have actually developed an orphan-drug-specific cost containment strategy. Genetic screening and other diagnostic screening requirements are becoming the minimum standard for prior authorization fulfillment, however more aggressive strategies are under contemplation and in the planning stages. Quantitative figures and specifics around preliminary, proposed standards of disease and drug segmentation will be found in the Case Study portion of this research.

CONCLUSIONS: Results reveal that MCO stakeholders see an urgent need for the ability to segment orphan diseases by severity, with different levels of utilization management being appropriate for different disease segments. Classification of drugs and associated levels of acceptable management may, or may not be achieved through cost effectiveness analysis, however stakeholders generally agree that an industry-wide set of benchmarks should be developed within the next 3-6 years to enable discussion and visibility into viable and acceptable management techniques.

SPONSORSHIP: Research was funded by Stratis Group.

R00-R99 Symptoms, Signs, and Abnormal Clinical and Laboratory Findings Not Elsewhere Classified (e.g., Pain, Opioids, Vasomotor, Urticaria, Nausea & Vomiting)

R02 Burden of Illness in Adult Patients with Nocturia

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BACKGROUND: Nocturia (interruption of sleep due to the need to urinate) affects an estimated 15% of men and 20% of women.

OBJECTIVE: To assess baseline data from a 1-year, prospective, observational study in order to estimate the humanistic and economic burden, including work productivity, healthcare resource utilization (HRU) and costs, associated with nocturia in adult patients.

METHODS: Adult patients enrolled in HealthCare Partners (HCP) Medical Group with nocturia for ≥6 months were recruited based on claims with ICD-9 codes for nocturia alone (788.43), or combined with overactive bladder (596.51) and/or benign prostate hyperplasia (600.0x). Demographic, nocturia, and treatment history, as well as quality of life and work productivity data (using the EQ-5D and WPAI, respectively) were obtained through telephone, web-based, or in-clinic questionnaires. HRU (outpatient, emergency room [ER], hospital, and
pharmacy utilization) and costs were identified from HCP claims in the 6 months before study enrollment. Results were stratified by nocturia frequency (1, 2-3, ≥ 4 episodes/night).

RESULTS: 899 patients were enrolled. With increasing nocturia episodes, EQ-5D mean scores decreased (0.86 ± 0.1, 0.83 ± 0.2, 0.80 ± 0.2 for 1, 2 to 3, ≥ 4 episodes respectively; P<0.01), while impact on work productivity increased in working participants (n = 196; 9.6% ± 17.7%, 18.4% ± 23.0%, 22.3% ± 28.0% for 1, 2-3, ≥ 4 episodes, P = 0.01). The proportion of patients visiting a primary care physician (85.1%, 93.0%, 91.0% for 1, 2-3, ≥ 4 episodes, P = 0.005), as well as the number of visits/patient (2.6 ± 1.9, 3.3 ± 2.6, 3.5 ± 2.3 for 1, 2-3, ≥ 4 episodes; P = 0.002), increased with nocturia frequency. The proportion of patients with any prescription claim (76.8%, 90.3%, 88.3% for 1, 2-3, ≥ 4 episodes; P<0.001) and the mean number of prescriptions/patient (16.8 ± 13.4, 20.9 ± 16.0, 25.1 ± 20.6 for 1, 2-3, ≥ 4 episodes; P<0.001) increased with nocturia frequency. ER visits and hospitalizations followed similar trends but were not statistically significant due to the small number of patients with qualifying event(s). Health plan paid total costs, including hospitalizations, ER visits, outpatient visits, and prescriptions, also increased with nocturia frequency (median costs: $1,618, $2,424, $2,969 for 1, 2-3, ≥ 4 episodes).

CONCLUSIONS: The humanistic and economic burden of nocturia increases with nocturic frequency. This suggests that management focused on reducing nocturic episodes may reduce HRU and associated costs and improve quality of life among patients with nocturia.

SPONSORSHIP: Allergan.

R05 Healthcare Costs Associated with Nausea and Vomiting in Patients Receiving Oral Immediate-Release Opioids for the Management of Acute Pain in the Outpatient Setting

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BACKGROUND: Nausea and vomiting (NV) are recognized side-effects of opioid use, although the financial burden of such occurrences to the healthcare system is not well documented.

OBJECTIVE: To assess the incremental impact of NV on healthcare costs among opioid-treated patients with acute pain from a commercial health plan perspective.

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 used to adjust for between group differences in baseline patient characteristics and comorbid conditions. Generalized linear regression was applied to further adjust for baseline healthcare costs and covariates that remained significant after PSM.

RESULTS: Of the 2,068,860 patients meeting inclusion criteria, 2.2% had a medical claim for NV, of whom 54.7% also had a prescription for an antiemetic. After PSM (n = 45,909 per group), mean total healthcare costs were $6,303 vs. $2,385 for patients with NV+AEm and No NV/AEm respectively. After regression adjustment, 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; adjusted cost ratio, ACR (95% CI): 7.68 (7.90-7.96)], outpatient costs [$4,107 vs. $1,641 P<0.0001; ACR (95% CI): 2.50 (2.45-2.56)], pharmacy costs [$230 vs. $174 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: Daichi 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 MCOs evaluate 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 categories were evaluated based on the potential impact DHTs can have on 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’ MCOs 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 in demand for implementation as a covered benefit. Diabetes (88.5%) and cardiovascular disease (86.9%) were ranked highest in potential impact for DHTs to address unmet needs. Peer reviewed literature (96.7%) was rated 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 the top evidence criteria selected for coverage determination. Advisory board meetings (70.5%) and continuing education sessions (57.4%) were identified as the preferred communication strategies between manufacturers and MCOs.

**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 conducted by Xcenda/Amerisource Bergen Consulting Services without external funding.

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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.

**CONCLUSIONS:** Of the 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.

**SPONSORSHIP:** This research was funded by Advera Health Analytics, a private corporation.

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**S00-T98 Injury, Poisoning, and Certain Other Consequences of External Causes (i.e., Adverse Events, Side Effects)**

**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 disproportional 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. AEIs 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 hypventilation (10% and 31% vs. 41%), nausea (41% and 46% vs. 72%), and vomiting (15% and 13% 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.
**U23 The U.S. Payor Landscape for Specialty Pharmacy: Results from a Survey of Medical and Pharmacy Directors**

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**BACKGROUND:** Specialty pharmacy (SP) products are pharmaceuticals designed to treat specific, complex chronic diseases. SP products are written by specialists, have few prescribers, 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 specialty pharmacies, 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, of those with 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 specialty pharmacies. Plans covered clinician administered products (i.e., injections and infusions) under the medical benefit (MB = 67.3%); none exclusively under the pharmacy benefit (PB = 0%); and 32.7% based on cost thresholds. Most plans (72.9%) do not anticipate a change, 18.8% expect a change before 2012-2016 and 1.1% prior to 2012-2018. 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 12-2016, 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 PT&T Committee members, have distinct opinions as to how to alter the process to adapt to these influences.

**SPONSORSHIP:** The TPG-NPRT (National Payor Roundtable).

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**U26 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-RCT 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, significant heterogeneity 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.

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 before and after 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 83.6% 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: NIH grant UL1TR000427.

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, 39.1% became adherent after the letter was mailed and the net change in PDC was 0.15 ± 0.28.

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.

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 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.

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.

SPONSORSHIP: The University of Arizona College of Pharmacy HOPE Center and SinfoniaRx.
BACKGROUND: State interest in improving care quality and lowering costs 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-out programs; calculate estimated savings from reduced hospitalizations/ED visits; (2) Pharmacist integration on care teams: pharmacists can be co-located/embedded/contracted for MTM services; pharmacists 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 fall 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.
the state specific factors that may be associated with this variability and the impact of New York’s ban on mandatory mail order.

**SPONSORSHIP:** University of Minnesota College of Pharmacy and Chapman University School of Pharmacy.

**U37** Pharmacists’ Perceptions of Biosimilars’ Impact on the Cost of Biologics and Patient Out-of-Pocket Spending

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**BACKGROUND:** The approval of a biosimilar pathway in the United States was focused on developing an abbreviated approval process for manufacturers to produce competition for existing and future biologics. Prior to the passage of The Biologics Price Competition and Innovation Act in 2009, no such abbreviated pathway existed in the United States. The approval of the first biosimilar in 2015 expanded questions as to whether the introduction of biosimilars in the United States would have a significant impact on costs. In addition, it remains unclear if any savings that is afforded will be passed along to the patients.

**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 predominantly 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.

**Z00-Z99** Factors Influencing Health Status and Contact with Health Services (e.g., Adherence, Oral Contraceptives)

**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 cleanse 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 evaluate the incidence of two high-cost events associated with bowel preparation prior to colonoscopy: repeat screening and hospitalization.

**METHODS:** This was a retrospective study of adults (aged ≥18 years) with ≥1 colonoscopy or sigmoidoscopy between July 1, 2012 and June 30, 2014, identified using the Truven Health MarketScan database. For each procedure, claims data were used to identify the bowel preparation agent, presence of a repeat screen within 90 days, and hospitalization within 10 days. Logistic regression was used to evaluate the association between preparation agent and the likelihood of a repeat screen or hospitalization, with adjustment for age, gender, and Charlson Comorbidity Index (CCI) score.

**RESULTS:** The inclusion criteria yielded 566,628 procedures associated with LV (n = 424,637), HV (n = 123,853) or other bowel preparation (n = 18,138). Mean age was 56.4 years and 53.5% of patients were female. A total of 33,574 endoscopic procedures were associated with P/MC. The mean age of P/MC patients was 51.5 years, 58.2% were female. The mean CCI score for the study sample was 0.96, compared with 0.49 for P/MC patients. The rate of repeat screens in P/MC patients was not significantly different compared with other patients overall (1.8% vs. 1.8%; P = 0.93), or in the adjusted analyses compared with all other patients (P = 0.67) or specifically LV patients (P = 0.10). A total of 3,433 hospitalizations were identified. The rate of non-CRC hospitalization (per 1,000 screens) was 3.78 for P/MC, 5.01 for other LV, and 6.13 for HV patients. There were no hospitalizations for hypotremia or dehydration in the P/MC group. The logistic regression model found no significant relationship between P/MC and these hospitalizations (P = 0.32).

**CONCLUSIONS:** Bowel preparation with P/MC was not associated with a significantly greater need for a repeat screen or hospitalization when compared with other bowel preparation agents.

**SPONSORSHIP:** Research was funded by Ferring Pharmaceuticals.

**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, fewer 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.

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.

Z18 Results of the Implementation of Pharmacy Network Continuing Participation Verification Program for a Large Managed Care Organization

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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.
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%-9% 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.

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, psoriatic arthritis, ankylosing spondylitis, 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). Regression analysis was conducted to compare biologic uptake (≥2 biologic claims) for MA versus control patients in the short-term (1-10 mos) and long-term (11-21 mos) after the ban lift, adjusted for patient characteristics and regional temporal trends. Separate analyses were conducted for lower income patients (household income < $50K).

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 diseases 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.

SPONSORSHIP: This study was designed, conducted, and financially supported by AbbVie.

Z22 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.

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 < 0.001), more likely to be female (67.3% vs. 64.3%; P < 0.001), and had fewer comorbidities (mean CCI 0.51 vs. 0.54, P < 0.004). PSP cohort had 33.9% lower expected per-patient out-of-pocket contribution for ADA ($211 vs. $319, P < 0.001) and 14.4% greater frequency of specialty pharmacy use for 1st ADA fill (60.2% vs. 52.6%, P < 0.001). Abandonment risk was 78% lower for PSP vs. non-PSP (4.9 vs. 22.9%; odds ratio = 0.223, P < 0.001), 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.

Z24 Specialty Medication Capture Rates Through Electronic Prescription Order Data Within a Health System

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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 electronically routed prescriptions is 22% whereas its capture rate for the sample of specialty medications 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 Stubbings, UIH Specialty Pharmacy Services.

Z28 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 significance of 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 PIMP
A Unique Method for Identifying Coordination of Benefit Recovery Opportunities in a Pediatric Medicaid Accountable Care Organization Claims Database

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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 as primary insurance.

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 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.

Virtual Academic Detailing: A Cost-Effective Approach to Align Payers and Physicians

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Indegenie Total Therapeutic Management

BACKGROUND: Through quality management programs such as HEDIS and CMS Star Ratings, payers and physicians have aligned incentives to improve population health at reduced costs. Academic detailing (AD) is a one-on-one dialog between detailer and physician centered on implementing evidence-based practices. For health plans, AD has demonstrated effectiveness in changing prescribing patterns, decreasing drug utilization and costs, and preventing drug-drug interactions. Virtual Academic Detailing (VAD) is AD conducted remotely through video streaming to simulate a face-to-face (F2F) interaction.

OBJECTIVE: To (a) summarize the drivers of virtual academic detailing and (b) determine the cost-effectiveness of virtual academic detailing (VAD) compared to traditional AD (F2F).

METHODS: A systematic review was conducted to identify the costs and effectiveness of VAD and F2F-AD programs. Articles from January 2000 to 2016 were compiled using search engines PubMed, Galileo, Ebscohost, and Google Scholar. Key terms were “academic detailing”, “educational outreach visits”, “electronic detailing”, “virtual academic detailing”, “virtual education visits”, “distance-learning detailing”, “technology-enabled academic detailing”, “face to face”, “cost”, “physician”, and “effectiveness.” Exclusion criteria included studies involving other methods of educational outreach and combination interventions.

RESULTS: A total of 20 relevant articles were retrieved. Findings revealed that decreasing cost-effectiveness of representatives, increasingly busy schedules for physicians, and increasing use of Internet and computer-based workflows by physicians are drivers for the growing adoption of virtual detailing programs. E-detailing, the pharmaceutical industry counterpart to VAD, consisted 1 to 2% of marketing in 2007 with estimated annual growth of 15%. Two studies of regional programs have directly compared F2F and VAD methods, demonstrating that although physicians are more willing to accept a recommendation through F2F, physicians accept VAD as a valid alternative method of communication. The corresponding cost-effectiveness of VAD has not been systematically assessed. A cost minimization model based on AD administrative expenses demonstrated a potential savings of 31% ($709 vs. $409 per provider) with VAD.

CONCLUSIONS: Health plan-sponsored VAD programs can minimize administrative costs of F2F-AD. Further research examining cost-effectiveness measures including prescribing patterns and drug utilization is required to support VAD’s value in connecting payers and providers to improve quality of care.

SPONSORSHIP: Indegenie Total Therapeutic Management.
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 (1,792, 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 1.5 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.

Z40 Medication Therapy Management Comprehensive Medication Reviews for Residents in Long-term Care Facilities: 2015 Results

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**PROBLEM DESCRIPTION:** Since 2013, Part D sponsors have been required to offer a Comprehensive Medication Review (CMR) to all Medicare fee-for-service beneficiaries enrolled in their MTM program at least annually, including those in long-term care settings (LTC) [e.g., skilled nursing facilities]. Since that time, MTM providers have found that accessing and successfully completing a CMR with these individuals is frequently prohibitively complex, as it often requires a live, face-to-face interactive interview where the beneficiary resides. However, with the migration of CMR Completion Rate from a Star Ratings display measure to an active measure, coupled with the new CMR Completion Rate cut points for 2016, accessing this population for CMR completion has heightened importance.

**GOAL:** To achieve a high CMR completion rate for residents in LTC using the 2015 CMS Standardized Format (CMS SF).

**PROGRAM DESCRIPTION:** Our proprietary consultant pharmacist (CP) software was programmed to produce a cover letter, medication action plan, and personal medication list per CMS specifications; CPs were trained to perform and document CMRs and the interactive interviews using this system. MTM-eligible Part D beneficiaries, identified by several contracted clients as residing in LTC serviced by Omnicare, were provided a CMR and written summary in CMS SF by CPs. Residents with cognitive impairment were identified using 3 data elements in the Minimum Data Set (MDS), including the Brief Interview for Mental Status Summary Score.

**OBSERVATIONS:** In 2015, 7,935 MTM-eligible beneficiaries were identified as receiving medications from an Omnicare pharmacy. Upon excluding those who were disenrolled by their PDP, discharged from the LTC, or resided in a LTC we no longer serviced, 3,993 residents remained available for CMR completion. Of these, only 3% refused the CMR offer, and 5,392 (96%) were completed successfully. Thirty-nine
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.

**SPONSORSHIP:** Omnicare.

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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 PCR 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 in the difference of years in practice between PCPs that preferred email (M = 25.7; SD = 9.7) versus those that preferred other modes of communication (M = 27.3; 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:** Cigna-HealthSpring and University of Houston College of Pharmacy.

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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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